SECTION 3

Criteria for Special Authorization of Select Drug Products

CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

The drug products listed in this section may be considered for coverage by special authorization for patients covered under Alberta Health-sponsored drug programs. (For Alberta Human Services clients, the special authorization criteria for coverage can be found in the Criteria for Special Authorization of Select Drug Products section of the *Alberta Human Services Drug Benefit Supplement.)*

Special Authorization Policy

DRUG PRODUCTS ELIGIBLE FOR CONSIDERATION BY SPECIAL AUTHORIZATION

Drug products may be considered for coverage by special authorization under one or more of the following circumstances, unless a specific product falls under the criteria for drug products **not** eligible for consideration by special authorization. Please see the end of this section for information regarding drug products not eligible for consideration by special authorization.

1. The drug is covered by Alberta Health under specified criteria (listed in the following sections). Drug Products and indications other than those specified are not eligible for consideration by special authorization.
2. The drug is normally covered by another government program or agency for a specific approved clinical condition, but is needed for the treatment of a clinical condition that is not covered by that government program or agency.
3. The drug is required because other drug products listed in the *Alberta Drug Benefit List* are contraindicated or inappropriate because of the clinical condition of the patient.
4. The particular brand of drug is considered essential in the care of a patient, where the LCA price policy would otherwise apply. Coverage of a specific brand may be considered where a patient has experienced significant allergic reactions or documented untoward therapeutic effects with alternate brands in an interchangeable grouping. Coverage of a brand name product will not be considered in situations where the interchangeable grouping includes a pseudo-generic to the brand name drug.
5. A particular drug product or dosage form of a drug is essential in the care of a patient where the MAC price policy would otherwise apply. Exceptions may occur at the product level. Coverage may be considered only where a patient has experienced significant allergic reactions or documented untoward therapeutic effects with the drug product which establishes the MAC pricing.

Prior approval must be granted by Alberta Blue Cross to ensure coverage by special authorization. For those special authorization requests that are approved, the effective date for authorization is the beginning of the month in which the physician's request is received by Alberta Blue Cross.

Special authorization is granted for a defined period as indicated in each applicable special authorization drug product criteria (the "Approval Period"). If continued treatment is necessary beyond the Approval Period, it is the responsibility of the patient and physician to **re-apply for coverage prior to the expiration date of the Approved Period, unless the Auto-Renewal Process or Step Therapy Approval Process apply** (see below).

AUTO-RENEWAL PROCESS

Selected drug products are eligible for the following auto-renewal process (for eligibility, see the Special Authorization criteria for each drug product).

1. For initial approval, a special authorization request must be submitted. If approval is granted, it will be effective for the Approval Period outlined in the drug product's Special Authorization criteria
2. As long as the patient has submitted a claim for the drug product within the preceding Approval Period (example: within the preceding 6 months), approval will be automatically renewed for a further Approval Period (example: a further 6 months). There is no need for the prescriber to submit a new request as the automated real-time claims adjudication system will read the patient's claims history to determine if a claim has been made within the preceding Approval Period.
3. If the patient does not make a claim for the drug product during the Approval Period, the approval will lapse and a new special authorization request must be submitted.

STEP THERAPY APPROVAL PROCESS

Select drug products are eligible for coverage via the step therapy process, outlined below.

1. If the patient has made a claim for the First-Line* drug product(s) within the preceding 12 months, the claim for the step therapy drug will be approved.
2. The automated real-time claims adjudication system will read the patient's claims history to determine if the required First-Line* drug product(s) have been claimed within the preceding 12 months.
3. Subsequent claims for drug product(s) permitted by step therapy will continue to be approved as long as the drug product has been claimed within the preceding 12 months.
4. The regular special authorization approval process will continue to be available for step therapy approvals for those patients whose First-Line* drug claims cannot be adjudicated through the automated real-time claims adjudication system.

* A First-Line drug product includes any drug(s) or drug product(s) that, under the drug product's Special Authorization criteria, are required to be utilized before reimbursement for the drug product is permitted.

DRUG PRODUCTS NOT ELIGIBLE FOR CONSIDERATION BY SPECIAL AUTHORIZATION

The following categories of drug products are **not** eligible for special authorization:

1. Drug products **deleted** from the *List*.
2. Drug products **not yet reviewed** by the Alberta Health Expert Committee on Drug Evaluation and Therapeutics. This applies to:
   * products where a complete submission has been received from the manufacturer and the product is under review,
   * products where an incomplete submission has been received from the manufacturer, and
   * products where the manufacturer has not made a submission for review.

Drug products not yet reviewed may encompass new pharmaceutical products, new strengths of products already listed, reformulated products and new interchangeable (generic) products.

3. Drug products that have **completed the review** process and are **not included** on the *List.*
4. Most drugs available through Health Canada's Special Access Program.
5. Drug products when prescribed for cosmetic indications.
6. Nonprescription or over-the-counter drug products are generally not eligible.

Criteria for Coverage

Wording that appears within quotation marks (" ") in this section is the official special authorization criteria, as recommended by the Alberta Health Expert Committee on Drug Evaluation and Therapeutics, and approved by the Minister of Health. Wording that is not enclosed in quotation marks outlines specific information required to interpret criteria, guidelines for submitting requests and/or information regarding conditions under which coverage cannot be provided.

Products Available through Health Canada's Special Access Program

PEMOLINE

"For the treatment of attention deficit hyperactivity disorder where approval has been provided by Health Canada's Special Access Program."

37.5 MG	**ORAL TABLET**
DIN N/A*	CYLERT
75 MG	**ORAL TABLET**
DIN N/A*	CYLERT

**As Cylert has been withdrawn from market, the DINs are no longer valid. Where authorizations for Cylert have been granted, coverage for this product will be provided under PIN 00000999917.*

Other Products

The remaining drug products in this section are listed alphabetically according to the generic ingredient name of the drug. These products can be found on the following pages.

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Rheumatoid Arthritis:

"Special authorization coverage may be provided for use in combination with methotrexate or other DMARDS, for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 12 weeks as follows:
- Abatacept intravenous infusion: five doses of up to 1000 mg/dose administered at 0, 2, 4, 8 and 12 weeks. Patients will be limited to receiving one dose of abatacept per prescription at their pharmacy.
- Abatacept subcutaneous injection: a single IV loading dose of up to 1000 mg/dose followed by 125 mg subcutaneous injection within a day, then once-weekly 125 mg SC injections. Patients who are unable to receive an infusion may initiate weekly subcutaneous injections without an intravenous loading dose. Patients will be limited to receiving one-month supply of abatacept subcutaneous injection per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial 12 weeks to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for abatacept will be provided for one intravenous dose of up to 1000 mg every 4 weeks, or one weekly 125 mg subcutaneous injection. Ongoing coverage

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may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- confirmation of maintenance of ACR20, OR
- maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for abatacept for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

125 MG / SYR INJECTION

00002402475	ORENCIA	BMS	$	373.7875

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Rheumatoid Arthritis:

"Special authorization coverage may be provided for use in combination with methotrexate or other DMARDS, for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 12 weeks as follows:
- Abatacept intravenous infusion: five doses of up to 1000 mg/dose administered at 0, 2, 4, 8 and 12 weeks. Patients will be limited to receiving one dose of abatacept per prescription at their pharmacy.
- Abatacept subcutaneous injection: a single IV loading dose of up to 1000 mg/dose followed by 125 mg subcutaneous injection within a day, then once-weekly 125 mg SC injections. Patients who are unable to receive an infusion may initiate weekly subcutaneous injections without an intravenous loading dose. Patients will be limited to receiving one-month supply of abatacept subcutaneous injection per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial 12 weeks to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for abatacept will be provided for one intravenous dose of up to 1000 mg every 4 weeks, or one weekly 125 mg subcutaneous injection. Ongoing coverage

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may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- confirmation of maintenance of ACR20, OR
- maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for abatacept for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Polyarticular Juvenile Idiopathic Arthritis:

"Special authorization coverage may be provided for the reduction in signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 6 years of age and older who:
- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDS) conventionally used in children (minimum three month trial), AND
- Are refractory to or intolerant to etanercept and/or adalimumab and/or tocilizumab (minimum 12 week trial).

'Refractory' is defined as lack of effect at the recommended doses and duration of treatments as listed above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary ("Pediatric Rheumatology Specialist").

- Coverage may be approved for one dose of 10 mg/kg (maximum dose 1000 mg) at 0, 2, 4, 8, 12 and 16 weeks (total of six doses).
- Patients will be limited to receiving one dose of abatacept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For potential coverage for retreatment with abatacept following a subsequent disease flare, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric Rheumatology Specialist after the initial 16 weeks, but no longer than 20 weeks after, treatment with this biologic agent to determine and document initial treatment response.

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2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
- 30% improvement from baseline in at least three of the following six response variables, with worsening of 30% or more in no more than one of the six variables. The variables include:
i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,
ii. global assessment of overall well-being by the patient or parent,
iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
iv. number of joints with limitation of motion,
v. functional ability based on CHAQ scores,
vi. ESR or CRP
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported.
Following assessment and confirmation of initial treatment response, coverage for retreatment with abatacept may be approved for one dose of 10 mg/kg (maximum dose 1000 mg) at 0, 2*, 4, 8, 12 and 16 weeks (total of up to six doses; *the week 2 dose on retreatment is optional, to be administered at the discretion of the Pediatric Rheumatology Specialist). In order to be considered for coverage for retreatment, the patient must meet the following criteria:
1) The patient has been assessed by a Pediatric Rheumatology Specialist and the presence of disease flare confirmed. Disease flare is defined as worsening of at least 30% or greater in at least 3 of 6 ACR Pedi 30 variables for pJIA and 30% or greater improvement in no more than one variable.
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient has had an initial treatment response (as assessed above) and that the patient has experienced a disease flare (as defined above)."

Please note: Coverage is provided for treatment of disease flares only. However, if a patient experiences a subsequent flare within 12 months of initiation of treatment with abatacept, they may be eligible for continuous coverage (i.e., one dose of 10 mg/kg (maximum dose 1000 mg) every 4 weeks) for a maximum period of two years, provided the patient has demonstrated a response to initial treatment."

All requests (including renewal requests) for abatacept for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Abatacept for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60010).

250 MG / VIAL (BASE)	INJECTION			
00002282097	ORENCIA	BMS	$	500.3400

ACAMPROSATE CALCIUM

"For the treatment of alcohol use disorder in patients who have been abstinent for at least four days and as a component of an alcohol counseling program.

Initial approval period: 6 months

Renewal may be considered for an additional 6 months.

Continued coverage requests beyond 12 months may be considered on a case by case basis."

333 MG (BASE)	ORAL	DELAYED-RELEASE TABLET		
00002293269	CAMPRAL	MYP	$	0.8691

ACLIDINIUM BROMIDE/ FORMOTEROL FUMARATE DIHYDRATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S): LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])

"For the long-term maintenance treatment of airflow obstruction in patients with moderate to severe (i.e., FEV1 < 80% predicted) chronic obstructive pulmonary disease (COPD), who have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA])."

"For the long-term maintenance treatment of airflow obstruction in patients with severe (i.e., FEV1 < 50% predicted) chronic obstructive pulmonary disease (COPD)."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for aclidinium bromide + formoterol fumarate dihydrate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

400 MCG / DOSE * 12 MCG / DOSE		**INHALATION**	**METERED INHALATION POWDER**		
00002439530	DUAKLIR GENUAIR		COV	$	1.0454

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Polyarticular Juvenile Idiopathic Arthritis

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 4 years of age and older who:
- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDS) conventionally used in children (minimum three month trial).

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects (e.g., leukopenia, hepatitis) or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric Rheumatology Specialist).

- Coverage may be approved for 24 mg per square meter body surface area (maximum dose 40 mg) every other week for 12 weeks.
- Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
- 30% improvement from baseline in at least three of the following six response variables, with worsening of 30% or more in no more than one of the six variables. The variables include:
i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,
ii. global assessment of overall well-being by the patient or parent,
iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
iv. number of joints with limitation of motion,
v. functional ability based on CHAQ scores,
vi. ESR or CRP
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Following this assessment, continued coverage may be approved for 24 mg per square meter body surface area (maximum dose 40 mg) every other week, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:
1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine

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response, and
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Once a child with pJIA has had two disease-free years, it is common clinical practice for drug treatment to be stopped."

All requests (including renewal requests) for adalimumab for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Adalimumab/Etanercept/Tocilizumab for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60011).

20 MG / SYR INJECTION SYRINGE

☒ 00002502380	HULIO (20 MG/0.4 ML INJ SYR)	BGP	$	235.6350
☒ 00002505258	HYRIMOZ (20 MG/0.4 ML INJ SYR)	SDZ	$	235.6350
☒ 00002459310	AMGEVITA (20 MG/0.4 ML INJ SYR)	AMG	$	235.6400

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Ankylosing Spondylitis

"Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

-a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
-a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
-who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

-Initial coverage may be approved for 12 weeks as follows: An initial 40 mg dose, followed by additional 40 mg doses administered every two weeks for up to 12 weeks after the first dose.
-Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
-Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
-Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
-Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed at 12 weeks by an RA Specialist after the initial twelve weeks of therapy to determine response.
2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
-Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
-Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for one 40 mg dose every other week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for adalimumab for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

Hidradenitis Suppurativa

"Special authorization may be provided for the treatment of adult patients with active moderate to severe Hidradenitis Suppurativa who meet all of the following criteria:

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- A total abscess and nodule (AN) count of 3 or greater.
- Lesions in at least two distinct anatomical areas, one of which must be Hurley Stage II or III.
- An inadequate response to a 90-day trial of systemic antibiotics AND documented non response to conventional therapy.

For coverage, this drug must be initiated by a Specialist in Dermatology ("Dermatology Specialist").

- Initial coverage may be approved for 12 weeks as follows: an initial dose of 160 mg, followed by one 80 mg dose two weeks later, then 40 mg every week beginning four weeks after the initial dose, for a total of eleven doses.
- Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial approval period the patient must meet the following criteria:

1) The patient must be assessed by a Dermatology Specialist after 12 weeks of treatment to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:

- Greater than or equal to 50% reduction in AN count from pre-treatment baseline AND
- no increase in abscess count or draining fistula count relative to pre-treatment baseline.

Note: Treatment with adalimumab should be discontinued if there is insufficient improvement after 12 weeks of treatment.

Following this assessment, continued coverage may be considered for one 40 mg dose of adalimumab every week for an additional period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for adalimumab for Hidradenitis Suppurativa must be completed using the Adalimumab for Hidradenitis Suppurativa Special Authorization Request Form (ABC 60058).

Moderately to Severely Active Crohn's Disease

"Special authorization coverage may be approved for coverage of adalimumab for the reduction in signs and symptoms and induction and maintenance of clinical remission of Moderately to Severely Active Crohn's Disease in patients who meet the following criteria:

-Adalimumab must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross for adalimumab for coverage for the treatment of Moderately to Severely Active Crohn's Disease patients ('Specialist').
-Patients must be 18 years of age or older to be considered for coverage of adalimumab.
-Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
-Patients may be allowed to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy (both primary loss of response and secondary loss of response) or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of

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induction dosing (e.g. initial coverage period).
-Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
-Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

Prior to initiation of adalimumab therapy for New Patients:
'New Patients' are patients who have never been treated with adalimumab by any health care provider.

Moderately to Severely Active Crohn's Disease:

Prior to initiation of adalimumab therapy, New Patients must have a current Modified (without the physical exam) Harvey Bradshaw Index score of greater than or equal to 7 (New Patient's Baseline Score), AND be Refractory.

Refractory is defined as one or more of the following:
1) Serious adverse effects or reactions to the treatments specified below; OR
2) Contraindications (as defined in product monographs) to the treatments specified below; OR
3) Previous documented lack of effect at doses and for duration of all treatments specified below:
a) mesalamine: minimum of 3 grams/day for a minimum of 6 weeks; AND refractory to, or dependent on, glucocorticoids: following at least one tapering dosing schedule of 40mg/day, tapering by 5 mg each week to 20 mg then tapering by 2.5mg each week to zero, or similar.

[Note: Patients who have used the above treatments in combination will not be required to be challenged with individual treatments as monotherapy]

AND
b) Immunosuppressive therapy as follows:
-Azathioprine: minimum of 2 mg/kg/day for a minimum of 3 months; OR
-6-mercaptopurine: minimum of 1mg/kg/day for a minimum of 3 months; OR
-Methotrexate: minimum of 15mg/week for a minimum of 3 months.
OR
-Immunosuppressive therapy discontinued at less than 3 months due to serious adverse effects or reactions.

Applications for coverage must include information regarding the dosages and duration of trial of each treatment the patient received, a description of any adverse effects, reactions, contraindications and/or lack of effect, as well as any other information requested by Alberta Blue Cross.

Coverage Criteria for Moderately to Severely Active Crohn's Disease

-New Patients must meet the criteria above prior to being considered for approval.
-All approvals are also subject to the following applicable criteria.

Induction Dosing for New Patients:

-Coverage for Induction dosing may only be approved for New Patients (those who have never been treated with adalimumab by any health care provider).
-'Induction Dosing' means a maximum of one 160 mg dose of adalimumab per New Patient at Week 0 followed by an 80 mg dose at Week 2.
-New Patients are eligible to receive Induction Dosing only once, after which time the Maintenance Dosing for New Patients and Continued Coverage for Maintenance Dosing criteria will apply.
-As an interim measure, 40mg doses of adalimumab will be provided at weeks 4, 6, 8 and 10 to allow time to determine whether the New Patient meets coverage criteria for

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Maintenance Dosing below.

Maintenance Dosing:

'Maintenance Dosing' means one 40 mg dose of adalimumab per patient provided no more often than every other week starting at Week 4 for a period of 12 months to:
-New Patients following the completion of Induction Dosing; OR
-Existing Patients, who are patients that are being treated, or have previously been treated, with adalimumab.

Maintenance Dosing for New Patients after Completion of Induction Dosing:

-The New Patient must be assessed by a Specialist within 12 weeks after the initiation of Induction Dosing to determine response by obtaining a Modified Harvey Bradshaw Index score for patients with Moderately to Severely Active Crohn's Disease; AND
-The Specialist must confirm the Modified Harvey Bradshaw Index score shows a decrease from the New Patient's Baseline Score of greater than or equal to 3 points for patients with Moderately to Severely Active Crohn's Disease.

Maintenance Dosing for Existing Patients:

-The patient must be assessed by a Specialist annually (within 2 months of the expiry of a patient's special authorization) at least 2 weeks after the day a dose of adalimumab was administered to the patient and prior to administration of the next dose to obtain: a Modified Harvey Bradshaw Index Score (Existing Patient's Baseline Score) for Moderately to Severely Active Crohn's Disease; AND
-these measures must be provided to Alberta Blue Cross for assessment for continued coverage for maintenance dosing.

Continued Coverage for Maintenance Dosing:

Continued coverage may be considered for one 40 mg dose of adalimumab per patient provided no more often than every other week for a period of 12 months, if the following criteria are met at the end of each 12 month period:

-The New Patient or the Existing Patient must be assessed by a Specialist annually (within 2 months of the expiry of a patient's special authorization) at least 2 weeks after the day a dose of adalimumab was administered to the patient and prior to administration of the next dose to obtain: a Modified Harvey Bradshaw Index Score for Moderately to Severely Active Crohn's Disease; AND
-For New Patients: The Specialist must confirm that the patient has maintained a greater than or equal to 3 point decrease from the New Patient's Baseline Score for Moderately to Severely Active Crohn's Disease; OR
-For Existing Patients: The Specialist must confirm that the patient has maintained the Existing Patient's Baseline Score."

All requests (including renewal requests) for adalimumab for Moderately to Severely Active Crohn's Disease must be completed using the Adalimumab/Vedolizumab for Crohn's/Infliximab for Crohn's/Fistulizing Crohn's Special Authorization Request Form (ABC 60031).

Plaque Psoriasis

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating psoriasis in patients who:
-Have a total PASI of 10 or more and a DLQI of more than 10, OR
-Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
-Who are refractory or intolerant to:
-Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater

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if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; OR
-Cyclosporine (6 weeks treatment); AND
-Phototherapy (unless restricted by geographic location)

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

-Initial coverage may be approved for an initial dose of 80 mg, followed by one 40 mg dose every other week beginning one week after the first dose, for a total of nine doses.
-Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
-Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
-Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
-Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond nine doses, the patient must meet all of the following criteria:
1) The patient must be assessed by a Dermatology Specialist after the initial nine doses to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
-Greater than or equal to 75% reduction in PASI score,
OR
-Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for one 40 mg dose of adalimumab every other week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for adalimumab for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Tildrakizumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

Polyarticular Juvenile Idiopathic Arthritis

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 4 years of age and older who:
- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND

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- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDS) conventionally used in children (minimum three month trial).

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects (e.g., leukopenia, hepatitis) or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric Rheumatology Specialist).

- Coverage may be approved for 24 mg per square meter body surface area (maximum dose 40 mg) every other week for 12 weeks.
- Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
- 30% improvement from baseline in at least three of the following six response variables, with worsening of 30% or more in no more than one of the six variables. The variables include:
i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,
ii. global assessment of overall well-being by the patient or parent,
iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
iv. number of joints with limitation of motion,
v. functional ability based on CHAQ scores,
vi. ESR or CRP
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Following this assessment, continued coverage may be approved for 24 mg per square meter body surface area (maximum dose 40 mg) every other week, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:
1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Once a child with pJIA has had two disease-free years, it is common clinical practice for

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drug treatment to be stopped."

All requests (including renewal requests) for adalimumab for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Adalimumab/Etanercept/Tocilizumab for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60011).

Psoriatic Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:

-Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
-An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above. 'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

-Initial coverage may be approved for 40 mg administered every other week for 8 weeks.
-Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
-Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
-Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
-Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after, treatment with this biologic agent to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
-ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
-An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 40 mg every other week, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:

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1) The patient has been assessed by an RA Specialist to determine response; and
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
-Confirmation of maintenance of ACR20 or
-Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for adalimumab for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

-Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
-Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
-Leflunomide (minimum 10 week trial at 20 mg daily).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

-Initial coverage may be approved for five doses as follows: An initial 40 mg dose, followed by additional 40 mg doses at 2, 4, 6 and 8 weeks after the first dose.
-Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
-Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
-Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
-Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
-Patients are limited to receiving one biologic agent at a time regardless of the condition

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for which it is being prescribed.

For continued coverage beyond 5 doses, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial five doses to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
-ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
-An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 40 mg every other week for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
-Confirmation of maintenance of ACR20, or
-Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for adalimumab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Ulcerative Colitis

"Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:
- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks; AND
- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:
i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

For coverage, this drug must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross ('Specialist').

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Initial coverage may be approved for an initial dose of 160 mg, followed by an 80 mg dose at week 2, then one 40 mg dose at weeks 4, 6 and 8. As an interim measure, an additional 40 mg dose of adalimumab will be provided at week 10 to allow time to determine whether the New Patient meets coverage criteria for Maintenance Dosing below, for a total of six doses.

- Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:
1) The patient must be assessed by a Specialist between weeks 8 and 12 after the initiation of therapy to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for a dose of 40 mg every 2 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist in Gastroenterology to determine response;
2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of adalimumab therapy."

All requests (including renewal requests) for adalimumab for Ulcerative Colitis must be completed using the Adalimumab/Golimumab/Infliximab/Tofacitinib/Vedolizumab for Ulcerative Colitis Special Authorization Request Form (ABC 60008).

40 MG / SYR INJECTION SYRINGE

☒	00002511045	ABRILADA (40 MG/0.8 ML INJ PEN)	PFI	$	471.2700
☒	00002511053	ABRILADA (40 MG/0.8 ML INJ SYR)	PFI	$	471.2700
☒	00002459299	AMGEVITA (40 MG/0.8 ML INJ SYR)	AMG	$	471.2700
☒	00002459302	AMGEVITA 40 MG/0.8 ML AUTOINJECTOR PEN	AMG	$	471.2700
☒	00002473100	HADLIMA (40 MG/0.8 ML INJ PEN)	SSB	$	471.2700
☒	00002473097	HADLIMA (40 MG/0.8 ML INJ SYR)	SSB	$	471.2700
☒	00002502402	HULIO (40 MG/0.8 ML INJ PEN)	BGP	$	471.2700
☒	00002502399	HULIO (40 MG/0.8 ML INJ SYR)	BGP	$	471.2700
☒	00002492156	HYRIMOZ (40 MG/0.8 ML INJ PEN)	SDZ	$	471.2700
☒	00002492164	HYRIMOZ (40 MG/0.8 ML INJ SYR)	SDZ	$	471.2700
☒	00002502674	IDACIO (40 MG/0.8 ML INJ PEN)	FKC	$	471.2700
☒	00002502682	IDACIO (40 MG/0.8 ML INJ SYR)	FKC	$	471.2700
☒	00002523957	SIMLANDI (40 MG/0.4 ML AUTO-INJECTOR PEN)	JPC	$	471.2700
☒	00002523949	SIMLANDI (40 MG/0.4 ML PREFILLED SYRINGE)	JPC	$	471.2700
☒	00002523779	YUFLYMA (PEN)	CHC	$	471.2700

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HIDRADENITIS SUPPURATIVA

"Special authorization may be provided for the treatment of adult patients with active moderate to severe Hidradenitis Suppurativa who meet all of the following criteria:

- A total abscess and nodule (AN) count of 3 or greater.
- Lesions in at least two distinct anatomical areas, one of which must be Hurley Stage II or III.
- An inadequate response to a 90-day trial of systemic antibiotics AND documented non response to conventional therapy.

For coverage, this drug must be initiated by a Specialist in Dermatology ("Dermatology Specialist").

- Initial coverage may be approved for 12 weeks as follows: an initial dose of 160 mg, followed by one 80 mg dose two weeks later, then 40 mg every week beginning four weeks after the initial dose, for a total of eleven doses.
- Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial approval period the patient must meet the following criteria:

1) The patient must be assessed by a Dermatology Specialist after 12 weeks of treatment to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:

- Greater than or equal to 50% reduction in AN count from pre-treatment baseline AND
- no increase in abscess count or draining fistula count relative to pre-treatment baseline.

Note: Treatment with adalimumab should be discontinued if there is insufficient improvement after 12 weeks of treatment.

Following this assessment, continued coverage may be considered for one 40 mg dose of adalimumab every week for an additional period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for adalimumab for Hidradenitis Suppurativa must be completed using the Adalimumab for Hidradenitis Suppurativa Special Authorization Request Form (ABC 60058).

MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE

"Special authorization coverage may be approved for coverage of adalimumab for the reduction in signs and symptoms and induction and maintenance of clinical remission of Moderately to Severely Active Crohn's Disease in patients who meet the following criteria:

-Adalimumab must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross for adalimumab for coverage for the treatment of Moderately to Severely Active Crohn's Disease patients ('Specialist').
-Patients must be 18 years of age or older to be considered for coverage of adalimumab.
-Patients will be limited to receiving a one-month supply of adalimumab per prescription

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at their pharmacy.
-Patients may be allowed to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy (both primary loss of response and secondary loss of response) or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
-Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
-Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

Prior to initiation of adalimumab therapy for New Patients:
'New Patients' are patients who have never been treated with adalimumab by any health care provider.

Moderately to Severely Active Crohn's Disease:

Prior to initiation of adalimumab therapy, New Patients must have a current Modified (without the physical exam) Harvey Bradshaw Index score of greater than or equal to 7 (New Patient's Baseline Score), AND be Refractory.

Refractory is defined as one or more of the following:
1) Serious adverse effects or reactions to the treatments specified below; OR
2) Contraindications (as defined in product monographs) to the treatments specified below; OR
3) Previous documented lack of effect at doses and for duration of all treatments specified below:
a) mesalamine: minimum of 3 grams/day for a minimum of 6 weeks; AND refractory to, or dependent on, glucocorticoids: following at least one tapering dosing schedule of 40mg/day, tapering by 5 mg each week to 20 mg then tapering by 2.5mg each week to zero, or similar.

[Note: Patients who have used the above treatments in combination will not be required to be challenged with individual treatments as monotherapy]

AND
b) Immunosuppressive therapy as follows:
-Azathioprine: minimum of 2 mg/kg/day for a minimum of 3 months; OR
-6-mercaptopurine: minimum of 1mg/kg/day for a minimum of 3 months; OR
-Methotrexate: minimum of 15mg/week for a minimum of 3 months.
OR
-Immunosuppressive therapy discontinued at less than 3 months due to serious adverse effects or reactions.

Applications for coverage must include information regarding the dosages and duration of trial of each treatment the patient received, a description of any adverse effects, reactions, contraindications and/or lack of effect, as well as any other information requested by Alberta Blue Cross.

Coverage Criteria for Moderately to Severely Active Crohn's Disease

-New Patients must meet the criteria above prior to being considered for approval.
-All approvals are also subject to the following applicable criteria.

Induction Dosing for New Patients:

-Coverage for Induction dosing may only be approved for New Patients (those who have never been treated with adalimumab by any health care provider).
-'Induction Dosing' means a maximum of one 160 mg dose of adalimumab per New Patient at Week 0 followed by an 80 mg dose at Week 2.

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-New Patients are eligible to receive Induction Dosing only once, after which time the Maintenance Dosing for New Patients and Continued Coverage for Maintenance Dosing criteria will apply.
-As an interim measure, 40mg doses of adalimumab will be provided at weeks 4, 6, 8 and 10 to allow time to determine whether the New Patient meets coverage criteria for Maintenance Dosing below.

Maintenance Dosing:

'Maintenance Dosing' means one 40 mg dose of adalimumab per patient provided no more often than every other week starting at Week 4 for a period of 12 months to:
-New Patients following the completion of Induction Dosing; OR
-Existing Patients, who are patients that are being treated, or have previously been treated, with adalimumab.

Maintenance Dosing for New Patients after Completion of Induction Dosing:

-The New Patient must be assessed by a Specialist within 12 weeks after the initiation of Induction Dosing to determine response by obtaining a Modified Harvey Bradshaw Index score for patients with Moderately to Severely Active Crohn's Disease; AND
-The Specialist must confirm the Modified Harvey Bradshaw Index score shows a decrease from the New Patient's Baseline Score of greater than or equal to 3 points for patients with Moderately to Severely Active Crohn's Disease.

Maintenance Dosing for Existing Patients:

-The patient must be assessed by a Specialist annually (within 2 months of the expiry of a patient's special authorization) at least 2 weeks after the day a dose of adalimumab was administered to the patient and prior to administration of the next dose to obtain: a Modified Harvey Bradshaw Index Score (Existing Patient's Baseline Score) for Moderately to Severely Active Crohn's Disease; AND
-these measures must be provided to Alberta Blue Cross for assessment for continued coverage for maintenance dosing.

Continued Coverage for Maintenance Dosing:

Continued coverage may be considered for one 40 mg dose of adalimumab per patient provided no more often than every other week for a period of 12 months, if the following criteria are met at the end of each 12 month period:

-The New Patient or the Existing Patient must be assessed by a Specialist annually (within 2 months of the expiry of a patient's special authorization) at least 2 weeks after the day a dose of adalimumab was administered to the patient and prior to administration of the next dose to obtain: a Modified Harvey Bradshaw Index Score for Moderately to Severely Active Crohn's Disease; AND
-For New Patients: The Specialist must confirm that the patient has maintained a greater than or equal to 3 point decrease from the New Patient's Baseline Score for Moderately to Severely Active Crohn's Disease; OR
-For Existing Patients: The Specialist must confirm that the patient has maintained the Existing Patient's Baseline Score."

All requests (including renewal requests) for adalimumab for Moderately to Severely Active Crohn's Disease must be completed using the Adalimumab/Vedolizumab for Crohn's/Infliximab for Crohn's/Fistulizing Crohn's Special Authorization Request Form (ABC 60031).

PLAQUE PSORIASIS

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating psoriasis in patients who:

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-Have a total PASI of 10 or more and a DLQI of more than 10, OR
-Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
-Who are refractory or intolerant to:
-Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; OR
-Cyclosporine (6 weeks treatment); AND
-Phototherapy (unless restricted by geographic location)

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

-Initial coverage may be approved for an initial dose of 80 mg, followed by one 40 mg dose every other week beginning one week after the first dose, for a total of nine doses.
-Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
-Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
-Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
-Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond nine doses, the patient must meet all of the following criteria:
1) The patient must be assessed by a Dermatology Specialist after the initial nine doses to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
-Greater than or equal to 75% reduction in PASI score,
OR
-Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for one 40 mg dose of adalimumab every other week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for adalimumab for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Tildrakizumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

ULCERATIVE COLITIS

ADALIMUMAB

"Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:
- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks; AND
- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:
i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

For coverage, this drug must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross ('Specialist').

Initial coverage may be approved for an initial dose of 160 mg, followed by an 80 mg dose at week 2, then one 40 mg dose at weeks 4, 6 and 8. As an interim measure, an additional 40 mg dose of adalimumab will be provided at week 10 to allow time to determine whether the New Patient meets coverage criteria for Maintenance Dosing below, for a total of six doses.

- Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:
1) The patient must be assessed by a Specialist between weeks 8 and 12 after the initiation of therapy to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for a dose of 40 mg every 2 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist in Gastroenterology to determine response;
2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of adalimumab therapy."

All requests (including renewal requests) for adalimumab for Ulcerative Colitis must be

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completed using the Adalimumab/Golimumab/Infliximab/Tofacitinib/Vedolizumab for Ulcerative Colitis Special Authorization Request Form (ABC 60008).

80 MG / SYR INJECTION SYRINGE				
00002523965	SIMLANDI (80 MG/0.8 ML PREFILLED SYRINGE)	JPC	$	942.5400

ALEMTUZUMAB

Relapsing Remitting Multiple Sclerosis (RRMS)

"Special authorization coverage may be provided for the treatment of highly active relapsing remitting multiple sclerosis (RRMS) to reduce the frequency of clinical relapses, to decrease the number and volume of active brain lesions identified on magnetic resonance imaging (MRI) scans and to delay the progression of physical disability, in adult patients (18 years of age or older) who are refractory or intolerant to at least TWO of the following disease modifying therapies (DMTs):

- cladribine
- dimethyl fumarate
- fingolimod
- glatiramer acetate
- interferon beta
- natalizumab
- ocrelizumab
- ofatumumab
- peginterferon beta
- teriflunomide

Definition of 'intolerant'
Demonstrating serious adverse effects or contraindications to treatments as defined in the product monograph, or a persisting adverse event that is unresponsive to recommended management techniques and which is incompatible with further use of that class of MS disease modifying therapy (DMT).

Definition of 'refractory'
-Development of neutralizing antibodies to interferon beta.
-When the above MS DMTs are taken at the recommended doses for a full and adequate course of treatment, within a consecutive 12-month period while the patient was on the MS DMT, the patient has:
1) Been adherent to the MS DMT (greater than 80% of approved doses have been administered);
2) Experienced at least two relapses* of MS confirmed by the presence of neurologic deficits on examination.
i. The first qualifying clinical relapse must have begun at least one month after treatment initiation.
ii. Both qualifying relapses must be classified with a relapse severity of moderate, severe or very severe**.
*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.
**Relapse severity: with moderate relapses modification or more time is required to carry out activities of daily living; with severe relapses there is inability to carry out some activities of daily living; with very severe relapses activities of daily living must be completed by others.
For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist.
To register to become an MS Neurologist, please complete the Registration for MS Neurologist Status Form (ABC 60002).
Coverage may be considered only if the following criteria are met:
1) The registered MS Neurologist must confirm a diagnosis of RRMS;
2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS DMT. In most cases this will be satisfied by the 'refractory' to treatment criterion but if a patient failed an MS DMT more than one year earlier, ongoing active disease must be confirmed.
3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to

ALEMTUZUMAB

5).
Coverage will not be approved when any MS DMT or other immunosuppressive therapy is to be used in combination with alemtuzumab.

Coverage of alemtuzumab will not be approved if the patient was deemed to be refractory to alemtuzumab in the past.

Following assessment of the request, alemtuzumab may be approved for coverage at a dose of 12 mg/day administered by intravenous (IV) infusion for 2 treatment courses:
- Initial Treatment Course: 12 mg/day for 5 consecutive days (60 mg total dose)
- Second Treatment Course: 12 mg/day for 3 consecutive days (36 mg total dose) administered 12 months after the initial treatment course.

Patients will be limited to receiving one treatment course (60 mg or 36 mg) of alemtuzumab per prescription at their pharmacy.

Coverage is limited to two treatment courses (i.e., eight doses)."

All requests for alemtuzumab must be completed using the Alemtuzumab For Multiple Sclerosis Special Authorization Request Form (ABC 60079).

12 MG / VIAL INJECTION

00002418320	LEMTRADA	GZM	$ 13031.1100

ALENDRONATE SODIUM

Osteoporosis:

"For the treatment of osteoporosis in patients with a 20% or greater 10-year fracture risk who have documented intolerance to alendronate 70 mg or risedronate 35 mg. Special authorization may be granted for 6 months."

"Requests for other osteoporosis medications covered via special authorization will not be considered until 6 months after the last dose of denosumab 60 mg/syr injection syringe."

"Requests for other osteoporosis medications covered via special authorization will not be considered until 12 months after the last dose of zoledronic acid 0.05 mg/ml injection."

Note: The fracture risk can be determined by the World Health Organization's fracture risk assessment tool, FRAX, or the most recent (2010) version of the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) table.

All requests for alendronate sodium for Osteoporosis must be completed using the Alendronate/Raloxifene/Risedronate for Osteoporosis Special Authorization Request Form (ABC 60043).

The following product(s) are eligible for auto-renewal for the treatment of osteoporosis.

Paget's Disease:

"For the treatment of Paget's disease. Special Authorization for this criteria may be granted to a maximum of 6 months."

"Coverage cannot be provided for two or more medications used in the treatment of Paget's disease when these medications are intended for use in combination or when therapy with two or more medications overlap."

10 MG ORAL TABLET

00002381486	**ALENDRONATE SODIUM**	**AHI**	$	**0.4986**
00002388545	**AURO-ALENDRONATE**	**AUR**	$	**0.4986**

ALFUZOSIN HCL

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): DOXAZOSIN OR TERAZOSIN

"For the treatment of the symptoms of benign prostatic hyperplasia (BPH) in patients who are unresponsive to a six-week trial with a non-selective alpha-blocker (e.g., terazosin) or in whom non-selective alpha-blockers are not tolerated or are contraindicated."

"Special authorization may be granted for 24 months"

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

10 MG ORAL SUSTAINED-RELEASE TABLET

00002447576	**ALFUZOSIN**	**SIV**	$	**0.2601**
00002519844	**ALFUZOSIN**	**SNS**	$	**0.2601**
00002315866	**APO-ALFUZOSIN**	**APX**	$	**0.2601**
00002443201	**AURO-ALFUZOSIN**	**AUR**	$	**0.2601**
00002304678	**SANDOZ ALFUZOSIN**	**SDZ**	$	**0.2601**
00002245565	XATRAL	SAV	$	1.0758

ALIROCUMAB

"Special authorization coverage may be provided for the reduction of Low Density Lipoprotein Cholesterol (LDL-C) if the following clinical criteria and conditions are met:

I) Patient has a definite or probable diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH) using the Simon Broome or Dutch Lipid Network criteria or genetic testing

AND

II) Patient is unable to reach LDL-C target (i.e., LDL-C < 2.0 mmol/L for secondary prevention or at least a 50% reduction in LDL-C from untreated baseline for primary prevention) despite:

a) Confirmed adherence to high dose statin (e.g., atorvastatin 80 mg or rosuvastatin 40 mg) in combination with ezetimibe for at least 3 months.

OR

b) Confirmed adherence to ezetimibe for at least 3 months.
AND
Patient is unable to tolerate high dose statin, defined as meeting all of the following:
i) Inability to tolerate at least two statins with at least one started at the lowest starting daily dose,
AND
ii) For each statin (two statins in total), dose reduction is attempted for intolerable symptom (myopathy) or biomarker abnormality (creatine kinase (CK) > 5 times the upper limit of normal) resolution rather than discontinuation of statin altogether,
AND
iii) For each statin (two statins in total), intolerable symptoms (myopathy) or abnormal biomarkers (CK > 5 times the upper limit of normal) changes are reversible upon statin discontinuation but reproducible by re-challenge of statins where clinically appropriate,
AND
iv) One of either:
- Other known determinants of intolerable symptoms or abnormal biomarkers have been ruled out,
OR
- Patient developed confirmed and documented rhabdomyolysis.

OR

c) Confirmed adherence to ezetimibe for at least 3 months.
AND
Patient is statin contraindicated, i.e., active liver disease or unexplained persistent elevations of serum transaminases exceeding 3 times the upper limit of normal.

Initial coverage may be approved for either 75 mg once every two weeks or 300 mg once every 4 weeks for a period of 12 weeks.

- Patients prescribed alirocumab 300 mg once every 4 weeks must use the 150 mg/dose formulation.
- Patients will be limited to receiving a 4 week supply of alirocumab per prescription at their pharmacy.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
- Patient is adherent to therapy.
- Patient has achieved a reduction in LDL-C of at least 40% from baseline (4-8 weeks after initiation of alirocumab).

Continued coverage may be approved for either 75 mg once every 2 weeks or 300 mg once every 4 weeks for a period 12 months. The dosage may be adjusted to the maximum dosage of 150 mg administered every 2 weeks, depending on patient response.
- Patients are limited to 26 syringes/pens per year.

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Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
- Patient is adherent to therapy.
- Patient continues to have a significant reduction in LDL-C (with continuation of alirocumab) of at least 40% from baseline since initiation of PCSK9 inhibitor. LDL-C should be checked periodically with continued treatment with PCSK9 inhibitors (e.g., every 6 months)."

All requests (including renewal requests) for alirocumab for Heterozygous Familial Hypercholesterolemia must be completed using the Alirocumab/Evolocumab for HeFH Special Authorization Request Form (ABC 60060).

75 MG / ML INJECTION				
00002453819	PRALUENT	SAV	$	267.8300
150 MG / ML INJECTION				
00002453835	PRALUENT	SAV	$	267.8300

ALMOTRIPTAN MALATE

(Refer to 28:32.28 of the Alberta Drug Benefit List for coverage of patients 18 to 64 years of age inclusive.)

"For the treatment of acute migraine attacks in patients 65 years of age and older where other standard therapy has failed."

"For the treatment of acute migraine attacks in patients 65 years of age and older who have been using almotriptan malate prior to turning 65."

"Special authorization for both criteria may be granted for 24 months."

In order to comply with the first criteria, information is required regarding previous medications utilized and the patient's response to therapy.

The following product(s) are eligible for auto-renewal.

6.25 MG (BASE) ORAL TABLET				
00002398435	MYLAN-ALMOTRIPTAN	MYP	$	7.0433
12.5 MG (BASE) ORAL TABLET				
00002466821	**ALMOTRIPTAN**	**SNS**	$	**2.3478**
00002398443	**MYLAN-ALMOTRIPTAN**	**MYP**	$	**2.3478**
00002405334	**SANDOZ ALMOTRIPTAN**	**SDZ**	$	**2.3478**
00002434849	**TEVA-ALMOTRIPTAN**	**TEV**	$	**2.3478**

AMIFAMPRIDINE

"For the symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 years and older.

For initial coverage, the following information must be provided:
- Baseline pre-treatment Triple Timed Up and Go (3TUG) test

Initial coverage may be approved for a period of 3 months.
For coverage, this drug must be initiated by a Specialist in Neurology, and the initial request and first renewal must be completed by the Specialist.

For coverage, dosing will be approved as follows:
- For patients weighing less than 45 kg: up to a maximum daily dose of 40 mg.
- For patients weighing greater than or equal to 45 kg: up to a maximum daily dose of 100 mg.

Patients will be limited to receiving a one-month supply of amifampridine per prescription at their pharmacy.

For continued coverage beyond the initial 3 months, the patient must demonstrate a response to treatment defined as:
- an improvement of at least 30% on the 3TUG test compared with the baseline measurement.

Renewal of special authorization may be granted for 12 months. Ongoing coverage may be considered only if patients have maintained a minimum improvement of at least 30% on the 3TUG test from baseline at the end of each 12-month period."

10 MG ORAL TABLET				
00002503034	RUZURGI	MDK	$	20.0000

AMPICILLIN

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For the treatment of infections caused by susceptible Shigella and Salmonella."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

250 MG ORAL CAPSULE				
00000020877	NOVO-AMPICILLIN	TEV	$	0.4434
500 MG ORAL CAPSULE				
00000020885	NOVO-AMPICILLIN	TEV	$	0.8406

ANAKINRA

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) in whom other biologics are contraindicated or in patients who have experienced serious adverse events while on other biologics and who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for one 100 mg dose administered daily for 8 weeks.
- Patients will be limited to receiving a one-month supply of anakinra per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 8 weeks but no longer than 12 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for one 100 mg dose administered once daily for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.

ANAKINRA

3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for anakinra must be completed using the Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

100 MG / SYR INJECTION SYRINGE

00002245913	KINERET	BVM	$	53.7889

APOMORPHINE HCL

"For adjunctive therapy in patients with advanced Parkinson's Disease (PD) who are receiving optimized PD therapy (including levodopa and derivatives AND dopaminergic agonists) for the acute, intermittent treatment of hypomobility "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes)."

For coverage, this drug must be initiated in consultation with a Neurologist.

Special authorization may be granted for 6 months.

For renewals, patients must continue to demonstrate clinically significant improvement in motor function.

10 MG / ML INJECTION

00002459132	MOVAPO	PAL	$	15.0068

"For adjunctive therapy in patients with Parkinson's Disease (PD) who are receiving optimized PD therapy (including levodopa and derivatives AND dopaminergic agonists) for the acute, intermittent treatment of hypomobility "off" episodes.

For coverage, this drug must be initiated in consultation with a Neurologist.

For renewals, patients must continue to demonstrate clinically significant improvement in motor function, as demonstrated by an improvement of at least 3.25 points in the Movement Disorders Society Unified Parkinson's Disease Rating Scale Part III (MDS-UPDRS III) score measured within 30 to 60 minutes after a titrated dose of apomorphine film is administered.

Special authorization may be granted for 12 months."

10 MG SUBLINGUAL FILM

00002500264	KYNMOBI	SUN	$	9.5400

APOMORPHINE HCL

"For adjunctive therapy in patients with Parkinson's Disease (PD) who are receiving optimized PD therapy (including levodopa and derivatives AND dopaminergic agonists) for the acute, intermittent treatment of hypomobility "off" episodes.

For coverage, this drug must be initiated in consultation with a Neurologist.

For renewals, patients must continue to demonstrate clinically significant improvement in motor function, as demonstrated by an improvement of at least 3.25 points in the Movement Disorders Society Unified Parkinson's Disease Rating Scale Part III (MDS-UPDRS III) score measured within 30 to 60 minutes after a titrated dose of apomorphine film is administered.

Special authorization may be granted for 12 months."

15 MG SUBLINGUAL FILM

00002500272	KYNMOBI	SUN	$	9.5400

"For adjunctive therapy in patients with Parkinson's Disease (PD) who are receiving optimized PD therapy (including levodopa and derivatives AND dopaminergic agonists) for the acute, intermittent treatment of hypomobility "off" episodes.

For coverage, this drug must be initiated in consultation with a Neurologist.

For renewals, patients must continue to demonstrate clinically significant improvement in motor function, as demonstrated by an improvement of at least 3.25 points in the Movement Disorders Society Unified Parkinson's Disease Rating Scale Part III (MDS-UPDRS III) score measured within 30 to 60 minutes after a titrated dose of apomorphine film is administered.

Special authorization may be granted for 12 months."

20 MG SUBLINGUAL FILM

00002500280	KYNMOBI	SUN	$	9.5400

"For adjunctive therapy in patients with Parkinson's Disease (PD) who are receiving optimized PD therapy (including levodopa and derivatives AND dopaminergic agonists) for the acute, intermittent treatment of hypomobility "off" episodes.

For coverage, this drug must be initiated in consultation with a Neurologist.

For renewals, patients must continue to demonstrate clinically significant improvement in motor function, as demonstrated by an improvement of at least 3.25 points in the Movement Disorders Society Unified Parkinson's Disease Rating Scale Part III (MDS-UPDRS III) score measured within 30 to 60 minutes after a titrated dose of apomorphine film is administered.

Special authorization may be granted for 12 months."

25 MG SUBLINGUAL FILM

00002500299	KYNMOBI	SUN	$	9.5400

APOMORPHINE HCL

"For adjunctive therapy in patients with Parkinson's Disease (PD) who are receiving optimized PD therapy (including levodopa and derivatives AND dopaminergic agonists) for the acute, intermittent treatment of hypomobility "off" episodes.

For coverage, this drug must be initiated in consultation with a Neurologist.

For renewals, patients must continue to demonstrate clinically significant improvement in motor function, as demonstrated by an improvement of at least 3.25 points in the Movement Disorders Society Unified Parkinson's Disease Rating Scale Part III (MDS-UPDRS III) score measured within 30 to 60 minutes after a titrated dose of apomorphine film is administered.

Special authorization may be granted for 12 months."

30 MG SUBLINGUAL FILM				
00002500302	KYNMOBI	SUN	$	9.5400

ARIPIPRAZOLE

"For the maintenance treatment of schizophrenia in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success and who possess clinical evidence of previous successful treatment with aripiprazole therapy;

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR
- Is refractory to trials of at least two other antipsychotic therapies.

Special Authorization may be granted for six months."

All requests (including renewal requests) for aripiprazole prolonged release injection must be completed using the Aripiprazole/Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 60024).

The following product(s) are eligible for auto-renewal.

300 MG / VIAL INJECTION				
00002420864	ABILIFY MAINTENA	OTS	$	456.1800
400 MG / VIAL INJECTION				
00002420872	ABILIFY MAINTENA	OTS	$	456.1800

ASENAPINE MALEATE

"For the acute treatment of manic or mixed episodes associated with bipolar I disorder as co-therapy with lithium or divalproex sodium."

"For the acute treatment of manic or mixed episodes associated with bipolar I disorder as monotherapy, after a trial of lithium or divalproex sodium has failed due to intolerance or lack of response, or the presence of a contraindication to lithium or divalproex sodium as defined by the product monographs."

"Special authorization coverage may be granted for 24 months."

These products are eligible for auto-renewal.

5 MG (BASE) ORAL SUBLINGUAL TABLET				
00002374803	SAPHRIS	ORC	$	1.5225
10 MG (BASE) ORAL SUBLINGUAL TABLET				
00002374811	SAPHRIS	ORC	$	1.5225

ASFOTASE ALFA

1. ELIGIBILITY CRITERIA FOR ASFOTASE ALFA COVERAGE

In order to maintain the integrity of the ADBL, and having regard to the financial and social implications of covering asfotase alfa for the treatment of perinatal/infantile or juvenile-onset hypophosphatasia (HPP), the following special authorization criteria must be satisfied.

In order to be eligible for asfotase alfa coverage for the treatment of HPP, a patient must have submitted a completed Application and have satisfied all of the following requirements:

The patient must:
1) Be diagnosed with HPP in accordance with the requirements specified in the Clinical Criteria for asfotase alfa;
2) Have Alberta government-sponsored drug coverage;
3) Meet the Registration Requirements;
4) Satisfy the Clinical Criteria for asfotase alfa (initial or continued coverage, as appropriate); AND
5) Meet the criteria specified in Discontinuance of Coverage.

There is no guarantee that any application, whether for initial or continued coverage, will be approved. Depending on the circumstances of each case, the Minister or the Minister's delegate may:
- approve an Application;
- approve an Application with conditions;
- deny an Application;
- discontinue an approved Application; OR
- defer an Application pending the provision of further supporting information.

The process for review and approval is explained in further detail below.

2. REGISTRATION REQUIREMENTS

If the patient is a citizen or permanent resident of Canada, the patient must be continuously registered in the Alberta Health Care Insurance Plan for a minimum of one (1) year prior to an application for coverage unless:
- the patient is less than one (1) year of age at the date of the application, then the patient's parent/guardian/legal representative must be registered continuously in the Alberta Health Care Insurance Plan for a minimum of one (1) year; OR
- the patient has moved to Alberta from another province or territory in Canada (the "province of origin"), and immediately prior to moving to Alberta, was covered for asfotase alfa in the province of origin by a provincial or territorial government sponsored drug plan, (or the province of origin provided equivalent coverage for asfotase alfa as does Alberta) and the patient has been registered in the Alberta Health Care Insurance Plan (the patient must provide supporting documentation from the province of origin to prove prior coverage).

If the patient is not a citizen or permanent resident of Canada, the patient must be continuously registered in the Alberta Health Care Insurance Plan for a minimum of five (5) years prior to an application for coverage unless:
- the patient is less than five years of age at the date of the application, then the patients parent/guardian/legal representative must be registered continuously in the Alberta Health Care Insurance Plan for a minimum of five years; OR
- the patient has moved to Alberta from another province or territory in Canada (the "province of origin"), and immediately prior to moving to Alberta, was covered for asfotase alfa in the province of origin by a provincial or territorial government sponsored drug plan, (or the province of origin provided equivalent coverage for asfotase alfa as does Alberta) and the patient has been registered in the Alberta Health Care Insurance Plan (the patient must provide supporting documentation from the province of origin to prove prior coverage).

The Minister reserves the right to modify or waive the Registration Requirements applicable to a given patient if the patient or the patient's parent/guardian/legal representative can establish to the satisfaction of the Minister that the patient has not moved to Alberta for the sole/primary

ASFOTASE ALFA

purpose of obtaining coverage of asfotase alfa.

3. CLINICAL CRITERIA

"For enzyme replacement therapy (ERT) in patients with a confirmed diagnosis of perinatal/infantile or juvenile -onset hypophosphatasia (HPP). These patients must have been diagnosed prior to 12 years of age and have documented onset of signs/symptoms of HPP prior to 12 years of age.

Initiation Criteria:

1. Confirmed diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia (HPP) as defined below:
- Confirmed diagnosis via genetic testing (documented tissue-nonspecific alkaline phosphatase (TNSALP) gene mutations(s) AND
- Serum alkaline phosphatase (ALP) level below the age-adjusted normal range (these are age and gender adjusted norms developed through CALIPER which are used as reference https://apps.sbgh.mb.ca/labmanual/test/view?seedId=3662) AND
NOTE: Below upper limit of normal refers to 2 or lower standard deviations above the mean
- Plasma pyridoxal-5-phosphate (PLP) above the upper limit of normal established and validated in testing laboratory AND
- Documented history of HPP-related skeletal abnormalities confirmed radiologically:
For Infantile HPP: Full skeletal survey done at baseline - examine chest, wrist, knees, and skull. Changes to monitor include: abnormalities of skeletal mineralization including severely undermineralized and even "absence" of some or all bones; undermineralized skull; functional craniosynostosis; gracile bones; thin ribs; chest deformities; evidence of recent/ healed fractures; non-traumatic fractures, recurrent or poorly healing fractures; at the ends of long bones evaluate widening of the growth plate (physis) with irregularity of the provisional zone of calcification; metaphyseal radiolucencies, flaring and fraying at ends of metaphyses and metadiaphyseal patchy focal sclerosis

For Juvenile HPP: Similar to above however generally milder

AND

2. Assessed by a metabolic specialist who determines that the criteria noted above has been met as well as documented signs/symptoms that includes:

a. For Infantile HPP: Failure to thrive AND poor growth AND gross motor delay with substantial skeletal disease. May also have hypercalcemia, B6-responsive seizures and/or respiratory failure, respiratory compromise, including decreased thoracic volume and/or pulmonary hypoplasia; need for respiratory support;

b. For Juvenile HPP: Poor weight gain; unusual gait or running; delayed walking (>15 months); impaired mobility, need for ambulatory assistance; knock-knees; or rickets/bowed legs; muscle weakness/hypotonia; joint pain; muscle pain; bone pain sufficient to limit activity and require medication

c. Childhood HPP (after 6 months of age): gait disturbance, fractures, rickets and RGIC score(NOTE: RGIC score is a 7-point score of Radiographic Global Impressive of Change ie RGIC score assesses changes from baseline and is obtained on paired sequential radiographs with a score of +2 indicating substantial healing/improvement in HPP-related skeletal abnormalities), Thacher score (NOTE: Thacher score is a 10-point Rickets Severity Scale validated for Vitamin D deficiency rickets (and also valid for HPP); score of 10 = severe rickets and 0 = no rickets based on quantified growth plate abnormalities at wrists and knees), bowing of legs, short stature unexplained by other reasons and/or pain score. RGIC and Thacher scores are ideal as they are validated in HPP but a comparable radiologic assessment by an expert bone pediatric radiologist could also be considered

3. Patient is not an adult (ie > 18 years of age) at the time treatment is initiated AND

ASFOTASE ALFA

4. Patient does not have odontoHPP, IE premature loss of deciduous teeth alone or pseudoHPP and vitamin D deficiency to be ruled out. Patients with craniosynostosis alone who do not have other criteria noted above for the diagnosis of HPP need to be followed closely as initiation of treatment with ERT may be indicated if other systemic signs and symptoms develop including muscle weakness, fractures, rickets, pain or nephrocalcinosis and/or if bony disease develops clinically and radiologically AND

5. Patients should be initiated on treatment and followed in a specialized clinic with expertise in the diagnosis and management of HPP. Goals of therapy should be developed on a case-by-case basis prior to the initiation of therapy depending on age and signs and symptoms at presentation.

Signs and symptoms to be monitored depend on age at diagnosis and may include:

a) For perinatal/infantile would expect in addition to above parameters to be followed goals of therapy should include discontinuation or reduction of ventilatory support, increased mobility (improvement in gait vs. baseline), attainment of age-appropriate gross motor milestones. Clinical, radiological and biochemical criteria should be surveilled and these pre-specified goals met at Coverage should be reassessed following a trial of 24 weeks of therapy or more frequently depending on clinical status of patient at initiation of therapy.

b) For juvenile Healing of rickets, improvement of bone mineralization and/bony deformities, fewer fractures, less pain, need for less pain medication, improved growth, increased mobility.

If Initiation Criteria met, 24 week trial to be followed by reassessment by a metabolic specialist

Of Note: Treatment with ERT may not be recommended for newborns who are unable to be successfully ventilated and who have respiratory failure, irreversible pulmonary hypoplasia (underdeveloped lungs with reduced number of alveoli for air exchange) as assessed postnatally by established clinical and radiologic criteria (narrow chest circumference and apparent low lung volumes, evidence for increased pulmonary resistance, MRI changes consistent with lung hypoplasia), very small chest walls, very thin or absent ribs radiologically as assessed by pediatric respirologist, radiologist and treating metabolic specialist. A 6 month trial of ERT may however be recommended for such infants by the treating metabolic specialist and consultants with the consent of the parents. Discontinuation of ERT should be considered at this point and baby moved to palliative care.

Continuation Criteria:
- Assessed by a metabolic specialist who determines that the pre-specified goals have been met and includes documented signs/symptoms noted above.
- Documented compliance by patient and family with respect to follow up visits and reevaluation of laboratory and radiological parameters.
- Additional 24 week trials to be followed by reassessment by a metabolic specialist.

If Continuation Criteria are not met, the treatment should not be continued. In addition, ERT should be discontinued for lack of compliance or if patient does not come for follow up appointments, in spite of all efforts to assist patient and family in this regard, development of craniosynostosis or premature loss of deciduous teeth alone would not signify failure of treatment and ERT should be continued provided other continuation criteria are met.

Stopping Criteria:
- Consider discontinuation after growth is completed based on objective measurement of height and closure of growth plates (closure to be confirmed by Xray criteria and report from a Radiologist).
- Criteria for tapering and discontinuing treatment should be developed by expert committee and evaluated on a case-by-case basis at all age groups.
- Babies with perinatal/infantile HPP who fail treatment trials of 6 months as described above may be discontinued from ERT and moved to palliative care.

*Reference will be made re: dosing and approved vial use to minimize wastage"

ASFOTASE ALFA

4. PROCESS FOR ASFOTASE ALFA COVERAGE

For both initial and continued coverage the following documents (the Application) must be completed and submitted:

- An Asfotase alfa Special Authorization Request Form completed by the patient's Metabolic Specialist;
- An Asfotase alfa Consent Form completed by the patient, or a patient's parent/guardian/legal representative, and the patients Metabolic Specialist (for any initial coverage application); AND
- Any other documentation that may be required by the Minister or the Minister's delegate.

a. Expert Review

Once the Minister or the Minister's delegate has confirmed that the patient meets the Registration Requirement or granted a waiver of the Registration Requirement, the Application will be given to one or more Expert Advisors for review.

The Application, together with the recommendation or recommendations of the Expert Advisor(s), is then forwarded to the Minister or the Minister's delegate for a decision regarding coverage.

After the Minister or Minister's delegate has rendered a decision, the patient's Metabolic Specialist and the patient or patient's parent/guardian/legal representative will be notified by letter of the Minister's decision.

5. APPROVAL OF COVERAGE

The Minister or the Minister's delegate's decision in respect of an Application will specify the effective date of asfotase alfa coverage, if coverage is approved.

Initial coverage may be approved for a period of up to 26 weeks as follows: One dose of 2 mg/kg of asfotase alfa administered three times a week or one dose of 1 mg/kg of asfotase alfa administered six times a week (total of 78 doses for the 2mg/kg dosage regimen and a total of 156 doses for the 1 mg/kg dosage regimen).

Continued coverage may be approved for up to one dose of 2 mg/kg of asfotase alfa administered three times a week or one dose of 1 mg/kg of asfotase alfa administered six times a week for a period of six (6) months (total of 78 doses for the 2mg/kg dose and a total of 156 doses for the 1 mg/kg dose).

If a patient is approved for coverage, prescriptions for asfotase alfa must be written by a Metabolic Specialist. To avoid wastage, prescription quantities are limited to a two week supply. Extended quantity and vacation supplies are not permitted. The Government is not responsible and will not pay for costs associated with wastage or improper storage of asfotase alfa.

Approval of coverage is granted for a specific period, to a maximum of 26 weeks. If continued treatment is necessary, it is the responsibility of the patient or patient's parent/guardian/legal representative and the Metabolic Specialist to submit a new Application to re-apply for asfotase alfa coverage, and receive a decision thereon, prior to the expiry date of the authorization period.

6. WITHDRAWAL

Therapy may be withdrawn at the request of the patient or the patient's parent/guardian/legal representative at any time. Notification of withdrawal from therapy must be made by the Metabolic Specialist or patient in writing.

Applications, withdrawal requests, and any other information to be provided must be sent to Clinical Drug Services, Alberta Blue Cross.

ASFOTASE ALFA

18 MG / VIAL INJECTION				
00002444615	STRENSIQ	APG	$	1358.6400
28 MG / VIAL INJECTION				
00002444623	STRENSIQ	APG	$	2113.4400
40 MG / VIAL INJECTION				
00002444631	STRENSIQ	APG	$	3019.2000
80 MG / VIAL INJECTION				
00002444658	STRENSIQ	APG	$	6038.4000

AZITHROMYCIN

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For the prevention of disseminated Mycobacterium avium complex disease in patients with advanced HIV infection or other immunocompromised conditions.

Special authorization may be granted for 6 months."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

The following product(s) are eligible for auto-renewal.

600 MG ORAL TABLET				
00002261642	PMS-AZITHROMYCIN	PMS	$	10.6652

AZTREONAM

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): TOBRAMYCIN INHALATION SOLUTION

"For the treatment of chronic pulmonary Pseudomonas aeruginosa infections when used as cyclic treatment (28-day cycles) in patients 6 years of age and older with moderate to severe cystic fibrosis (CF) and deteriorating clinical condition despite treatment with inhaled tobramycin.

Coverage will not be considered when inhaled aztreonam and other inhaled antibiotic(s) (e.g. levofloxacin, tobramycin) are intended for use in combination.

Special authorization may be granted for 6 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

75 MG / VIAL INHALATION POWDER FOR SOLUTION				
00002329840	CAYSTON	GIL	$	44.0631

BARICITINIB

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial) [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 2 mg once daily for three months.
- Patients will be limited to receiving a one-month supply of baricitinib per prescription at their pharmacy.
- Patients will not be permitted to switch back to baricitinib if they were deemed unresponsive to therapy.

For continued coverage beyond three months, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial three months to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 2 mg once daily for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- confirmation of maintenance of ACR20, or
- maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Coverage cannot be provided for baricitinib when intended for use in combination with a biologic agent or other Janus kinase (JAK) inhibitors."

All requests (including renewal requests) for baricitinib for Rheumatoid Arthritis must be completed using the

BARICITINIB

Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

2 MG ORAL TABLET

00002480018	OLUMIANT	LIL	$	52.2940

BENRALIZUMAB

"Special authorization coverage may be provided for add-on maintenance treatment of adult patients with severe eosinophilic asthma if the following clinical criteria and conditions are met:
Patient is inadequately controlled with high-dose inhaled corticosteroids (ICS) and one or more additional asthma controller(s) (e.g., a long-acting beta-agonist [LABA]).
AND
Patient has a blood eosinophil count of greater than or equal to 300 cells/mcL AND has experienced two or more clinically significant asthma exacerbations* in the 12 months prior to treatment initiation with benralizumab;
OR
Patient has a blood eosinophil count of greater than or equal to 150 cells/mcL AND is receiving daily maintenance treatment with oral corticosteroids (OCS).

For coverage, the drug must be initiated and monitored by a respirologist or clinical immunologist or allergist.

Initial coverage may be approved for a period of 12 months at a dosage of 30 mg administered every 4 weeks for the first 3 doses and 30 mg administered every 8 weeks thereafter.

-Patients will be limited to receiving one dose of benralizumab per prescription at their pharmacy.
-Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
-Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
-Coverage cannot be provided for benralizumab when this medication is intended for use in combination with other biologics for the treatment of asthma.

If ALL of the following criteria are met, special authorization may be approved for 30 mg administered every 8 weeks for a further 12-month period:
1) An improvement in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 when compared to pre-treatment baseline or an ACQ-5 score of less than or equal to 1; AND
2) Maintenance or reduction in the number of clinically significant exacerbations* compared to the 12 months prior to initiation of treatment with benralizumab; AND
3) For patients on daily maintenance therapy with OCS prior to initiating benralizumab, a decrease in the OCS dose.

Continued coverage may be considered for 30 mg administered every 8 weeks if ALL of the following criteria are met at the end of each additional 12-month period:
1) The ACQ-5 score achieved during the first 12 months of therapy is at least maintained throughout treatment or the ACQ-5 score is less than or equal to 1; AND
2) Maintenance or reduction in the number of clinically significant exacerbations* compared to the previous 12-month period; AND
3) For patients on daily maintenance therapy with OCS prior to initiating benralizumab, the reduction in the OCS dose achieved after the first 12 months of therapy is at least maintained throughout treatment.

* Clinically significant asthma exacerbation is defined as worsening of asthma such that the treating physician elected to administer systemic glucocorticoids for at least 3 days or the patient visited an emergency department or was hospitalized."

All requests (including renewal requests) for benralizumab must be completed using the Benralizumab/Mepolizumab Special Authorization Request Form (ABC 60061).

30 MG / SYR INJECTION SYRINGE

☒ 00002496135	FASENRA (PEN)	AZC	$	4035.8700
☒ 00002473232	FASENRA	AZC	$	4070.7600

BIMEKIZUMAB

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:
- Have a total PASI of 10 or more and a DLQI of more than 10, OR
- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
- Cyclosporine (6 weeks treatment); AND
- Phototherapy (unless restricted by geographic location)
Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.
'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.
For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").
- Initial coverage may be approved for 16 weeks as follows:
- Five monthly doses of 320 mg of bimekizumab at weeks 0, 4, 8, 12 and 16.
- Patients will be limited to receiving one dose of bimekizumab per prescription at their pharmacy. Each 320 mg dose is provided as two subcutaneous injections of 160 mg.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of the initial coverage period.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.
For continued coverage beyond five doses, the patient must meet all of the following criteria:
1) The patient must be assessed by a Dermatology Specialist after the initial five doses to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Greater than or equal to 75% reduction in PASI score, OR
- Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.
Following this assessment, continued coverage may be considered for one 320 mg dose of bimekizumab every 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for bimekizumab for Plaque Psoriasis must be completed using the Adalimumab/Bimekizumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Tildrakizumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

160 MG / SYR INJECTION SYRINGE

☒ 00002525267	BIMZELX	UCB	$	1625.0000
☒ 00002525275	BIMZELX (AUTO-INJECTOR)	UCB	$	1625.0000

BRIVARACETAM

"For adjunctive therapy in patients with refractory partial-onset seizures who meet all of the following criteria:
- Are currently receiving two or more antiepileptic medications, AND
- Have failed or demonstrated intolerance to three other antiepileptic medications, AND
- Patients are not receiving concurrent therapy with levetiracetam, AND,
- Therapy must be initiated by a Neurologist.

For the purpose of administering these criteria failure is defined as inability to achieve satisfactory seizure control.

Special authorization may be granted for six months.

Coverage cannot be provided for brivaracetam, eslicarbazepine, lacosamide or perampanel when these medications are intended for use in combination."

Each of these products is eligible for auto-renewal.

10 MG ORAL TABLET				
00002452936	BRIVLERA	UCB	$	4.3200
25 MG ORAL TABLET				
00002452944	BRIVLERA	UCB	$	4.3200
50 MG ORAL TABLET				
00002452952	BRIVLERA	UCB	$	4.3200
75 MG ORAL TABLET				
00002452960	BRIVLERA	UCB	$	4.3200
100 MG ORAL TABLET				
00002452979	BRIVLERA	UCB	$	4.3200

BUDESONIDE

"For the treatment of inflammatory bowel disease (e.g. Crohn's, ulcerative colitis, ulcerative ileitis, etc.). This drug product must be prescribed by a specialist in Gastroenterology, Internal Medicine or Pediatrics (or by a specialist in General Surgery on a case-by-case basis, in geographic areas where access to these specialties is not available).

Special authorization may be granted for 12 months."

The following product(s) are eligible for auto-renewal.

3 MG ORAL CONTROLLED-RELEASE CAPSULE				
00002483874	**BUDESONIDE**	**TPG**	$	**1.7157**
00002229293	ENTOCORT	TPG	$	1.8635

BUDESONIDE/ FORMOTEROL FUMARATE DIHYDRATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

ASTHMA

FIRST-LINE DRUG PRODUCT(S): INHALED CORTICOSTEROID (ICS)

"For the treatment of asthma in patients uncontrolled on inhaled steroid therapy."

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S): LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])

"For the long-term maintenance treatment of airflow obstruction in patients with moderate to severe (i.e., FEV1 < 80% predicted) chronic obstructive pulmonary disease (COPD), who have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA])."

"For the long-term maintenance treatment of airflow obstruction in patients with severe (i.e., FEV1 < 50% predicted) chronic obstructive pulmonary disease (COPD)."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for budesonide + formoterol fumarate dihydrate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

100 MCG / DOSE * 6 MCG / DOSE INHALATION METERED INHALATION POWDER				
00002245385	SYMBICORT 100 TURBUHALER	AZC	$	0.5985
200 MCG / DOSE * 6 MCG / DOSE INHALATION METERED INHALATION POWDER				
00002245386	SYMBICORT 200 TURBUHALER	AZC	$	0.7781

BUDESONIDE/ GLYCOPYRRONIUM BROMIDE/ FORMOTEROL FUMARATE DIHYDRATE

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S):
LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])

SECOND-LINE DRUG PRODUCT(S):
LONG-ACTING BRONCHODILATOR DUAL THERAPY (I.E., LONG-ACTING BETA-2 AGONIST [LABA] AND LONG-ACTING MUSCARINIC ANTAGONIST [LAMA]) OR DUAL THERAPY OF INHALED CORTICOSTEROID [ICS] AND LONG-ACTING BETA-2 AGONIST [LABA])

"For the long-term maintenance treatment of chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema, in patients who are not controlled on optimal dual inhaled therapy (i.e., long-acting beta-2 agonist [LABA]/long-acting muscarinic antagonist [LAMA] OR inhaled corticosteroid [ICS]/long-acting beta-2 agonist [LABA])."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the third-line therapy drug.

UP - First-line therapy ineffective

All requests for budesonide + glycopyrronium bromide + formoterol fumarate dihydrate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

182 MCG / DOSE * 8.2 MCG / DOSE * 5.8 MCG / DOSE (BASE)		INHALATION	METERED DOSE AEROSOL	
00002518058	BREZTRI AEROSPHERE	AZC	$	1.0583

BUROSUMAB

"For the treatment of X-linked hypophosphatemia (XLH) in patients who meet ALL of the following criteria:
Treatment is initiated in pediatric patients who are at least one year of age and in whom epiphyseal closure has not yet occurred, and who have:
- fasting hypophosphatemia, and
- normal renal function (defined as fasting serum creatinine below the age-adjusted upper limit of normal), and
- radiographic evidence of rickets with a rickets severity score (RSS) total score of two or greater, and
- a confirmed phosphate-regulating endopeptidase homolog, X-linked (PHEX) gene variant in either the patient or in a directly related family member with appropriate X-linked inheritance.

For coverage, this drug must be prescribed by a Specialist in Medical Genetics, Endocrinology, Nephrology, Orthopedic Surgery or Rheumatology.

- Coverage may be approved for a starting dose of 0.8 mg/kg every 2 weeks, then increased up to a maximum dose of 2 mg/kg (up to a maximum of 90 mg) every two weeks.

Special authorization may be granted for 12 months.
Patients will be limited to receiving a 4-week supply of burosumab per prescription at their pharmacy.

For continued coverage beyond 12 months, the patient must meet the following criteria:
1. In pediatric patients in whom epiphyseal closure has not yet occurred:
- for the first renewal, improvement of 12-month RSS total score when compared to pre-treatment baseline, and
- for subsequent renewals, the RSS total score achieved after the first 12 months of therapy is at least maintained.
2. In adolescent or adult patients who initiated burosumab based on the criteria for pediatric patients, coverage may be renewed unless any of the following occur:
- hyperparathyroidism, or
- nephrocalcinosis, or
- evidence of fracture or pseudofracture based on radiographic assessment."

All requests (including renewal requests) for burosumab must be completed using the Burosumab Special Authorization Request Form (ABC 60096).

10 MG / ML INJECTION			
00002483629	CRYSVITA	KKL	$ 4514.9400
20 MG / ML INJECTION			
00002483637	CRYSVITA	KKL	$ 9029.9000
30 MG / ML INJECTION			
00002483645	CRYSVITA	KKL	$ 13544.8400

BUSERELIN ACETATE

"When prescribed for non-cancer, non-cosmetic or non-fertility indications.

Special authorization may be granted for 6 months."

Information is required regarding the patient's diagnosis/indication for use of this medication.

The following product(s) are eligible for auto-renewal.

1 MG / ML (BASE) INJECTION			
00002225166	SUPREFACT	CAG	$ 12.7967
6.3 MG (BASE) INJECTION IMPLANT			
00002228955	SUPREFACT DEPOT	CAG	$ 869.2425

CABERGOLINE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): BROMOCRIPTINE

"For the treatment of hyperprolactinemia in patients who are intolerant to or who have failed bromocriptine. Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

0.5 MG ORAL TABLET

00002455897	**APO-CABERGOLINE**	**APX**	$	**12.3941**
00002242471	DOSTINEX	PAL	$	16.0753

CANAGLIFLOZIN

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): METFORMIN
SECOND-LINE DRUG PRODUCT(S): SULFONYLUREAS
AND WHERE INSULIN IS NOT AN OPTION

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:
- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated
CA - Prior adverse reaction
CB - Previous treatment failure
CJ - Product is not effective

All requests for canagliflozin must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

100 MG ORAL TABLET

00002425483	INVOKANA	JAI	$	2.8560

300 MG ORAL TABLET

00002425491	INVOKANA	JAI	$	2.8560

CASPOFUNGIN

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For treatment of esophageal candidiasis in patients who are resistant or intolerant to fluconazole or itraconazole.

For treatment of invasive candidiasis resistant or intolerant to fluconazole.

For treatment of Invasive Aspergillosis in patients who are refractory to or intolerant of other therapies."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

50 MG / VIAL INJECTION				
00002460947	**CASPOFUNGIN**	**JUN**	$	**188.7000**
00002244265	CANCIDAS	MFC	$	222.0000
70 MG / VIAL INJECTION				
00002460955	**CASPOFUNGIN**	**JUN**	$	**188.7000**
00002244266	CANCIDAS	MFC	$	222.0000

CEFADROXIL

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For the treatment of skin and skin structure infections."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

500 MG ORAL CAPSULE				
00002240774	**APO-CEFADROXIL**	**APX**	$	**0.8421**
00002235134	**TEVA-CEFADROXIL**	**TEV**	$	**0.8421**

CEFOXITIN SODIUM

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For the treatment of Mycobacterium abscessus infection."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

1 G / VIAL (BASE) INJECTION				
00002291711	**CEFOXITIN**	**APX**	$	**10.6000**
00002128187	**CEFOXITIN SODIUM**	**TEV**	$	**10.6000**
2 G / VIAL (BASE) INJECTION				
00002291738	**CEFOXITIN**	**APX**	$	**21.2500**
00002128195	**CEFOXITIN SODIUM**	**TEV**	$	**21.2500**

CELECOXIB

"1) For patients who are at high risk of upper gastrointestinal (GI) complications due to a proven history of prior complicated GI events (e.g. GI perforation, obstruction or major bleeding) or

2) For patients who have a documented history of ulcers proven radiographically and/or endoscopically.

Special authorization for both criteria may be granted for 6 months."

All requests for celecoxib must be completed using the Celecoxib Special Authorization Request Form (ABC 60032).

The following product(s) are eligible for auto-renewal.

100 MG ORAL CAPSULE

00002437570	**AG-CELECOXIB**	**AGP**	$	**0.1279**
00002418932	**APO-CELECOXIB**	**APX**	$	**0.1279**
00002445670	**AURO-CELECOXIB**	**AUR**	$	**0.1279**
00002426382	**BIO-CELECOXIB**	**BMD**	$	**0.1279**
00002429675	**CELECOXIB**	**SIV**	$	**0.1279**
00002436299	**CELECOXIB**	**SNS**	$	**0.1279**
00002424533	**JAMP-CELECOXIB**	**JPC**	$	**0.1279**
00002495465	**M-CELECOXIB**	**MTR**	$	**0.1279**
00002420058	**MAR-CELECOXIB**	**MAR**	$	**0.1279**
00002412497	**MINT-CELECOXIB**	**MPI**	$	**0.1279**
00002479737	**NRA-CELECOXIB**	**NRA**	$	**0.1279**
00002517116	**PMSC-CELECOXIB**	**PMS**	$	**0.1279**
00002239941	CELEBREX	UJC	$	0.7641

200 MG ORAL CAPSULE

00002437589	**AG-CELECOXIB**	**AGP**	$	**0.2558**
00002418940	**APO-CELECOXIB**	**APX**	$	**0.2558**
00002445689	**AURO-CELECOXIB**	**AUR**	$	**0.2558**
00002426390	**BIO-CELECOXIB**	**BMD**	$	**0.2558**
00002429683	**CELECOXIB**	**SIV**	$	**0.2558**
00002436302	**CELECOXIB**	**SNS**	$	**0.2558**
00002424541	**JAMP-CELECOXIB**	**JPC**	$	**0.2558**
00002495473	**M-CELECOXIB**	**MTR**	$	**0.2558**
00002420066	**MAR-CELECOXIB**	**MAR**	$	**0.2558**
00002412500	**MINT-CELECOXIB**	**MPI**	$	**0.2558**
00002479745	**NRA-CELECOXIB**	**NRA**	$	**0.2558**
00002517124	**PMSC-CELECOXIB**	**PMS**	$	**0.2558**
00002239942	CELEBREX	UJC	$	1.5286

CERTOLIZUMAB PEGOL

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial) [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for an initial dose of 400 mg (given as 2 subcutaneous injections of 200 mg each) at Weeks 0, 2 and 4. As an interim measure, coverage will be provided for additional doses of 400 mg per 4 weeks up to week 12, to allow time to determine whether the New Patient meets coverage criteria for Maintenance Dosing below.
- Patients will be limited to receiving a one-month supply of certolizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial five doses to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 400 mg per 4 weeks, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- confirmation of maintenance of ACR20, or
- maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1)

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decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for certolizumab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Ankylosing Spondylitis

"Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

Initial coverage may be approved for an initial dose of 400 mg (given as 2 subcutaneous injections of 200 mg each) at Weeks 0, 2 and 4. As an interim measure, coverage will be provided for additional doses of 400 mg per 4 weeks up to week 12, to allow time to determine whether the New Patient meets coverage criteria for Maintenance Dosing below.
- Patients will be limited to receiving a one-month supply of certolizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial 5 doses to determine response.
2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
- Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for 400 mg per 4 weeks, for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

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All requests (including renewal requests) for certolizumab for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

Psoriatic Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial). Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for an initial dose of 400 mg (given as 2 subcutaneous injections of 200 mg each) at Weeks 0, 2 and 4. As an interim measure, coverage will be provided for additional doses of 400 mg per 4 weeks up to week 12, to allow time to determine whether the New Patient meets coverage criteria for Maintenance Dosing below.
- Patients will be limited to receiving a one-month supply of certolizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial 5 doses to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 400 mg per 4 weeks, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or

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- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests. It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for certolizumab for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

200 MG / SYR INJECTION SYRINGE

☒ 00002331675	CIMZIA	UCB	$	664.5100
☒ 00002465574	CIMZIA AUTO-INJECTOR	UCB	$	664.5100

CLADRIBINE

"Special authorization coverage may be provided for the treatment of relapsing remitting multiple sclerosis (RRMS) to reduce the frequency of clinical relapses, to decrease the number and volume of active brain lesions identified on magnetic resonance imaging (MRI) scans and to delay the progression of physical disability, in adult patients (18 years of age or older) who are refractory or intolerant to:

At least ONE of the following:
- dimethyl fumarate
- glatiramer acetate
- interferon beta
- ocrelizumab
- ofatumumab
- peginterferon beta
- teriflunomide

Definition of 'intolerant'
Demonstrating serious adverse effects or contraindications to treatments as defined in the product monograph, or a persisting adverse event that is unresponsive to recommended management techniques and which is incompatible with further use of that class of MS disease modifying therapy (DMT).

Definition of 'refractory'
-Development of neutralizing antibodies to interferon beta.
-When the above MS DMTs are taken at the recommended doses for a full and adequate course of treatment, within a consecutive 12-month period while the patient was on the MS DMT, the patient has:

1) Been adherent to the MS DMT (greater than 80% of approved doses have been administered);

2) Experienced at least two relapses* of MS confirmed by the presence of neurologic deficits on examination.

i. The first qualifying clinical relapse must have begun at least one month after treatment initiation.
ii. Both qualifying relapses must be classified with a relapse severity of moderate, severe or very severe**.

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

**Relapse severity: with moderate relapses modification or more time is required to carry out activities of daily living; with severe relapses there is inability to carry out some activities of daily living; with very severe relapses activities of daily living must be completed by others.

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist.

To register to become an MS Neurologist, please complete the Registration for MS Neurologist Status Form (ABC 60002).

Coverage may be considered only if the following criteria are met:

1) The registered MS Neurologist must confirm a diagnosis of RRMS;

2) The patient must have active disease which is defined as at least two relapses* of MS during

CLADRIBINE

the previous two years or in the two years prior to starting an MS DMT. In most cases this will be satisfied by the 'refractory' to treatment criterion but if a patient failed an MS DMT more than one year earlier, ongoing active disease must be confirmed.

3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).

Coverage will not be approved when any MS DMT or other immunosuppressive therapy is to be used in combination with cladribine.

Coverage of cladribine will not be approved if the patient was deemed to be refractory to cladribine in the past.

Following assessment of the request, cladribine may be approved for coverage at a cumulative dose of 3.5 mg/kg over 2 years, administered as 1 treatment course of 1.75 mg/kg per year. Each treatment course consists of 2 treatment weeks, with each treatment week consisting of 4 or 5 days on which a patient receives 10 mg or 20 mg (one or two tablets) as a single daily dose, depending on body weight.

- The Initial Treatment Course is administered in one treatment week at the beginning of the first month and one treatment week at the beginning of the second month of the same year.

-The Second Treatment Course is administered in the subsequent year in two treatment weeks one month apart, in the same manner as the initial treatment course.

Patients will be limited to receiving one treatment week of cladribine per prescription at their pharmacy.

Coverage is limited to two treatment courses.

All requests for cladribine must be completed using the Cladribine/Fingolimod/Natalizumab For Multiple Sclerosis Special Authorization Request Form (ABC 60000).

10 MG ORAL TABLET

00002470179	MAVENCLAD	SRO	$	3212.0000

CLINDAMYCIN PHOSPHATE/ BENZOYL PEROXIDE

"For the treatment of severe acne as defined by scarring acne.

Special Authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

1 % * 3 % TOPICAL GEL

00002382822	CLINDOXYL ADV	GSK	$	0.8084

"For the treatment of severe acne as defined by scarring acne.

Special Authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

1 % (BASE) * 5 % TOPICAL GEL

00002440180	**TARO-CLINDAMYCIN/BENZOYL PEROXIDE**	**TAR**	$	**0.6857**
00002243158	CLINDOXYL	GSK	$	0.9883

CLINDAMYCIN PHOSPHATE/ BENZOYL PEROXIDE

"For the treatment of severe acne as defined by scarring acne.

Special Authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

1 % (BASE) * 5 % TOPICAL GEL				
00002464519	**TARO-BENZOYL PEROXIDE/CLINDAMYCIN KIT**	**TAR**	$	**0.7422**
00002248472	BENZACLIN	VCL	$	1.0844

CYCLOSPORINE

"For the treatment of severe psoriasis in those patients where other standard therapy has failed. This drug product must be prescribed by a specialist in Dermatology."

"For the treatment of severe rheumatoid arthritis in patients who are unable to tolerate or have failed an adequate trial of methotrexate. This drug product must be prescribed by a specialist in Rheumatology (or by a Specialist in Internal Medicine with an interest in Rheumatology on a case-by-case basis, in geographic areas where access to this specialty is not available)."

"For the treatment of steroid dependent and steroid resistant nephrotic syndrome. Consideration will be given where cyclosporine is used for the induction and maintenance of remissions or for the maintenance of steroid induced remissions. This drug product must be prescribed by a specialist in Pediatrics or Nephrology."

"Special authorization for all criteria may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

10 MG ORAL CAPSULE				
00002237671	NEORAL	NOV	$	0.6818
25 MG ORAL CAPSULE				
00002247073	**SANDOZ CYCLOSPORINE**	**SDZ**	$	**0.7870**
00002150689	NEORAL	NOV	$	1.5853
50 MG ORAL CAPSULE				
00002247074	**SANDOZ CYCLOSPORINE**	**SDZ**	$	**1.5350**
00002150662	NEORAL	NOV	$	3.0920
100 MG ORAL CAPSULE				
00002242821	**SANDOZ CYCLOSPORINE**	**SDZ**	$	**3.0720**
00002150670	NEORAL	NOV	$	6.1860
100 MG / ML ORAL SOLUTION				
00002150697	NEORAL	NOV	$	5.5004

CYPROTERONE ACETATE

"When prescribed for non-cancer, non-cosmetic indications.

Special authorization may be granted for 6 months."

Information is required regarding the patient's diagnosis/indication for use of this medication.

The following product(s) are eligible for auto-renewal.

50 MG ORAL TABLET

00000704431	**ANDROCUR**	**PMS**	$	**1.4000**
00002245898	**CYPROTERONE**	**AAP**	$	**1.4000**
00002390760	**MED-CYPROTERONE**	**GMP**	$	**1.4000**

100 MG / ML INJECTION

00000704423	ANDROCUR DEPOT	PMS	$	32.8000

CYSTEAMINE BITARTRATE

"For use in patients with an established diagnosis of infantile nephropathic cystinosis with documented high levels of mixed leukocyte (WBC) cystine or granulocyte cystine.

For coverage, this drug must be prescribed by or in consultation with physician with experience in the diagnosis and management of cystinosis.

Special authorization may be granted for 12 months."

This product is eligible for auto-renewal.

25 MG ORAL DELAYED-RELEASE CAPSULE

00002464705	PROCYSBI	RAP	$	5.9537

"For use in patients with an established diagnosis of infantile nephropathic cystinosis with documented high levels of mixed leukocyte (WBC) cystine or granulocyte cystine.

For coverage, this drug must be prescribed by or in consultation with physician with experience in the diagnosis and management of cystinosis.

Special authorization may be granted for 12 months."

This product is eligible for auto-renewal.

75 MG ORAL DELAYED-RELEASE CAPSULE

00002464713	PROCYSBI	RAP	$	17.8610

CYSTEAMINE HYDROCHLORIDE

For the treatment of corneal cystine crystal deposits (CCCDs) in adults and children from 2 years of age with a diagnosis of cystinosis.

For coverage, this drug must be initiated by an ophthalmologist experienced in the management of the ocular manifestations of cystinosis.

Special authorization may be granted for 12 months.

The following product(s) are eligible for auto-renewal.

0.37 % (BASE) OPHTHALMIC SOLUTION

00002485605	CYSTADROPS	RRD	$	397.2000

DABIGATRAN ETEXILATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): WARFARIN

For at-risk patients (CHADS2 score of greater than or equal to 1) with non-valvular atrial fibrillation (AF) for the prevention of stroke and systemic embolism AND in whom:

a) Anticoagulation is inadequate (at least 35% of INR testing results outside the desired range) following a reasonable trial on warfarin (minimum two months of therapy); OR
b) Anticoagulation with warfarin is contraindicated as per the product monograph or not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate less than 30mL/min) OR hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis; OR prosthetic heart valves.should not receive dabigatran.

Patients 75 years of age and greater should have documented stable renal function (creatinine clearance or estimated glomerular filtration rate maintained for at least three months of 30-49 ml/min for 110mg twice daily dosing or greater than or equal to 50 ml/min for 150mg twice daily dosing).

Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see Drug Product Monograph).

Patients starting the drug product should have ready access to appropriate medical services to manage a major bleeding event.

There is currently no data to support that the Drug Product provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so Drug Product is not recommended in these populations.

Special Authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

All requests for dabigatran must be completed using the Apixaban/Dabigatran/Edoxaban/Rivaroxaban Special Authorization Request Form (ABC 60019).

110 MG ORAL CAPSULE				
00002468905	**APO-DABIGATRAN**	**APX**	$	**1.2540**
00002312441	PRADAXA	BOE	$	1.7309
150 MG ORAL CAPSULE				
00002468913	**APO-DABIGATRAN**	**APX**	$	**1.2540**
00002358808	PRADAXA	BOE	$	1.7309

DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE

Heart Failure

FIRST-LINE DRUG PRODUCT(S): Note two out of the three following drug classes are required.
- ANGIOTENSIN CONVERTING ENZYME INHIBITOR (ACEI) OR ANGIOTENSIN II RECEPTOR ANTAGONIST (ARB) AND/OR
- BETA-BLOCKER AND/OR
- MINERALOCORTICOID RECEPTOR ANTAGONIST (MRA)

"As add-on therapy for the treatment of heart failure with reduced ejection fraction (HFrEF) patients with the following criteria:
1) Reduced left ventricular ejection fraction (LVEF) (less than or equal to 40%)
And
2) New York Heart Association (NYHA) class II or III HF symptoms
And
3) When used as adjunctive therapy to standard therapy including:
- a stable dose of an angiotensin converting enzyme inhibitor (ACEI) OR angiotensin II receptor antagonist (ARB)
And
- a beta-blocker
And,
-if tolerated, a mineralocorticoid receptor antagonist (MRA)

Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

All requests for dapagliflozin for Heart Failure must be completed using the Dapagliflozin for Heart Failure Special Authorization Request Form (ABC 60097).

Diabetes Mellitus Type 2

FIRST-LINE DRUG PRODUCT(S): METFORMIN OR SULFONYLUREAS
SECOND-LINE DRUG PRODUCT(S): SULFONYLUREAS OR METFORMIN
AND WHERE INSULIN IS NOT AN OPTION

As add-on therapy to metformin or a sulfonylurea for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:
- a sufficient trial (i.e. a minimum of 6 months) of metformin who have a contraindication or intolerance to a sulfonylurea, OR a sulfonylurea who have a contraindication or intolerance to metformin,
- AND for whom insulin is not an option.

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated
CA - Prior adverse reaction
CB - Previous treatment failure

DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE

CJ - Product is not effective

All requests for dapagliflozin must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

5 MG (BASE) ORAL TABLET				
00002435462	FORXIGA	AZC	$	2.7300
10 MG (BASE) ORAL TABLET				
00002435470	FORXIGA	AZC	$	2.7300

DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE/ METFORMIN HCL

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): METFORMIN OR SULFONYLUREAS
SECOND-LINE DRUG PRODUCT(S): SULFONYLUREAS OR METFORMIN
AND WHERE INSULIN IS NOT AN OPTION

"For the treatment of Type 2 diabetes in patients with inadequate glycemic control on:
- a sufficient trial (i.e. a minimum of 6 months) of metformin who have a contraindication or intolerance to a sulfonylurea, OR
- a sulfonylurea who have failed a sufficient trial of metformin, AND
- for whom insulin is not an option.

Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated
CA - Prior adverse reaction
CB - Previous treatment failure
CJ - Product is not effective

All requests for dapagliflozin+metformin must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

5 MG * 850 MG ORAL TABLET				
00002449935	XIGDUO	AZC	$	1.2683
5 MG * 1,000 MG ORAL TABLET				
00002449943	XIGDUO	AZC	$	1.2863

DAPTOMYCIN

For the treatment of:
- Culture confirmed gram-positive infections from sterile sites, specifically Methicillin-resistant Staphylococcus aureus (MRSA), AND
- In patients who do not respond to, or exhibit multidrug intolerance to, or allergy to vancomycin, AND
- to facilitate patient discharge from hospital where it otherwise would not be possible.

This product must be prescribed in consultation with a specialist in Infectious Diseases in all instances.

Special Authorization may be granted for 12 months.

500 MG / VIAL INJECTION				
00002465493	CUBICIN RF	CUB	$	161.0000

DARBEPOETIN

"For the treatment of anemia of chronic renal failure in patients with low hemoglobin (<95 g/L and falling). Patients must be iron replete prior to initiation of therapy as indicated by transferrin saturation >20%. Special authorization will be granted for twelve months.

According to current clinical practice, hemoglobin levels should be maintained between 95 g/L to 110 g/L and the dose should be held or reduced when hemoglobin is greater than or equal to 115 g/L. Doses should not exceed 300 mcg per month."

"For the treatment of chemotherapy-induced anemia in patients with non-myeloid malignancies with low hemoglobin (<100 g/L) in whom blood transfusions are not possible due to transfusion reactions, cross-matching difficulties or iron overload. If hemoglobin is rising by more than 20 g/L per month, the dose should be reduced by about 25%. Special authorization will be granted for twelve months."

In order to comply with the first criterion information must be provided regarding the patient's hemoglobin and transferrin saturation.

In order to comply with the second criterion: if the patient has iron overload the prescriber must state this in the request or alternatively, information is required regarding the patient's transferrin saturation, along with the results of liver function tests if applicable.

For the second criterion, renewal requests may be considered if the patient's hemoglobin is < 110 g/L while on therapy.

The following product(s) are eligible for auto-renewal for the indication of the treatment of anemia of chronic renal failure.

All requests for darbepoetin must be completed using the Darbepoetin/Epoetin Special Authorization Request Form (ABC 60006).

100 MCG / SYR INJECTION SYRINGE				
00002391775	ARANESP (0.5 ML SYRINGE)	AMG	$	268.0000
10 MCG / SYR INJECTION SYRINGE				
00002392313	ARANESP (0.4 ML SYRINGE)	AMG	$	26.8000
20 MCG / SYR INJECTION SYRINGE				
00002392321	ARANESP (0.5 ML SYRINGE)	AMG	$	53.6000
30 MCG / SYR INJECTION SYRINGE				
00002392348	ARANESP (0.3 ML SYRINGE)	AMG	$	80.4000
40 MCG / SYR INJECTION SYRINGE				
00002391740	ARANESP (0.4 ML SYRINGE)	AMG	$	107.2000
50 MCG / SYR INJECTION SYRINGE				
00002391759	ARANESP (0.5 ML SYRINGE)	AMG	$	134.0000

DARBEPOETIN

60 MCG / SYR INJECTION SYRINGE				
00002392356	ARANESP (0.3 ML SYRINGE)	AMG	$	160.8000
80 MCG / SYR INJECTION SYRINGE				
00002391767	ARANESP (0.4 ML SYRINGE)	AMG	$	214.4000
130 MCG / SYR INJECTION SYRINGE				
00002391783	ARANESP (0.65 ML SYRINGE)	AMG	$	348.4000
150 MCG / SYR INJECTION SYRINGE				
00002391791	ARANESP (0.3 ML SYRINGE)	AMG	$	439.7550
200 MCG / SYR INJECTION SYRINGE				
00002391805	ARANESP (0.4 ML SYRINGE)	AMG	$	652.3100
300 MCG / SYR INJECTION SYRINGE				
00002391821	ARANESP (0.6 ML SYRINGE)	AMG	$	998.2200
500 MCG / SYR INJECTION SYRINGE				
00002392364	ARANESP (1.0 ML SYR)	AMG	$	1663.7100

DARIFENACIN HYDROBROMIDE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): SOLIFENACIN OR TOLTERODINE LA

"For patients who have failed on or are intolerant to solifenacin or tolterodine LA."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

All requests for darifenacin hydrobromide must be completed using the darifenacin hydrobromide/Fesoterodine fumarate/Mirabegron/Trospium chloride Special Authorization Request Form (ABC 60088).

7.5 MG (BASE) ORAL EXTENDED-RELEASE TABLET				
00002452510	**APO-DARIFENACIN**	**APX**	$	**0.8058**
00002491869	**JAMP DARIFENACIN**	**JPC**	$	**0.8058**
00002273217	ENABLEX	SLP	$	1.6400
15 MG (BASE) ORAL EXTENDED-RELEASE TABLET				
00002452529	**APO-DARIFENACIN**	**APX**	$	**0.8058**
00002491877	**JAMP DARIFENACIN**	**JPC**	$	**0.8058**
00002273225	ENABLEX	SLP	$	1.6400

DEFERASIROX

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): DEFEROXAMINE

"For patients who require iron chelation therapy but who have an inadequate response to a sufficient trial (i.e. a minimum of 6 months) of deferoxamine, or for whom deferoxamine is contraindicated.

Contraindications may include one or more of the following: known or suspected sensitivity to deferoxamine, recurrent injection or infusion-site reactions associated with deferoxamine administration (e.g., cellulitis), inability to obtain or maintain vascular access, severe needle phobia, concomitant bleeding disorders, immunocompromised patients with a risk of infection with parenteral administration, or risk of bleeding due to anticoagulation.

According to the product monograph, Jadenu (deferasirox) is contraindicated in high risk myelodysplastic syndrome (MDS) patients, any other MDS patient with a life expectancy less than one year and patients with other hematological and nonhematological malignancies who are not expected to benefit from chelation therapy due to the rapid progression of their disease.

Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

90 MG ORAL TABLET

00002485265	**APO-DEFERASIROX (TYPE J)**	**APX**	$	**2.6303**
00002528290	**PMS-DEFERASIROX (TYPE J)**	**PMS**	$	**2.6303**
00002489899	**SANDOZ DEFERASIROX (TYPE J)**	**SDZ**	$	**2.6303**
00002507315	**TARO-DEFERASIROX (TYPE J)**	**TAR**	$	**2.6303**
00002452219	JADENU	NOV	$	10.5210

DEFERASIROX

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): DEFEROXAMINE

"For patients who require iron chelation therapy but who have an inadequate response to a sufficient trial (i.e. a minimum of 6 months) of deferoxamine, or for whom deferoxamine is contraindicated.

Contraindications may include one or more of the following: known or suspected sensitivity to deferoxamine, recurrent injection or infusion-site reactions associated with deferoxamine administration (e.g., cellulitis), inability to obtain or maintain vascular access, severe needle phobia, concomitant bleeding disorders, immunocompromised patients with a risk of infection with parenteral administration, or risk of bleeding due to anticoagulation.

According to the product monograph, Jadenu (deferasirox) is contraindicated in high risk myelodysplastic syndrome (MDS) patients, any other MDS patient with a life expectancy less than one year and patients with other hematological and nonhematological malignancies who are not expected to benefit from chelation therapy due to the rapid progression of their disease.

Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

180 MG ORAL TABLET

00002485273	**APO-DEFERASIROX (TYPE J)**	**APX**	$	**5.2610**
00002528304	**PMS-DEFERASIROX (TYPE J)**	**PMS**	$	**5.2610**
00002489902	**SANDOZ DEFERASIROX (TYPE J)**	**SDZ**	$	**5.2610**
00002507323	**TARO-DEFERASIROX (TYPE J)**	**TAR**	$	**5.2610**
00002452227	JADENU	NOV	$	21.0440

DEFERASIROX

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): DEFEROXAMINE

"For patients who require iron chelation therapy but who have an inadequate response to a sufficient trial (i.e. a minimum of 6 months) of deferoxamine, or for whom deferoxamine is contraindicated.

Contraindications may include one or more of the following: known or suspected sensitivity to deferoxamine, recurrent injection or infusion-site reactions associated with deferoxamine administration (e.g., cellulitis), inability to obtain or maintain vascular access, severe needle phobia, concomitant bleeding disorders, immunocompromised patients with a risk of infection with parenteral administration, or risk of bleeding due to anticoagulation.

According to the product monograph, Jadenu (deferasirox) is contraindicated in high risk myelodysplastic syndrome (MDS) patients, any other MDS patient with a life expectancy less than one year and patients with other hematological and nonhematological malignancies who are not expected to benefit from chelation therapy due to the rapid progression of their disease.

Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

360 MG ORAL TABLET

00002485281	**APO-DEFERASIROX (TYPE J)**	**APX**	$	**10.5228**
00002528312	**PMS-DEFERASIROX (TYPE J)**	**PMS**	$	**10.5228**
00002489910	**SANDOZ DEFERASIROX (TYPE J)**	**SDZ**	$	**10.5228**
00002507331	**TARO-DEFERASIROX (TYPE J)**	**TAR**	$	**10.5228**
00002452235	JADENU	NOV	$	42.0910

DEFERASIROX

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): DEFEROXAMINE

"For patients who require iron chelation therapy but who have an inadequate response to a sufficient trial (i.e. a minimum of 6 months) of deferoxamine, or for whom deferoxamine is contraindicated.

Contraindications may include one or more of the following: known or suspected sensitivity to deferoxamine, recurrent injection or infusion-site reactions associated with deferoxamine administration (e.g., cellulitis), inability to obtain or maintain vascular access, severe needle phobia, concomitant bleeding disorders, immunocompromised patients with a risk of infection with parenteral administration, or risk of bleeding due to anticoagulation.

According to the product monograph, Exjade (deferasirox) is contraindicated in high risk myelodysplastic syndrome (MDS) patients, any other MDS patient with a life expectancy less than one year and patients with other hematological and nonhematological malignancies who are not expected to benefit from chelation therapy due to the rapid progression of their disease.

Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

125 MG ORAL DISPERSIBLE TABLET FOR SUSPENSION

00002461544	**APO-DEFERASIROX**	**APX**	$	**5.2408**
00002464454	**SANDOZ DEFERASIROX**	**SDZ**	$	**5.2408**
00002287420	EXJADE	NOV	$	10.6625

DEFERASIROX

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): DEFEROXAMINE

"For patients who require iron chelation therapy but who have an inadequate response to a sufficient trial (i.e. a minimum of 6 months) of deferoxamine, or for whom deferoxamine is contraindicated.

Contraindications may include one or more of the following: known or suspected sensitivity to deferoxamine, recurrent injection or infusion-site reactions associated with deferoxamine administration (e.g., cellulitis), inability to obtain or maintain vascular access, severe needle phobia, concomitant bleeding disorders, immunocompromised patients with a risk of infection with parenteral administration, or risk of bleeding due to anticoagulation.

According to the product monograph, Exjade (deferasirox) is contraindicated in high risk myelodysplastic syndrome (MDS) patients, any other MDS patient with a life expectancy less than one year and patients with other hematological and nonhematological malignancies who are not expected to benefit from chelation therapy due to the rapid progression of their disease.

Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

250 MG ORAL DISPERSIBLE TABLET FOR SUSPENSION

00002461552	**APO-DEFERASIROX**	**APX**	$	**10.4820**
00002464462	**SANDOZ DEFERASIROX**	**SDZ**	$	**10.4820**
00002287439	EXJADE	NOV	$	21.3257

DEFERASIROX

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): DEFEROXAMINE

"For patients who require iron chelation therapy but who have an inadequate response to a sufficient trial (i.e. a minimum of 6 months) of deferoxamine, or for whom deferoxamine is contraindicated.

Contraindications may include one or more of the following: known or suspected sensitivity to deferoxamine, recurrent injection or infusion-site reactions associated with deferoxamine administration (e.g., cellulitis), inability to obtain or maintain vascular access, severe needle phobia, concomitant bleeding disorders, immunocompromised patients with a risk of infection with parenteral administration, or risk of bleeding due to anticoagulation.

According to the product monograph, Exjade (deferasirox) is contraindicated in high risk myelodysplastic syndrome (MDS) patients, any other MDS patient with a life expectancy less than one year and patients with other hematological and nonhematological malignancies who are not expected to benefit from chelation therapy due to the rapid progression of their disease.

Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

500 MG ORAL DISPERSIBLE TABLET FOR SUSPENSION

00002461560	**APO-DEFERASIROX**	**APX**	$	**20.9649**
00002464470	**SANDOZ DEFERASIROX**	**SDZ**	$	**20.9649**
00002287447	EXJADE	NOV	$	42.6532

DEFERIPRONE

"For the treatment of transfusional iron overload due to thalassemia syndromes in patients who require iron chelation therapy but who have an inadequate response to a sufficient trial (i.e. a minimum of 6 months) of deferoxamine, or for whom deferoxamine is contraindicated.

Contraindications to deferoxamine may include one or more of the following: known or suspected sensitivity to deferoxamine, recurrent injection or infusion-site reactions associated with deferoxamine administration (e.g., cellulitis), inability to obtain or maintain vascular access, severe needle phobia, concomitant bleeding disorders, immunocompromised patients with a risk of infection with parenteral administration, or risk of bleeding due to anticoagulation.

Special authorization may be granted for 6 months."

This product is eligible for auto-renewal.

All requests (including renewal requests) for deferiprone must be completed using the Deferiprone Special Authorization Request Form (ABC 60054).

1,000 MG ORAL TABLET				
00002436558	FERRIPROX	CCC	$	33.4719
100 MG / ML ORAL SOLUTION				
00002436523	FERRIPROX	CCC	$	3.3472

DENOSUMAB

"For the treatment of osteoporosis in patients who have:

A high 10-year risk (i.e., greater than 20%) of experiencing a major osteoporotic fracture,
OR
A moderate 10-year fracture risk (10-20%) and have experienced a prior fragility fracture;

AND

at least one of the following:

1) For whom oral bisphosphonates are contraindicated due to drug-induced hypersensitivity (i.e., immunologically mediated),

OR

2) For whom oral bisphosphonates are contraindicated due to an abnormality of the esophagus which delays esophageal emptying,

OR

3) For whom bisphosphonates are contraindicated due to severe renal impairment (i.e. creatinine clearance < 35 mL/min),

OR

4) Who have demonstrated persistent severe gastrointestinal intolerance to a course of therapy with either alendronate or risedronate,

OR

5) Who had an unsatisfactory response (defined as a fragility fracture despite adhering to oral alendronate or risedronate treatment fully for 1 year and evidence of a decline in BMD below pre-treatment baseline level).

Note: The fracture risk can be determined by the World Health Organization's fracture risk assessment tool, FRAX, or the most recent (2010) version of the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) table.

Special authorization may be granted for 12 months.

Patients will be limited to receiving one dose of denosumab per prescription at their pharmacy.

-Coverage cannot be provided for two or more osteoporosis medications (alendronate, denosumab, raloxifene, risedronate, zoledronic acid) when these medications are intended for use as combination therapy.

-Requests for other osteoporosis medications covered via special authorization will not be considered until 6 months after the last dose of denosumab 60 mg/syr injection syringe.

-Requests for other osteoporosis medications covered via special authorization will not be considered until 12 months after the last dose of zoledronic acid 0.05 mg/ml injection."

All requests for denosumab must be completed using the Denosumab/Zoledronic Acid for Osteoporosis Special Authorization Request Form (ABC 60007).

The following product(s) are eligible for auto-renewal.

60 MG / SYR	**INJECTION**	**SYRINGE**		
00002343541	PROLIA	AMG	$	397.4900

DIENOGEST

"For the management of pelvic pain associated with endometriosis in patients for whom one or more less costly hormonal options are either ineffective or not tolerated."

"Special authorization may be granted for 6 months."

"This Drug Product is eligible for auto-renewal."

2 MG ORAL TABLET

00002493055	**ASPEN-DIENOGEST**	**APC**	$	**1.0231**
00002498189	**JAMP DIENOGEST**	**JPC**	$	**1.0231**
00002374900	VISANNE	BAI	$	2.1136

DIMETHYL FUMARATE

Relapsing Remitting Multiple Sclerosis (RRMS):

"Special authorization may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory adult patients (18 years of age or older) with relapsing remitting multiple sclerosis.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.

To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

1) The registered MS Neurologist must confirm a diagnosis of RRMS;

2) The adult patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

3) The adult patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).

Coverage may be approved for up to 12 months. Adult patients will be limited to receiving a one-month supply of dimethyl fumarate per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

For continued coverage beyond the initial coverage period, the adult patient must meet the following criteria:

1) The adult patient must be assessed by a registered MS Neurologist;

2) The registered MS Neurologist must confirm a diagnosis of RRMS;

3) The registered MS Neurologist must provide a current updated EDSS score. The adult patient must not have an EDSS score of 7.0 or above sustained for one year or more.

Coverage of this drug may be considered in an adult patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.

Continued coverage may be approved for up to 12 months. Adult patients may receive up to 100 days' supply of dimethyl fumarate per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

DIMETHYL FUMARATE

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the adult patient must meet the following criteria:

1) At least one relapse* per 12 month period; or

2) At least two relapses* during the previous 24 month period."

All requests (including renewal requests) for dimethyl fumarate must be completed using the Dimethyl Fumarate/Glatiramer Acetate/Interferon Beta-1a/Ocrelizumab/Peginterferon Beta-1a/Teriflunomide for RRMS/Interferon Beta-1b for SPMS or RRMS Special Authorization Request Form (ABC 60001).

120 MG ORAL DELAYED-RELEASE CAPSULE				
00002495341	**ACH-DIMETHYL FUMARATE**	**AHI**	$	**4.4266**
00002505762	**APO-DIMETHYL FUMARATE**	**APX**	$	**4.4266**
00002494809	**GLN-DIMETHYL FUMARATE**	**GLM**	$	**4.4266**
00002516047	**JAMP DIMETHYL FUMARATE**	**JPC**	$	**4.4266**
00002502690	**MAR-DIMETHYL FUMARATE**	**MAR**	$	**4.4266**
00002497026	**PMS-DIMETHYL FUMARATE**	**PMS**	$	**4.4266**
00002513781	**SANDOZ DIMETHYL FUMARATE**	**SDZ**	$	**4.4266**
00002404508	TECFIDERA	BIO	$	17.7064
240 MG ORAL DELAYED-RELEASE CAPSULE				
00002505770	**APO-DIMETHYL FUMARATE**	**APX**	$	**8.6888**
00002497034	**PMS-DIMETHYL FUMARATE**	**PMS**	$	**8.6888**
00002513803	**SANDOZ DIMETHYL FUMARATE**	**SDZ**	$	**8.6888**

DONEPEZIL HCL

"For the treatment of Alzheimer's disease in patients who meet the following criteria:
- a Mini Mental State Exam (MMSE) score between 10-26, or
- a St. Louis University Mental Status Examination (SLUMS) score between 6-26, or
- a Rowland Universal Dementia Assessment Scale (RUDAS) score between 9-22, or
- an InterRAI-Cognitive Performance Scale score between 1-4

Coverage cannot be provided for two or more medications used in the treatment of Alzheimer's disease (donepezil, galantamine, rivastigmine) when these medications are intended for use in combination.

Special Authorization coverage may be granted for a maximum of 24 months per request.

For each request, an updated score (MMSE, SLUMS, RUDAS or InterRAI-Cognitive Performance Scale) and the date on which the exam was administered must be provided.

Renewal requests may be considered for patients where an updated score while on this drug meets the following criteria:
- MMSE score is 10 or higher, or
- SLUMS score is 6 or higher, or
- RUDAS score is 9 or higher, or
- InterRAI-Cognitive Performance Scale is 4 or lower."

All requests (including renewal requests) for donepezil HCI must be completed using the Donepezil/Galantamine/Rivastigmine Special Authorization Request From (ABC 60034).

5 MG ORAL TABLET

00002432684	**AG-DONEPEZIL**	**AGP**	$	**0.4586**
00002362260	**APO-DONEPEZIL**	**APX**	$	**0.4586**
00002400561	**AURO-DONEPEZIL**	**AUR**	$	**0.4586**
00002412853	**BIO-DONEPEZIL**	**BMD**	$	**0.4586**
00002420597	**DONEPEZIL**	**SIV**	$	**0.4586**
00002426846	**DONEPEZIL**	**SNS**	$	**0.4586**
00002475278	**DONEPEZIL**	**RIV**	$	**0.4586**
00002402645	**DONEPEZIL HYDROCHLORIDE**	**AHI**	$	**0.4586**
00002416948	**JAMP-DONEPEZIL**	**JPC**	$	**0.4586**
00002467453	**M-DONEPEZIL**	**MTR**	$	**0.4586**
00002402092	**MAR-DONEPEZIL**	**MAR**	$	**0.4586**
00002408600	**MINT-DONEPEZIL**	**MPI**	$	**0.4586**
00002439557	**NAT-DONEPEZIL**	**NTP**	$	**0.4586**
00002322331	**PMS-DONEPEZIL**	**PMS**	$	**0.4586**
00002381508	**RAN-DONEPEZIL**	**RAN**	$	**0.4586**
00002328666	**SANDOZ DONEPEZIL**	**SDZ**	$	**0.4586**
00002428482	**SEPTA DONEPEZIL**	**SEP**	$	**0.4586**
00002340607	**TEVA-DONEPEZIL**	**TEV**	$	**0.4586**
00002232043	ARICEPT	PFI	$	5.0779

DONEPEZIL HCL

10 MG ORAL TABLET

00002432692	**AG-DONEPEZIL**	**AGP**	$	**0.4586**
00002362279	**APO-DONEPEZIL**	**APX**	$	**0.4586**
00002400588	**AURO-DONEPEZIL**	**AUR**	$	**0.4586**
00002412861	**BIO-DONEPEZIL**	**BMD**	$	**0.4586**
00002420600	**DONEPEZIL**	**SIV**	$	**0.4586**
00002426854	**DONEPEZIL**	**SNS**	$	**0.4586**
00002475286	**DONEPEZIL**	**RIV**	$	**0.4586**
00002402653	**DONEPEZIL HYDROCHLORIDE**	**AHI**	$	**0.4586**
00002416956	**JAMP-DONEPEZIL**	**JPC**	$	**0.4586**
00002467461	**M-DONEPEZIL**	**MTR**	$	**0.4586**
00002402106	**MAR-DONEPEZIL**	**MAR**	$	**0.4586**
00002408619	**MINT-DONEPEZIL**	**MPI**	$	**0.4586**
00002439565	**NAT-DONEPEZIL**	**NTP**	$	**0.4586**
00002322358	**PMS-DONEPEZIL**	**PMS**	$	**0.4586**
00002381516	**RAN-DONEPEZIL**	**RAN**	$	**0.4586**
00002328682	**SANDOZ DONEPEZIL**	**SDZ**	$	**0.4586**
00002428490	**SEPTA DONEPEZIL**	**SEP**	$	**0.4586**
00002340615	**TEVA-DONEPEZIL**	**TEV**	$	**0.4586**
00002232044	ARICEPT	PFI	$	5.0779

DUPILUMAB

"Special authorization coverage may be provided for the treatment of moderate-to-severe atopic dermatitis in patients 12 years of age and older who:
- Have an Investigator's Global Assessment (IGA) score >/= 3 and an Eczema Area and Severity Index (EASI) score >/= 16; AND
- Who are refractory or intolerant to:
- topical prescription corticosteroid and/or topical calcineurin inhibitors (TCIs); AND
- at least two conventional systemic immunomodulatory drugs (steroid-sparing); AND
- phototherapy (unless restricted by geographic location)

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").
Initial coverage may be approved for 6 months as follows:
- For adolescent patients weighing less than 60 kg, coverage may be approved for an initial loading dose of 400 mg (2 subcutaneous injections of 200 mg) followed by 200 mg every other week.
- For adolescent patients weighing 60 kg or more, and for adult patients, coverage may be approved for initial loading dose of 600 mg (2 subcutaneous injections of 300 mg) followed by 300 mg every other week.
- Patients will be limited to receiving a 4-week supply of dupilumab per prescription at their pharmacy.
- Dupilumab is not to be used in combination with phototherapy or immunomodulating drugs.
-Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial approval period, the patient must meet the following criteria:
1) The patient must be assessed by a Dermatology Specialist after the initial 6 months to determine response.
The Dermatology Specialist must confirm that the patient is a 'responder' who meets the following criteria:
- EASI-75 response (greater than or equal to 75% improvement from baseline).

Following this assessment, continued coverage may be approved for 200 mg every other week for adolescent patients less than 60 kg, or 300 mg every other week for adults and adolescent patients 60 kg or more. Special Authorization may be granted for 6 months.

Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 6 months and is confirmed to be continuing to respond to therapy by confirmation of maintenance of EASI-75."

All requests (including renewal requests) for dupilumab for Atopic Dermatitis must be completed using the Dupilumab for Atopic Dermatitis Special Authorization Request Form (ABC 60099).

200 MG / SYR INJECTION				
00002492504	DUPIXENT	SAV	$	978.7000
300 MG / SYR INJECTION				
00002470365	DUPIXENT	SAV	$	978.7000
200 MG / SYR INJECTION SYRINGE				
00002524252	DUPIXENT (PEN)	SAV	$	978.7000
300 MG / SYR INJECTION SYRINGE				
00002510049	DUPIXENT (PEN)	SAV	$	978.7000

ECULIZUMAB

1. ELIGIBILITY CRITERIA FOR ECULIZUMAB COVERAGE

In order to maintain the integrity of the ADBL, and having regard to the financial and social implications of covering eculizumab for the treatment of paroxysmal nocturnal hemoglobinuria (PNH), the following special authorization criteria must be satisfied.

In order to be eligible for eculizumab coverage for the treatment of PNH, a patient must have submitted a completed Application and have satisfied all of the following requirements:

The patient must:
1) Be diagnosed with PNH in accordance with the requirements specified in the Clinical Criteria for eculizumab;
2) Have Alberta government-sponsored drug coverage;
3) Meet the Registration Requirements;
4) Satisfy the Clinical Criteria for eculizumab (initial or continued coverage, as appropriate); AND
5) Meet the criteria specified in Contraindications to Coverage and Discontinuance of Coverage.

There is no guarantee that any application, whether for initial or continued coverage, will be approved. Depending on the circumstances of each case, the Minister or the Minister's delegate may:
- approve an Application;
- approve an Application with conditions;
- deny an Application;
- discontinue an approved Application; OR
- defer an Application pending the provision of further supporting information.

The process for review and approval is explained in further detail below.

2. REGISTRATION REQUIREMENTS

If the patient is a citizen or permanent resident of Canada, the patient must be continuously registered in the Alberta Health Care Insurance Plan for a minimum of one (1) year prior to an application for coverage unless:
- the patient is less than one (1) year of age at the date of the application, then the patient's parent/guardian/legal representative must be registered continuously in the Alberta Health Care Insurance Plan for a minimum of one (1) year; OR
- the patient has moved to Alberta from another province or territory in Canada (the" province of origin"), and immediately prior to moving to Alberta, was covered for eculizumab in the province of origin by a provincial or territorial government sponsored drug plan, (or the province of origin provided equivalent coverage for eculizumab as does Alberta) and the patient has been registered in the Alberta Health Care Insurance Plan (the patient must provide supporting documentation from the province of origin to prove prior coverage).

If the patient is not a citizen or permanent resident of Canada, the patient must be continuously registered in the Alberta Health Care Insurance Plan for a minimum of five (5) years prior to an application for coverage unless:
- the patient is less than five years of age at the date of the application, then the patients parent/guardian/legal representative must be registered continuously in the Alberta Health Care Insurance Plan for a minimum of five years; OR
- the patient has moved to Alberta from another province or territory in Canada (the "province of origin"), and immediately prior to moving to Alberta, was covered for eculizumab in the province of origin by a provincial or territorial government sponsored drug plan, (or the province of origin provided equivalent coverage for eculizumab as does Alberta) and the patient has been registered in the Alberta Health Care Insurance Plan (the patient must provide supporting documentation from the province of origin to prove prior coverage).

The Minister reserves the right to modify or waive the Registration Requirements applicable to a given patient if the patient or the patient's parent/guardian/legal representative can establish to the satisfaction of the Minister that the patient has not moved to Alberta for the sole/primary purpose of obtaining coverage of eculizumab.

ECULIZUMAB

3. CLINICAL CRITERIA

In addition to meeting Sections 1 and Sections 2 herein, to be considered for coverage of eculizumab, a patient must be assessed by a Specialist in Hematology (i.e. a physician who holds specialty certification in Hematology from the Royal College of Physicians and Surgeons of Canada) and meet all of the following clinical criteria (initial or continued coverage, as appropriate).

a. Clinical Criteria - Initial Coverage
All of the following Clinical Criteria must be established on the basis of evidence to the satisfaction of the Minister or the Minister's delegate for initial coverage:

1) The diagnosis of PNH must have been established by flow cytometry and/or a FLAER test. The proportion of circulating cells of each type which are GPI-deficient and hence of the PNH clone is quantitated by flow cytometry. Patients must have a:
- PNH granulocyte or monocyte clone size equal to or greater than 10%, AND
- Raised LDH (value at least 1.5 times the upper limit of normal for the reporting laboratory).

2) Patients with a granulocyte or monocyte clone size equal to or greater than 10% also require AT LEAST ONE of the following:
- Thrombosis: Evidence that the patient has had a thrombotic or embolic event which required the institution of therapeutic anticoagulant therapy;
- Transfusions: Evidence that the patient has been transfused with at least four (4) units of red blood cells in the last twelve (12) months;
- Anemia: Evidence that the patient has chronic or recurrent anemia where causes other than hemolysis have been excluded and demonstrated by more than one measure of less than or equal to 70g/L or by more than one measure of less than or equal to 100 g/L with concurrent symptoms of anemia;
- Pulmonary insufficiency: Evidence that the patient has debilitating shortness of breath and/or chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded;
- Renal insufficiency: Evidence that the patient has a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60mL/min/1.73m^2, where causes other than PNH have been excluded; OR
- Smooth muscle spasm: Evidence that the patient has recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded.

AND

3) All patients must receive meningococcal immunization with a quadravalent vaccine (A, C, Y and W135) at least two (2) weeks prior to receiving the first dose of eculizumab. Treating physicians will be required to submit confirmation of meningococcal immunizations in order for their patients to continue to be eligible for treatment with eculizumab. Pneumococcal immunization with a 23-valent polysaccharide vaccine and a 13-valent conjugate vaccine, and a Haemophilus influenza type b (Hib) vaccine must be given according to current clinical guidelines. All patients must be monitored and reimmunized according to current clinical guidelines for vaccine use.

b. Clinical Criteria - Continued Coverage
All of the following Clinical Criteria must be established on the basis of evidence to the satisfaction of the Minister or the Minister's delegate for continued coverage:
1) Patient eligibility must be reviewed six (6) months after commencing therapy and every six (6) months thereafter;

AND

2) Continued eligibility will be subject to the assessment of evidence, in accordance with the following monitoring requirements, which demonstrates:

ECULIZUMAB

- Clinical improvement in the patient, OR
- Stabilization of the patient's condition;

Monitoring requirements;

The patient's Specialist in Hematology must provide the following monitoring information every six (6) months:
- Lactate dehydrogenase (LDH);
- Full blood count and reticulocytes;
- Transfusion history for previous six months;
- Iron studies;
- Urea, electrolytes and eGFR;
- Recent clinical history; AND
- Any other information requested by the Minister, the Minister's delegate, or an Expert Advisor.

The patient's Specialist in Hematology must provide the following monitoring information every twelve (12) months:
- Confirmation that the patient has been immunized or reimmunized (meningococcal, pneumococcal 23-valent, pneumococcal 13-valent and Hib) according to current clinical guidelines for vaccine use;
- Progress reports on the clinical symptoms that formed the basis of initial eligibility;
- Quality of life, through clinical narrative;
- Granulocyte or monocyte clone size (by flow cytometry): AND
- Any other information requested by the Minister, the Minister's delegate, or an Expert Advisor.

c. Contraindications to Coverage

- Small clone size - granulocyte and monocyte clone sizes below 10%;
- Aplastic anaemia with two or more of the following: neutrophil count below 0.5 x 10^9/L, platelet count below 20 x 10^9/L, reticulocytes below 25 x 10^9/L, or severe bone marrow hypocellularity;
- Patients with a presence of another life threatening or severe disease where the long term prognosis is unlikely to be influenced by therapy (for example acute myeloid leukaemia or high-risk myelodysplastic syndrome); OR
- The presence of another medical condition that in the opinion of the Minister or Minister's delegate might reasonably be expected to compromise a response to therapy.

d. Discontinuation of Coverage

Coverage may be discontinued where one or more of the following situations apply:
- The patient or the patient's Specialist in Hematology fails to comply adequately with treatment or measures, including monitoring requirements, taken to evaluate the effectiveness of the therapy;
- There is a failure to provide the Minister, the Minister's delegate, or an Expert Advisor with information as required or as requested;
- If in the opinion of the Minister or the Minister's delegate, therapy fails to relieve the symptoms of disease that originally resulted in the patient being approved by the Minister or the Minister's delegate;
- The patient has (or develops) a condition referred to in Contraindications to Coverage.

The patient's Specialist in Hematology will be advised if their patient is at risk of being withdrawn from treatment for failure to comply with the above requirements or other perceived "non-compliance" and given a reasonable period of time to respond prior to coverage being discontinued.

4. PROCESS FOR ECULIZUMAB COVERAGE

For both initial and continued coverage the following documents (the Application) must be completed and submitted:

ECULIZUMAB

- An Eculizumab Special Authorization Request Form completed by the patient's Specialist in Hematology;
- An Eculizumab Consent Form completed by the patient, or a patient's parent/guardian/legal representative, and the patients Specialist in Hematology (for any initial coverage application); AND
- Any other documentation that may be required by the Minister or the Minister's delegate.

a. Expert Review

Once the Minister or the Minister's delegate has confirmed that the patient meets the Registration Requirement or granted a waiver of the Registration Requirement, the Application will be given to one or more Expert Advisors for review.

The Application, together with the recommendation or recommendations of the Expert Advisor(s), is then forwarded to the Minister or the Minister's delegate for a decision regarding coverage.

After the Minister or Minister's delegate has rendered a decision, the patient's Specialist in Hematology and the patient or patient's parent/guardian/legal representative will be notified by letter of the Minister's decision.

5. APPROVAL OF COVERAGE

The Minister or the Minister's delegate's decision in respect of an Application will specify the effective date of eculizumab coverage, if coverage is approved.

Initial coverage may be approved for a period of up to six (6) months as follows: One dose of 600mg of eculizumab administered weekly for the first four (4) weeks of treatment (total of four 600mg doses), followed by one dose of 900mg of eculizumab administered every two (2) weeks from week five (5) of treatment (total of eleven 900mg doses).

Continued coverage may be approved for up to one dose of 900mg of eculizumab administered every two (2) weeks, for a period of six (6) months (total of thirteen 900mg doses). If the patient restarts treatment after a lapse in therapy, continued coverage may be approved for a period of up to six (6) months as follows: One dose of 600mg of eculizumab administered weekly for the first four (4) weeks of treatment (total of four 600mg doses), followed by one dose of 900mg of eculizumab administered every two (2) weeks from week five (5) of treatment (total of eleven 900mg doses).

If a patient is approved for coverage, prescriptions for eculizumab must be written by a Specialist in Hematology. To avoid wastage, prescription quantities are limited to a two week supply. Extended quantity and vacation supplies are not permitted. The Government is not responsible and will not pay for costs associated with wastage or improper storage of eculizumab.

Approval of coverage is granted for a specific period, to a maximum of six (6) months. If continued treatment is necessary, it is the responsibility of the patient or patient's parent/guardian/legal representative and the Specialist in Hematology to submit a new Application to re-apply for eculizumab coverage, and receive a decision thereon, prior to the expiry date of the authorization period.

6. WITHDRAWAL

Therapy may be withdrawn at the request of the patient or the patient's parent/guardian/legal representative at any time. Notification of withdrawal from therapy must be made by the Specialist in Hematology or patient in writing.

Applications, withdrawal requests, and any other information to be provided must be sent to Clinical Drug Services, Alberta Blue Cross.

300 MG / VIAL INJECTION

ECULIZUMAB

00002322285	SOLIRIS	APG	$	6675.3000

EDARAVONE

For patients who have a probable or definite diagnosis of amyotrophic lateral sclerosis (ALS), as defined by World Federation of Neurology (WFN) criteria, and who meet ALL of the following:
- scores of at least two points on each item of the ALS Functional Rating Scale - Revised (ALSFRS-R), AND
- a forced vital capacity (FVC) greater than or equal to 80% of predicted, AND
- ALS symptoms for two years or less, AND
- not currently requiring permanent non-invasive or invasive ventilation.

For coverage, this drug must be prescribed by a Specialist in Neurology.

Initial coverage may be approved for a first treatment cycle of 60mg IV daily for 14 days, followed by a 14-day drug-free period, and 5 subsequent cycles of 60mg IV daily for 10 days out of 14-day periods, followed by 14-day drug-free periods.

Special authorization may be granted for 6 months.

Patients will be limited to receiving a 28-day supply of edaravone per prescription at their pharmacy.

Coverage cannot be renewed once the patient:
- becomes non-ambulatory (ALSFRS-R score less than or equal to 1 for item 8) AND is unable to cut food and feed themselves without assistance, irrespective of whether a gastrostomy is in place (ALSFRS-R score less than 1 for item 5a or 5b);
OR
- requires permanent non-invasive or invasive ventilation.

Continued coverage may be considered for treatment cycles of 60mg IV daily for 10 days out of 14-day periods, followed by 14-day drug-free periods, for a period of 6 months.

All requests (including renewal requests) for edaravone must be completed using the Edaravone Special Authorization Request Form (ABC 60080).

0.3 MG / ML INJECTION

00002475472	RADICAVA	MIT	$	4.6000

EDOXABAN TOSYLATE MONOHYDRATE

"AT RISK PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION

SPECIAL AUTHORIZATION (step therapy approval process)

FIRST-LINE DRUG PRODUCT(S): WARFARIN

For at-risk patients (CHADS2 score of greater than or equal to 1) with non-valvular atrial fibrillation (AF) for the prevention of stroke and systemic embolism AND in whom one of the following is also present:
- Inadequate anticoagulation (at least 35% of INR testing results outside the desired range) following a reasonable trial of warfarin (minimum two months of therapy); OR
- Anticoagulation with warfarin is contraindicated as per the product monograph or not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, or at home).

Note: Some or all direct oral anticoagulants may have contraindications to use or precautions with use, for example: related to prosthetic heart valve disease, rheumatic valvular heart disease, renal function, or age. Refer to the product monograph for additional information.

Special Authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.
UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

VENOUS THROMBOEMBOLIC EVENTS

SPECIAL AUTHORIZATION

For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE).

The recommended dose of edoxaban for patients initiating DVT or PE treatment is 60 mg once daily following initial use of a parenteral anticoagulant for 5-10 days. A reduced dose of 30 mg once daily is recommended for patients with one or more of the following clinical factors:
- moderate renal impairment (creatinine clearance (CrCL) 30-50 mL/min)
- low body weight <= 60 kg (132 lbs)
- concomitant use of p-glycoprotein inhibitors except amiodarone and verapamil.

Drug plan coverage for edoxaban is an alternative to heparin/warfarin for up to 6 months. When used for greater than 6 months, edoxaban is more costly than heparin/warfarin. As such, patients with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin.

Special authorization may be granted for up to 6 months."

All requests for edoxaban must be completed using the Apixaban/Dabigatran/Edoxaban/Rivaroxaban Special Authorization Request Form (ABC 60019).

15 MG (BASE) ORAL TABLET				
00002458640	LIXIANA	SEV	$	2.9393
30 MG (BASE) ORAL TABLET				
00002458659	LIXIANA	SEV	$	2.9393
60 MG (BASE) ORAL TABLET				
00002458667	LIXIANA	SEV	$	2.9393

ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR/ IVACAFTOR

For the treatment of cystic fibrosis (CF) in patients age six (6) years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. Patients should be optimized with best supportive care for their CF at the time of initiation.

For initial coverage, the following pre-treatment information must be provided:
1. Baseline spirometry measurement of FEV1 % predicted (within the last 3 months), AND
2. Number of days treated with oral and/or IV antibiotics for pulmonary exacerbations in the previous 6 months or number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months, AND
3. Number of CF-related hospitalizations in the previous 6 months, AND
4. Baseline Body Mass Index (BMI) or BMI z-score in children

This drug must be prescribed by a prescriber affiliated with one of the following Alberta Cystic Fibrosis Clinics:
- Cystic Fibrosis Clinic, Adult: Kaye Edmonton Clinic
- Cystic Fibrosis Services - Adult Outpatient: Foothills Medical Centre
- Cystic Fibrosis Clinic, Pediatric: Stollery Children's Hospital
- Pediatric Cystic Fibrosis Clinic: Alberta Children's Hospital

For coverage, dosing will be approved as follows:
Patients 6 to < 12 years weighing <30 kg: Two tablets (each containing elexacaftor 50 mg, tezacaftor 25 mg and ivacaftor 37.5 mg) in the morning and one tablet (ivacaftor 75 mg) in the evening.

Patients 6 to < 12 years weighing >/= 30 kg: Two tablets (each containing elexacaftor 100 mg, tezacaftor 50 mg and ivacaftor 75 mg) in the morning and one tablet (ivacaftor 150 mg) in the evening.

Patients >/= 12 years: Two tablets (each containing elexacaftor 100 mg, tezacaftor 50 mg and ivacaftor 75 mg) in the morning and one tablet (ivacaftor 150 mg) in the evening.

Patients will be limited to receiving a one-month supply per prescription at their pharmacy.

Initial coverage may be approved for 6 months.
Subsequent renewal of coverage may be approved for 12 months.

For continued coverage beyond the initial 6-month authorization, patients must demonstrate a benefit in at least ONE of the following:
1. Documented improvement in % predicted FEV1 of at least 5% compared with the baseline measurement, OR
2. A decrease in the total number of days for which the patient received treatment with oral and/or IV
antibiotics for pulmonary exacerbations in the previous 6 months compared with the 6-month period prior to initiating treatment; or, a decrease in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months compared with the 6-month period prior to initiating treatment, OR
3. Decreased number of CF-related hospitalizations in the previous 6 months compared with the 6-month period prior to initiating treatment, OR
4. No decline in BMI or BMI z-score compared with the baseline BMI or BMI z-score assessment

Ongoing coverage may be considered only if patients have maintained a benefit in at least ONE of the parameters noted above at the end of each 12-month period.

Coverage cannot be provided for elexacaftor/tezacaftor/ivacaftor and ivacaftor for the following:
1. When intended for use in combination with other CFTR modulators; OR
2. Patient is the previous recipient of a double lung transplant.

All requests (including renewal requests) for elexacaftor/tezacaftor/ivacaftor + ivacaftor must be completed using the Combination CFTR Modulators Special Authorization Request From (ABC 60090).

ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR/ IVACAFTOR

50 MG * 25 MG * 37.5 MG * 75 MG ORAL TABLET				
00002526670	TRIKAFTA	VER	$	280.0000
100 MG * 50 MG * 75 MG * 150 MG ORAL TABLET				
00002517140	TRIKAFTA	VER	$	280.0000

EMPAGLIFLOZIN

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

"FIRST-LINE DRUG PRODUCT(S): METFORMIN

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:
- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.
Or, for whom these products are contraindicated.

As an adjunct to diet, exercise, and standard care therapy to reduce the incidence of cardiovascular (CV) death in patients with Type 2 diabetes and established cardiovascular diseases who have an inadequate glycemic control, if the following criteria are met:
- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- established cardiovascular disease* as defined in the EMPA-REG OUTCOME trial

* Established cardiovascular disease is defined on the basis of one of the following:
1) History of myocardial infarction (MI)
2) Multi-vessel coronary artery disease in two or more major coronary arteries (irrespective of revascularization status)
3) Single-vessel coronary artery disease with significant stenosis and either a positive non-invasive stress test or discharged from hospital with a documented diagnosis of unstable angina within the last 12 months
4) Last episode of unstable angina greater than 2 months prior with confirmed evidence of coronary multi-vessel or single-vessel disease
5) History of ischemic or hemorrhagic stroke
6) Occlusive peripheral artery disease

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated
CA - Prior adverse reaction
CB - Previous treatment failure
CJ - Product is not effective"

All requests for empagliflozin must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

10 MG ORAL TABLET				
00002443937	JARDIANCE	BOE	$	2.7576
25 MG ORAL TABLET				
00002443945	JARDIANCE	BOE	$	2.7576

EMPAGLIFLOZIN/ METFORMIN HCL

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

"FIRST-LINE DRUG PRODUCT(S): METFORMIN

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:
- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

As an adjunct to diet, exercise, and standard care therapy to reduce the incidence of cardiovascular (CV) death in patients with Type 2 diabetes and established cardiovascular diseases who have an inadequate glycemic control, if the following criteria are met:
- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- established cardiovascular disease* as defined in the EMPA-REG OUTCOME trial

* Established cardiovascular disease is defined on the basis of one of the following:
1) History of myocardial infarction (MI)
2) Multi-vessel coronary artery disease in two or more major coronary arteries (irrespective of revascularization status)
3) Single-vessel coronary artery disease with significant stenosis and either a positive non-invasive stress test or discharged from hospital with a documented diagnosis of unstable angina within the last 12 months
4) Last episode of unstable angina greater than 2 months prior with confirmed evidence of coronary multi-vessel or single-vessel disease
5) History of ischemic or hemorrhagic stroke
6) Occlusive peripheral artery disease

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated
CA - Prior adverse reaction
CB - Previous treatment failure
CJ - Product is not effective"

All requests for empagliflozin+metformin must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

5 MG * 500 MG ORAL TABLET				
00002456575	SYNJARDY	BOE	$	1.3935
5 MG * 850 MG ORAL TABLET				
00002456583	SYNJARDY	BOE	$	1.3935
5 MG * 1,000 MG ORAL TABLET				
00002456591	SYNJARDY	BOE	$	1.3935
12.5 MG * 500 MG ORAL TABLET				
00002456605	SYNJARDY	BOE	$	1.3935
12.5 MG * 850 MG ORAL TABLET				
00002456613	SYNJARDY	BOE	$	1.3935
12.5 MG * 1,000 MG ORAL TABLET				
00002456621	SYNJARDY	BOE	$	1.3935

EPLERENONE

"For persons suffering from New York Heart Association (NYHA) class II chronic heart failure with left ventricular systolic dysfunction with ejection fraction less than or equal to 35 per cent, as a complement to standard therapy."

Special authorization will be granted for 12 months.

This product is eligible for auto-renewal.

All requests (including renewal requests) for eplerenone must be completed using the Eplerenone/Ivabradine/Sacubitril+Valstartan Special Authorization Request Form (ABC 60050).

25 MG ORAL TABLET				
00002471442	**MINT-EPLERENONE**	**MPI**	$	**2.0595**
00002323052	INSPRA	UJC	$	3.0396
50 MG ORAL TABLET				
00002471450	**MINT-EPLERENONE**	**MPI**	$	**2.0595**
00002323060	INSPRA	UJC	$	3.0396

EPOETIN ALFA

"For the treatment of anemia of chronic renal failure in patients with low hemoglobin (< 95 g/L and falling). Patients must be iron replete prior to initiation of therapy as indicated by transferrin saturation >20%. Special authorization will be granted for twelve months.

According to current clinical practice, hemoglobin levels should be maintained between 95 g/L to 110 g/L and the dose should be held or reduced when hemoglobin is greater than or equal to 115 g/L. Doses should not exceed 60,000 units per month."

"For the treatment of anemia in AZT-treated/HIV infected patients. Special authorization will be granted for twelve months."

"For the treatment of chemotherapy-induced anemia in patients with non-myeloid malignancies with low hemoglobin (<100 g/L) in whom blood transfusions are not possible due to transfusion reactions, cross-matching difficulties or iron overload. If hemoglobin is rising by more than 20 g/L per month, the dose should be reduced by about 25%. Special authorization will be granted for twelve months."

In order to comply with the first criterion information must be provided regarding the patient's hemoglobin and transferrin saturation.

In order to comply with the third criterion: if the patient has iron overload the prescriber must state this in the request or alternatively, information is required regarding the patient's transferrin saturation, along with the results of liver function tests if applicable.

For the third criterion, renewal requests may be considered if the patient's hemoglobin is < 110 g/L while on therapy.

The following product(s) are eligible for auto-renewal for the indication of treatment of anemia of chronic renal failure.

All requests for epoetin alfa must be completed using the Darbepoetin/Epoetin Special Authorization Request Form (ABC 60006).

1,000 UNIT / SYR INJECTION SYRINGE				
00002231583	EPREX (0.5 ML SYRINGE)	JAI	$	14.2500
2,000 UNIT / SYR INJECTION SYRINGE				
00002231584	EPREX (0.5 ML SYRINGE)	JAI	$	28.5000
3,000 UNIT / SYR INJECTION SYRINGE				
00002231585	EPREX (0.3 ML SYRINGE)	JAI	$	42.7500

EPOETIN ALFA

4,000 UNIT / SYR INJECTION SYRINGE				
00002231586	EPREX (0.4 ML SYRINGE)	JAI	$	57.0000
5,000 UNIT / SYR INJECTION SYRINGE				
00002243400	EPREX (0.5 ML SYRINGE)	JAI	$	71.2500
6,000 UNIT / SYR INJECTION SYRINGE				
00002243401	EPREX (0.6 ML SYRINGE)	JAI	$	85.5000
8,000 UNIT / SYR INJECTION SYRINGE				
00002243403	EPREX (0.8 ML SYRINGE)	JAI	$	114.0000
10,000 UNIT / SYR INJECTION SYRINGE				
00002231587	EPREX (1 ML SYRINGE)	JAI	$	142.5000
20,000 UNIT / SYR INJECTION SYRINGE				
00002243239	EPREX (0.5 ML SYRINGE)	JAI	$	313.3200

EPOETIN ALFA

"For the treatment of chemotherapy-induced anemia in patients with non-myeloid malignancies with low hemoglobin (<100 g/L) in whom blood transfusions are not possible due to transfusion reactions, cross-matching difficulties or iron overload. If hemoglobin is rising by more than 20 g/L per month, the dose should be reduced by about 25%. Patients may be granted a maximum allowable dose of 40,000 IU per week. Special authorization will be granted for twelve months."

In order to comply with this criterion, if the patient has iron overload the prescriber must state this in the request, or alternatively, information is required regarding the patient's transferrin saturation, along with the results of liver function tests, if applicable.

Renewal requests may be considered if the patient's hemoglobin is <110 g/L while on therapy.

All requests for epoetin alfa must be completed using the Darbepoetin/Epoetin Special Authorization Request Form (ABC 60006).

30,000 UNIT / SYR INJECTION SYRINGE				
00002288680	EPREX	JAI	$	360.8300
40,000 UNIT / SYR INJECTION SYRINGE				
00002240722	EPREX	JAI	$	470.0200

ERTAPENEM

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For therapy of complicated polymicrobial skin and skin structure infections."*

"For the therapy of community-acquired intra-abdominal infections."*

"For culture & susceptibility directed therapy against infections with Enterobacteriaceae producing AmpC or extended-spectrum beta-lactamases (ESBLs) where there is resistance to first line agents."*

"For use in other Health Canada approved indications, in consultation with a specialist in Infectious Diseases."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

In order to comply with all of the above criteria, information is required regarding the type of infection and organisms involved. Also, where the criteria restrict coverage of the requested drug to non-first line therapy, information is required regarding previous first-line antibiotic therapy that has been utilized, the patient's response to therapy, and the first line agents the organism is resistant to or why other first-line therapies cannot be used in this patient. Also, where applicable, the specialist in Infectious Diseases that recommended this drug is required.

1 G / VIAL INJECTION				
00002247437	INVANZ	MFC	$	58.3529

ESLICARBAZEPINE ACETATE

"For adjunctive therapy in patients with refractory partial-onset seizures who meet all of the following criteria:
- Are currently receiving two or more antiepileptic medications, AND
- Have failed or demonstrated intolerance to three other antiepileptic medications, AND
- Therapy must be initiated by a Neurologist.

For the purpose of administering these criteria failure is defined as inability to achieve satisfactory seizure control.

Special authorization may be granted for six months.

Coverage cannot be provided for brivaracetam, eslicarbazepine, lacosamide or perampanel when these medications are intended for use in combination."

Each of these products is eligible for auto-renewal.

200 MG ORAL TABLET				
00002426862	APTIOM	SUN	$	9.8700
400 MG ORAL TABLET				
00002426870	APTIOM	SUN	$	9.8700
600 MG ORAL TABLET				
00002426889	APTIOM	SUN	$	9.8700
800 MG ORAL TABLET				
00002426897	APTIOM	SUN	$	9.8700

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25 MG / SYR INJECTION SYRINGE

00002462877	ERELZI	SDZ	$	120.5000

Ankylosing Spondylitis

"Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed at week 12 by an RA Specialist after the initial twelve weeks of therapy to determine response.
2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
- Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for etanercept for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

Plaque Psoriasis

All Special Authorization requests for etanercept for patients weighing 63 kg or more will be assessed for coverage with an etanercept biosimilar. The originator drug, Enbrel, will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg.

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:

- Have a total PASI of 10 or more and a DLQI of more than 10, OR

- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND

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- Who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
- Cyclosporine (6 weeks treatment); AND
- Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

-Initial coverage may be approved for up to 100 mg per week for 12 weeks.
-Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet all of the following criteria:
1) The patient must be assessed by a Dermatology Specialist after the initial 12 weeks of therapy to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Greater than or equal to 75% reduction in PASI score, OR
- Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI

Following this assessment, continued coverage may be considered for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for etanercept for Plaque Psoriasis must be completed using the
Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Tildrakizumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

Polyarticular Juvenile Idiopathic Arthritis

All Special Authorization requests for etanercept for patients weighing 63 kg or more will be assessed for coverage with an etanercept biosimilar. The originator drug, Enbrel, will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg.

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 4 years of age and older who:
- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDS) conventionally

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used in children (minimum three month trial).

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects (e.g., leukopenia, hepatitis) or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric Rheumatology Specialist).

- Coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
- 30% improvement from baseline in at least three of the following six response variables, with worsening of 30% or more in no more than one of the six variables. The variables include:
i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,
ii. global assessment of overall well-being by the patient or parent,
iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
iv. number of joints with limitation of motion,
v. functional ability based on CHAQ scores,
vi. ESR or CRP
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request

Following this assessment, continued coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:
1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Once a child with pJIA has had two disease-free years, it is common clinical practice for drug treatment to be stopped."

All requests (including renewal requests) for etanercept for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Adalimumab/Etanercept/Tocilizumab for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60011).

Psoriatic Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial

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of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology (''RA Specialist'').

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.''

All requests (including renewal requests) for etanercept for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

Rheumatoid Arthritis

''Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND

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- Leflunomide (minimum 10 week trial at 20 mg daily).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for etanercept for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

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50 MG / SYR INJECTION SYRINGE

☒ 00002455323 BRENZYS SSB $ 241.0000

Ankylosing Spondylitis

"Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed at week 12 by an RA Specialist after the initial twelve weeks of therapy to determine response.
2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
- Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for etanercept for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

Plaque Psoriasis

All Special Authorization requests for etanercept for patients weighing 63 kg or more will be assessed for coverage with an etanercept biosimilar. The originator drug, Enbrel, will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg.

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:

- Have a total PASI of 10 or more and a DLQI of more than 10, OR

- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND

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- Who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
- Cyclosporine (6 weeks treatment); AND
- Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

-Initial coverage may be approved for up to 100 mg per week for 12 weeks.
-Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet all of the following criteria:
1) The patient must be assessed by a Dermatology Specialist after the initial 12 weeks of therapy to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Greater than or equal to 75% reduction in PASI score, OR
- Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI

Following this assessment, continued coverage may be considered for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for etanercept for Plaque Psoriasis must be completed using the
Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Tildrakizumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

Polyarticular Juvenile Idiopathic Arthritis

All Special Authorization requests for etanercept for patients weighing 63 kg or more will be assessed for coverage with an etanercept biosimilar. The originator drug, Enbrel, will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg.

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 4 years of age and older who:
- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDS) conventionally

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used in children (minimum three month trial).

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects (e.g., leukopenia, hepatitis) or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric Rheumatology Specialist).

- Coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
- 30% improvement from baseline in at least three of the following six response variables, with worsening of 30% or more in no more than one of the six variables. The variables include:
i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,
ii. global assessment of overall well-being by the patient or parent,
iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
iv. number of joints with limitation of motion,
v. functional ability based on CHAQ scores,
vi. ESR or CRP
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request

Following this assessment, continued coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:
1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Once a child with pJIA has had two disease-free years, it is common clinical practice for drug treatment to be stopped."

All requests (including renewal requests) for etanercept for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Adalimumab/Etanercept/Tocilizumab for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60011).

Psoriatic Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial

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of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology (''RA Specialist'').

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.''

All requests (including renewal requests) for etanercept for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

Rheumatoid Arthritis

''Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND

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- Leflunomide (minimum 10 week trial at 20 mg daily).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology (''RA Specialist'').

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.''

All requests (including renewal requests) for etanercept for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

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Ankylosing Spondylitis

''Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

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- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed at week 12 by an RA Specialist after the initial twelve weeks of therapy to determine response.
2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
- Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for etanercept for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

Plaque Psoriasis

All Special Authorization requests for etanercept for patients weighing 63 kg or more will be assessed for coverage with an etanercept biosimilar. The originator drug, Enbrel, will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg.

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:

- Have a total PASI of 10 or more and a DLQI of more than 10, OR

- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
- Cyclosporine (6 weeks treatment); AND
- Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to

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complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

-Initial coverage may be approved for up to 100 mg per week for 12 weeks.
-Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet all of the following criteria:
1) The patient must be assessed by a Dermatology Specialist after the initial 12 weeks of therapy to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Greater than or equal to 75% reduction in PASI score, OR
- Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI

Following this assessment, continued coverage may be considered for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for etanercept for Plaque Psoriasis must be completed using the
Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Tildrakizumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

Polyarticular Juvenile Idiopathic Arthritis

All Special Authorization requests for etanercept for patients weighing 63 kg or more will be assessed for coverage with an etanercept biosimilar. The originator drug, Enbrel, will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg.

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 4 years of age and older who:
- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDS) conventionally used in children (minimum three month trial).

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects (e.g., leukopenia, hepatitis) or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric Rheumatology Specialist).

- Coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly for 12 weeks.

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- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
- 30% improvement from baseline in at least three of the following six response variables, with worsening of 30% or more in no more than one of the six variables. The variables include:
i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,
ii. global assessment of overall well-being by the patient or parent,
iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
iv. number of joints with limitation of motion,
v. functional ability based on CHAQ scores,
vi. ESR or CRP
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request

Following this assessment, continued coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:
1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Once a child with pJIA has had two disease-free years, it is common clinical practice for drug treatment to be stopped."

All requests (including renewal requests) for etanercept for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Adalimumab/Etanercept/Tocilizumab for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60011).

Psoriatic Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

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'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology (''RA Specialist'').

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.''

All requests (including renewal requests) for etanercept for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

Rheumatoid Arthritis

''Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments

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as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for etanercept for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

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Ankylosing Spondylitis

"Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

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'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed at week 12 by an RA Specialist after the initial twelve weeks of therapy to determine response.
2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
- Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for etanercept for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

Plaque Psoriasis

All Special Authorization requests for etanercept for patients weighing 63 kg or more will be assessed for coverage with an etanercept biosimilar. The originator drug, Enbrel, will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg.

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:

- Have a total PASI of 10 or more and a DLQI of more than 10, OR

- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
- Cyclosporine (6 weeks treatment); AND
- Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology

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Specialist").

-Initial coverage may be approved for up to 100 mg per week for 12 weeks.
-Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet all of the following criteria:
1) The patient must be assessed by a Dermatology Specialist after the initial 12 weeks of therapy to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Greater than or equal to 75% reduction in PASI score, OR
- Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI

Following this assessment, continued coverage may be considered for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for etanercept for Plaque Psoriasis must be completed using the
Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Tildrakizumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

Polyarticular Juvenile Idiopathic Arthritis

All Special Authorization requests for etanercept for patients weighing 63 kg or more will be assessed for coverage with an etanercept biosimilar. The originator drug, Enbrel, will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg.

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 4 years of age and older who:
- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDS) conventionally used in children (minimum three month trial).

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects (e.g., leukopenia, hepatitis) or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric Rheumatology Specialist).

- Coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under

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exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
- 30% improvement from baseline in at least three of the following six response variables, with worsening of 30% or more in no more than one of the six variables. The variables include:
i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,
ii. global assessment of overall well-being by the patient or parent,
iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
iv. number of joints with limitation of motion,
v. functional ability based on CHAQ scores,
vi. ESR or CRP
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request

Following this assessment, continued coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:
1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Once a child with pJIA has had two disease-free years, it is common clinical practice for drug treatment to be stopped."

All requests (including renewal requests) for etanercept for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Adalimumab/Etanercept/Tocilizumab for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60011).

Psoriatic Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial

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of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for etanercept for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to

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serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for etanercept for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

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Ankylosing Spondylitis

"Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial

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of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed at week 12 by an RA Specialist after the initial twelve weeks of therapy to determine response.
2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
- Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for etanercept for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

Plaque Psoriasis

All Special Authorization requests for etanercept for patients weighing 63 kg or more will be assessed for coverage with an etanercept biosimilar. The originator drug, Enbrel, will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg.

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:

- Have a total PASI of 10 or more and a DLQI of more than 10, OR

- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
- Cyclosporine (6 weeks treatment); AND
- Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

-Initial coverage may be approved for up to 100 mg per week for 12 weeks.
-Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).

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- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet all of the following criteria:
1) The patient must be assessed by a Dermatology Specialist after the initial 12 weeks of therapy to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Greater than or equal to 75% reduction in PASI score, OR
- Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI

Following this assessment, continued coverage may be considered for 50 mg per week for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for etanercept for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Tildrakizumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

Polyarticular Juvenile Idiopathic Arthritis

All Special Authorization requests for etanercept for patients weighing 63 kg or more will be assessed for coverage with an etanercept biosimilar. The originator drug, Enbrel, will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg.

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 4 years of age and older who:
- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDS) conventionally used in children (minimum three month trial).

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects (e.g., leukopenia, hepatitis) or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric Rheumatology Specialist).

- Coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):

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- 30% improvement from baseline in at least three of the following six response variables, with worsening of 30% or more in no more than one of the six variables. The variables include:
i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,
ii. global assessment of overall well-being by the patient or parent,
iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
iv. number of joints with limitation of motion,
v. functional ability based on CHAQ scores,
vi. ESR or CRP
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request

Following this assessment, continued coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:
1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Once a child with pJIA has had two disease-free years, it is common clinical practice for drug treatment to be stopped."

All requests (including renewal requests) for etanercept for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Adalimumab/Etanercept/Tocilizumab for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60011).

Psoriatic Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 8 weeks, the patient must meet the following criteria:

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1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for etanercept for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

ETANERCEPT

For continued coverage beyond 8 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for etanercept for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

EVOLOCUMAB

"Special authorization coverage may be provided for the reduction of Low Density Lipoprotein Cholesterol (LDL-C) if the following clinical criteria and conditions are met:

I) Patient has a definite or probable diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH) using the Simon Broome or Dutch Lipid Network criteria or genetic testing.

AND

II) Patient is unable to reach LDL-C target (i.e., LDL-C < 2.0 mmol/L for secondary prevention or at least a 50% reduction in LDL-C from untreated baseline for primary prevention) despite:

a) Confirmed adherence to high dose statin (e.g., atorvastatin 80 mg or rosuvastatin 40 mg) in combination with ezetimibe for at least 3 months.

OR

b) Confirmed adherence to ezetimibe for at least 3 months.
AND
Patient is unable to tolerate high dose statin, defined as meeting all of the following:

i) Inability to tolerate at least two statins with at least one started at the lowest starting daily dose,
AND
ii) For each statin (two statins in total), dose reduction is attempted for intolerable symptom (myopathy) or biomarker abnormality (creatine kinase (CK) > 5 times the upper limit of normal) resolution rather than discontinuation of statin altogether,
AND

iii) For each statin (two statins in total), intolerable symptoms (myopathy) or abnormal biomarkers (CK > 5 times the upper limit of normal) changes are reversible upon statin discontinuation but reproducible by re-challenge of statins where clinically appropriate,
AND
iv) One of either:
- Other known determinants of intolerable symptoms or abnormal biomarkers have been ruled out,
OR
- Patient developed confirmed and documented rhabdomyolysis.

OR

c) Confirmed adherence to ezetimibe for at least 3 months.
AND
Patient is statin contraindicated, i.e., active liver disease or unexplained persistent elevations of serum transaminases exceeding 3 times the upper limit of normal.

- Initial coverage may be approved for either 140 mg every two weeks or 420 mg every month for a period of 3 months.
- Patients prescribed evolocumab 420 mg every month must use the 420 mg/dose formulation.
- Patients will be limited to receiving a one-month supply of evolocumab per prescription at their pharmacy.

For continued coverage beyond 3 months, the patient must meet the following criteria:
- Patient is adherent to therapy.
- Patient has achieved a reduction in LDL-C of at least 40% from baseline (4-8 weeks after initiation of evolocumab).

Continued coverage may be approved for 140 mg every 2 weeks or 420 mg every month for a period 12 months. Patients prescribed evolocumab 140 mg every 2 weeks are limited to 26 doses per year. Patients prescribed evolocumab 420 mg every month are limited to 12 doses per year.

EVOLOCUMAB

Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
- Patient is adherent to therapy.
- Patient continues to have a significant reduction in LDL-C (with continuation of evolocumab) of at least 40% from baseline since initiation of PCSK9 inhibitor. LDL-C should be checked periodically with continued treatment with PCSK9 inhibitors (e.g., every 6 months)."

All requests (including renewal requests) for evolocumab for Heterozygous Familial Hypercholesterolemia must be completed using the Alirocumab/Evolocumab for HeFH Special Authorization Request Form (ABC 60060).

420 MG INJECTION CARTRIDGE				
00002459779	REPATHA	AMG	$	587.7500
140 MG / SYR INJECTION SYRINGE				
00002446057	REPATHA AUTOINJECTOR	AMG	$	271.2700

FEBUXOSTAT

"For the treatment of symptomatic gout in patients with a documented hypersensitivity to allopurinol.

Special authorization may be granted for 6 months."

Please note: Hypersensitivity to allopurinol is a rare condition that is characterized by a major skin manifestation, fever, multi-organ involvement, lymphadenopathy and hematological abnormalities (eosinophilia, atypical lymphocytes). Intolerance or lack of response to allopurinol will not be covered by this criteria.

All requests for febuxostat must be completed using the Febuxostat Special Authorization Request Form (ABC 60037).

The following product(s) are eligible for auto-renewal.

80 MG ORAL TABLET				
00002490870	**JAMP-FEBUXOSTAT**	**JPC**	$	**0.3975**
00002473607	**MAR-FEBUXOSTAT**	**MAR**	$	**0.3975**
00002466198	**TEVA-FEBUXOSTAT**	**TEV**	$	**0.3975**

FENTANYL

"For the treatment of persistent, severe chronic pain in those patients who require continuous around-the-clock analgesia for an extended period of time in those patients who cannot swallow. Special authorization may be granted for 6 months."

"For the treatment of persistent, severe chronic pain in those patients who require continuous around-the-clock analgesia for an extended period of time in those patients who require opioid therapy at a total daily dose of at least 60 mg/day oral morphine equivalents. Patients must have tried and not been able to tolerate at least two discrete courses of therapy with two of the following agents: morphine, hydromorphone and oxycodone, if not contraindicated. Special authorization may be granted for 6 months."

Information is required regarding previous medications utilized and the patient's response to therapy. Also, information regarding the number of discrete (separate) courses of these medications is required. A discrete course is defined as a separate treatment course, which may involve more than 1 agent, used at one time to manage the patient's condition.

All requests for fentanyl must be completed using the Fentanyl Special Authorization Request Form (ABC 60005).

(Please note: The following fentanyl products are benefits not requiring special authorization for individuals approved by Alberta Health for Palliative Coverage. Refer to the Palliative Coverage Drug Benefit Supplement for additional information on this coverage.)

The following product(s) are eligible for auto-renewal.

12 MCG/HR TRANSDERMAL PATCH				
00002327112	**SANDOZ FENTANYL PATCH**	**SDZ**	$	**2.2280**
00002311925	**TEVA-FENTANYL**	**TEV**	$	**2.2280**
25 MCG/HR TRANSDERMAL PATCH				
00002327120	**SANDOZ FENTANYL PATCH**	**SDZ**	$	**3.6560**
00002282941	**TEVA-FENTANYL**	**TEV**	$	**3.6560**
50 MCG/HR TRANSDERMAL PATCH				
00002327147	**SANDOZ FENTANYL PATCH**	**SDZ**	$	**6.8820**
00002282968	**TEVA-FENTANYL**	**TEV**	$	**6.8820**
75 MCG/HR TRANSDERMAL PATCH				
00002327155	**SANDOZ FENTANYL PATCH**	**SDZ**	$	**9.6800**
00002282976	**TEVA-FENTANYL**	**TEV**	$	**9.6800**
100 MCG/HR TRANSDERMAL PATCH				
00002327163	**SANDOZ FENTANYL PATCH**	**SDZ**	$	**12.0500**
00002282984	**TEVA-FENTANYL**	**TEV**	$	**12.0500**
50 MCG / ML INJECTION				
00002496143	**FENTANYL (100 MCG/ 2 ML)**	**STM**	$	**1.9103**
00002496178	**FENTANYL (1000 MCG/ 20 ML)**	**STM**	$	**1.9103**
00002496151	**FENTANYL (250 MCG/ 5 ML)**	**STM**	$	**1.9103**
00002496186	**FENTANYL (2500 MCG/ 50 ML)**	**STM**	$	**1.9103**
00002240434	**FENTANYL CITRATE**	**SDZ**	$	**1.9103**

FERRIC DERISOMALTOSE

"For the treatment of iron deficiency anemia (IDA) in adult patients who have intolerance OR have an inadequate response to a trial of oral iron therapy, OR in whom oral iron therapy is contraindicated.

"Intolerance" is defined as the persistence of gastrointestinal side-effects despite having tried:
-an adequate trial of at least two different formulations of oral iron (e.g. iron salts, polysaccharide iron, heme iron), or
-taking oral iron with small amounts of food, or
-utilizing alternate day dosing regimen of oral iron, or
-oral iron has been titrated up from low-dose.

"Inadequate response" is defined as one or more of the following:
-Hemoglobin (Hb) continues to decline while on oral iron therapy (Hb <90 g/L), or
-Hb increases less than 10 g/L after three months of oral iron therapy.

Contraindications to oral iron therapy may include the following:
-Patients have clinical malabsorption (e.g. history of bariatric surgery, clinically active Inflammatory Bowel Disease (IBD), Celiac disease, Chronic Kidney Disease, short bowel syndrome), or
-Patients have chronic blood loss, in which the pace of iron loss exceed ability to replete from oral iron intake, or
-Patients have time-limited conditions (i.e. perioperative) where oral iron will not provide adequate Hb levels.

This Product must be administered in a setting where appropriate monitoring and management of hypersensitivity reactions can be provided.

Special authorization may be granted for 12 months.
Renewal requests may be considered if intravenous iron is required to maintain normal hemoglobin in patients for whom the underlying cause of iron deficiency anemia cannot be resolved (e.g. ongoing blood losses)."

All requests for iron ferric derisomaltose must be completed using the Iron (Intravenous) Special Authorization Request Form (ABC 60085).

100 MG / ML (BASE)	**INJECTION**			
00002477777	MONOFERRIC	PFI	$	45.0000

FESOTERODINE FUMARATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): SOLIFENACIN OR TOLTERODINE LA

"For patients who have failed on or are intolerant to solifenacin or tolterodine LA."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

All requests for fesoterodine fumarate must be completed using the darifenacin hydrobromide/Fesoterodine fumarate/Mirabegron/Trospium chloride Special Authorization Request Form (ABC 60088).

4 MG ORAL EXTENDED-RELEASE TABLET				
00002521768	**SANDOZ FESOTERODINE FUMARATE**	**SDZ**	$	**1.1250**
00002380021	TOVIAZ	PFI	$	1.5500
8 MG ORAL EXTENDED-RELEASE TABLET				
00002521776	**SANDOZ FESOTERODINE FUMARATE**	**SDZ**	$	**1.1250**
00002380048	TOVIAZ	PFI	$	1.5500

FIDAXOMICIN

For the treatment of:
1) C. difficile infection (CDI) where the patient has failed, or is intolerant of oral vancomycin; or
2) Patients with third or greater recurrence of CDI (i.e. 4th or greater episode of CDI)

Note:
- Fidaxomicin should not be used as an add-on to existing therapy (metronidazole or vancomycin).
- Not studied in multiple recurrences or those with life-threatening or fulminant CDI, toxic megacolon, or inflammatory bowel disease.

Special authorization coverage for fidaxomicin will be provided for one treatment course (10 days) plus one additional treatment course for an early relapse occurring within 8 weeks of the start of the most recent fidaxomicin course.

New episode of CDI after 8 weeks will require treatment with first line therapy before fidaxomicin coverage may be considered.

All requests (including renewal requests) for fidaxomicin must be completed using the Fidaxomicin Special Authorization Request Form (ABC 60014).

200 MG ORAL TABLET				
00002387174	DIFICID	MFC	$	94.6000

FILGRASTIM

"In patients with non-myeloid malignancies, receiving myelosuppressive anti-neoplastic drugs with curative intent, to decrease the incidence of infection, as manifested by febrile neutropenia."

"Following induction and consolidation treatment for acute myeloid leukemia, for the reduction in the duration of neutropenia, fever, antibiotic use and hospitalization."

"In patients with a diagnosis of congenital, cyclic or idiopathic neutropenia, to increase neutrophil counts and to reduce the incidence and duration of infection."

Please note for the first criterion: Coverage cannot be considered for palliative patients.

All requests for filgrastim must be completed using the Filgrastim/Pegfilgrastim/Plerixafor Special Authorization Request Form (ABC 60013).

0.3 MG / ML INJECTION				
00002485591	NIVESTYM	PFI	$	144.3100
00002485656	NIVESTYM (1.6 ML)	PFI	$	144.3125
0.3 MG / SYR INJECTION SYRINGE				
☒ 00002485575	NIVESTYM (0.5 ML SYRINGE)	PFI	$	144.3100
☒ 00002441489	GRASTOFIL (0.5 ML SYRINGE)	APX	$	144.3135
☒ 00002485583	NIVESTYM (0.8 ML SYRINGE)	PFI	$	230.9000
☒ 00002454548	GRASTOFIL (0.8 ML SYRINGE)	APX	$	230.9017

FINGOLIMOD HYDROCHLORIDE

Relapsing Remitting Multiple Sclerosis (RRMS)

"Special authorization coverage may be provided for the treatment of relapsing remitting multiple sclerosis (RRMS) to reduce the frequency of clinical relapses, to decrease the number and volume of active brain lesions identified on magnetic resonance imaging (MRI) scans and to delay the progression of physical disability, in adult patients (18 years of age or older) who are refractory or intolerant to at least ONE of the following:
- dimethyl fumarate
- glatiramer acetate
- interferon beta
- ocrelizumab
- ofatumumab
- peginterferon beta
- teriflunomide

Definition of 'intolerant'
Demonstrating serious adverse effects or contraindications to treatments as defined in the product monograph, or a persisting adverse event that is unresponsive to recommended management techniques and which is incompatible with further use of that class of MS disease modifying therapy (DMT).

Definition of 'refractory'
-Development of neutralizing antibodies to interferon beta.

-When the above MS DMTs are taken at the recommended doses for a full and adequate course of treatment, within a consecutive 12-month period while the patient was on the MS DMT, the patient has:

1) Been adherent to the MS DMT (greater than 80% of approved doses have been administered);

2) Experienced at least two relapses* of MS confirmed by the presence of neurologic deficits on examination.
i. The first qualifying clinical relapse must have begun at least one month after treatment initiation.
ii. Both qualifying relapses must be classified with a relapse severity of moderate, severe or very severe**.

* A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

**Relapse Severity: with moderate relapses modification or more time is required to carry out activities of daily living; with severe relapses there is inability to carry out some activities of daily living; with very severe relapses activities of daily living must be completed by others.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.
To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).
Initial Coverage
1) The registered MS Neurologist must confirm a diagnosis of RRMS;
2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS DMT. In most cases this will be satisfied by the refractory to treatment criterion but if a patient failed an MS DMT more than one

FINGOLIMOD HYDROCHLORIDE

year earlier, ongoing active disease must be confirmed.
3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).
Coverage will not be approved when any MS DMT or other immunosuppressive therapy is to be used in combination with fingolimod.
Coverage of fingolimod will not be approved if the patient was deemed to be refractory to fingolimod in the past, i.e., has not met the 'responder' criteria below in 'Continued Coverage'.
Following assessment of the request, coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of fingolimod per prescription at their pharmacy for the first 12 months of coverage.
Continued Coverage
For continued coverage beyond the initial coverage period, the patient must meet the following criteria:
1) The patient must be assessed by a registered MS Neurologist;
2) The registered MS Neurologist must confirm a diagnosis of RRMS;
3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more;
Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.
4) The registered MS Neurologist must confirm in writing that the patient is a 'responder' who has experienced no more than one inflammatory event in the last year (defined as either a clinical relapse or new T2 lesion or gadolinium-enhancing lesion). In instances where a patient has had four or more clinical relapses in the year prior to starting treatment, there must be at least a 50% reduction in relapse rate over the entire treatment period.
Following assessment of the request, continued coverage may be approved for maintenance therapy for up to 12 months. Patients may receive up to 100 days' supply of fingolimod per prescription at their pharmacy.
Restarting After an Interruption in Therapy Greater Than 12 Months
In order to be eligible for coverage, after an interruption of therapy greater than 12 months, the patient must meet the following criteria:
1) At least one relapse* per 12 month period; or
2) At least two relapses* during the previous 24 month period."

All requests (including renewal requests) for fingolimod must be completed using the Cladribine/Fingolimod/Natalizumab For Multiple Sclerosis Special Authorization Request Form (ABC 60000).

0.5 MG (BASE) ORAL CAPSULE

00002469936	**APO-FINGOLIMOD**	**APX**	$	**21.7381**
00002487772	**JAMP FINGOLIMOD**	**JPC**	$	**21.7381**
00002474743	**MAR-FINGOLIMOD**	**MAR**	$	**21.7381**
00002469715	**MYLAN-FINGOLIMOD**	**MYP**	$	**21.7381**
00002469782	**PMS-FINGOLIMOD**	**PMS**	$	**21.7381**
00002482606	**SANDOZ FINGOLIMOD**	**SDZ**	$	**21.7381**
00002469618	**TARO-FINGOLIMOD**	**TAR**	$	**21.7381**
00002469561	**TEVA-FINGOLIMOD**	**TEV**	$	**21.7381**
00002365480	GILENYA	NOV	$	86.9525

FLUCONAZOLE

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For susceptible infections in patients who cannot swallow tablets."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

10 MG / ML ORAL SUSPENSION

00002024152	DIFLUCAN	PFI	$	1.2648

FLUTAMIDE

"When prescribed for non-cancer, non-cosmetic indications.

Special authorization may be granted for 6 months."

Information is required regarding the patient's diagnosis/indication for use of this medication.

The following product(s) are eligible for auto-renewal.

250 MG ORAL TABLET

00002238560	FLUTAMIDE	AAP	$	1.8894

FLUTICASONE FUROATE/ UMECLIDINIUM BROMIDE/ VILANTEROL TRIFENATATE

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S):
LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])

SECOND-LINE DRUG PRODUCT(S):
LONG-ACTING BRONCHODILATOR DUAL THERAPY (I.E., LONG-ACTING BETA-2 AGONIST [LABA] AND LONG-ACTING MUSCARINIC ANTAGONIST [LAMA]) OR DUAL THERAPY OF INHALED CORTICOSTEROID [ICS] AND LONG-ACTING BETA-2 AGONIST [LABA])

"For the long-term maintenance treatment of chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema, in patients who are not controlled on optimal dual inhaled therapy (i.e., long-acting beta-2 agonist [LABA]/long-acting muscarinic antagonist [LAMA] OR inhaled corticosteroid [ICS]/long-acting beta-2 agonist [LABA])."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the third-line therapy drug.

UP - First-line therapy ineffective

All requests for fluticasone furoate + umeclidinium + vilanterol must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

100 MCG / DOSE * 62.5 MCG / DOSE (BASE)	* 25 MCG / DOSE (BASE)	INHALATION	METERED INHALATION POWDER	
00002474522	TRELEGY ELLIPTA	GSK	$	4.5890

FLUTICASONE FUROATE/ VILANTEROL TRIFENATATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

ASTHMA

FIRST-LINE DRUG PRODUCT(S): INHALED CORTICOSTEROID (ICS)

"For the treatment of asthma in patients uncontrolled on inhaled steroid therapy."

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S): LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])

"For the long-term maintenance treatment of airflow obstruction in patients with moderate to severe (i.e., FEV1 < 80% predicted) chronic obstructive pulmonary disease (COPD), who have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA])."

"For the long-term maintenance treatment of airflow obstruction in patients with severe (i.e., FEV1 < 50% predicted) chronic obstructive pulmonary disease (COPD)."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for fluticasone furoate + vilanterol trifenatate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

100 MCG / DOSE * 25 MCG / DOSE (BASE)	INHALATION	METERED INHALATION POWDER		
00002408872	BREO ELLIPTA	GSK	$	3.0209

FLUTICASONE FUROATE/ VILANTEROL TRIFENATATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

ASTHMA

FIRST-LINE DRUG PRODUCT(S): INHALED CORTICOSTEROID (ICS)

"For the treatment of asthma in patients uncontrolled on inhaled steroid therapy."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for fluticasone furoate + vilanterol trifenatate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

200 MCG / DOSE * 25 MCG / DOSE	**INHALATION**	**METERED INHALATION POWDER**		
00002444186	BREO ELLIPTA	GSK	$	4.7312

FORMOTEROL FUMARATE DIHYDRATE/ MOMETASONE FUROATE

STEP THERAPY/SPECIAL AUTHORIZATION

FIRST-LINE DRUG PRODUCT(S): INHALED CORTICOSTEROID (ICS)

"For the treatment of asthma in patients uncontrolled on inhaled steroid therapy."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for formoterol fumarate dihydrate + mometasone furoate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

5 MCG / DOSE * 100 MCG / DOSE	**INHALATION**	**METERED DOSE AEROSOL**		
00002361752	ZENHALE 100/5	ORC	$	0.9116
5 MCG / DOSE * 200 MCG / DOSE	**INHALATION**	**METERED DOSE AEROSOL**		
00002361760	ZENHALE 200/5	ORC	$	1.1048

FREMANEZUMAB

''Special authorization coverage may be provided for the prevention of episodic or chronic migraine in adult patients (18 years of age or older) who at baseline are refractory or intolerant to at least TWO oral prophylactic migraine medications of different classes.

'Episodic migraine' is defined as experiencing headaches for less than 15 days per month for more than three months of which at least four days per month of this period are with migraine.

'Chronic migraine' is defined as experiencing headaches for at least 15 days per month for more than three months of which at least eight days per month of this period are with migraine.

'Refractory' is defined as lack of effect in reducing the frequency of migraine days.

'Intolerant' is defined as demonstrating serious adverse effects to treatments as defined in product monographs.

Only one Drug Product of an anti-calcitonin gene related peptide or onabotulinumtoxinA for the prevention of migraine would be allowed for coverage at a time.

For coverage, the patient should be under the care of a physician who has appropriate experience in the management of patients with migraine headaches.
-Initial coverage may be approved for 225 mg every month or 675 mg every 3 months for a period of 6 months.
-For initial coverage, the baseline number of migraine days per month must be provided.
-Patients will be limited to receiving a one-dose supply of fremanezumab per prescription at their pharmacy.

For continued coverage beyond 6 months the patient must meet the following criteria:
1) The patient must be assessed by the physician after the initial 6 months of therapy to determine response.
2) The physician must confirm in writing, that the patient is a 'responder' that meets the following criteria:
-Reduction of at least 50% in the average number of migraine days per month compared to baseline.

Following this assessment, continued coverage may be approved for 225 mg every month or 675 mg every 3 months for a period of 6 months. Ongoing coverage may be considered if the patient is re-assessed by the physician every 6 months, and is confirmed to be continuing to respond to therapy by maintaining a reduction of at least 50% in the average number of migraine days per month compared to baseline.''

All requests for fremanezumab (including renewal requests) must be completed using the Fremanezumab for Migraine Prevention Special Authorization Request Form (ABC 60095).

225 MG / SYR INJECTION SYRINGE

☒ 00002497859	AJOVY	TMP	$	553.9300
☒ 00002509474	AJOVY (AUTO-INJECTOR)	TMP	$	553.9300

GALANTAMINE HYDROBROMIDE

"For the treatment of Alzheimer's disease in patients who meet the following criteria:
- a Mini Mental State Exam (MMSE) score between 10-26, or
- a St. Louis University Mental Status Examination (SLUMS) score between 6-26, or
- a Rowland Universal Dementia Assessment Scale (RUDAS) score between 9-22, or
- an InterRAI-Cognitive Performance Scale score between 1-4

Coverage cannot be provided for two or more medications used in the treatment of Alzheimer's disease (donepezil, galantamine, rivastigmine) when these medications are intended for use in combination.

Special Authorization coverage may be granted for a maximum of 24 months per request.

For each request, an updated score (MMSE, SLUMS, RUDAS or InterRAI-Cognitive Performance Scale) and the date on which the exam was administered must be provided.

Renewal requests may be considered for patients where an updated score while on this drug meets the following criteria:
- MMSE score is 10 or higher, or
- SLUMS score is 6 or higher, or
- RUDAS score is 9 or higher, or
- InterRAI-Cognitive Performance Scale is 4 or lower."

All requests (including renewal requests) for galantamine hydrobromide must be completed using the Donepezil/Galantamine/Rivastigmine Special Authorization Request From (ABC 60034).

8 MG (BASE) ORAL EXTENDED-RELEASE CAPSULE				
00002425157	**AURO-GALANTAMINE ER**	**AUR**	$	**1.2463**
00002443015	**GALANTAMINE ER**	**SNS**	$	**1.2463**
00002339439	**MYLAN-GALANTAMINE ER**	**MYP**	$	**1.2463**
00002398370	**PMS-GALANTAMINE ER**	**PMS**	$	**1.2463**
16 MG (BASE) ORAL EXTENDED-RELEASE CAPSULE				
00002425165	**AURO-GALANTAMINE ER**	**AUR**	$	**1.2463**
00002443023	**GALANTAMINE ER**	**SNS**	$	**1.2463**
00002339447	**MYLAN-GALANTAMINE ER**	**MYP**	$	**1.2463**
24 MG (BASE) ORAL EXTENDED-RELEASE CAPSULE				
00002425173	**AURO-GALANTAMINE ER**	**AUR**	$	**1.2463**
00002443031	**GALANTAMINE ER**	**SNS**	$	**1.2463**
00002339455	**MYLAN-GALANTAMINE ER**	**MYP**	$	**1.2463**

GALCANEZUMAB

''Special authorization coverage may be provided for the prevention of episodic or chronic migraine in adult patients (18 years of age or older) who at baseline are refractory or intolerant to at least TWO oral prophylactic migraine medications of different classes.

'Episodic migraine' is defined as experiencing headaches for less than 15 days per month for more than three months of which at least four days per month of this period are with migraine.

'Chronic migraine' is defined as experiencing headaches for at least 15 days per month for more than three months of which at least eight days per month of this period are with migraine.

'Refractory' is defined as lack of effect in reducing the frequency of migraine days.

'Intolerant' is defined as demonstrating serious adverse effects to treatments as defined in product monographs.

Only one Drug Product of an anti-calcitonin gene related peptide or onabotulinumtoxinA for the prevention of migraine would be allowed for coverage at a time.

For coverage, the patient should be under the care of a physician who has appropriate experience in the management of patients with migraine headaches.
-Initial coverage may be approved for an initial dose of 240 mg (two 120 mg injections), followed by a 120 mg dose once monthly for a total period of 6 months.
-For initial coverage, the baseline number of migraine days per month must be provided.
-Patients will be limited to receiving a one-dose supply of galcanezumab per prescription at their pharmacy.

For continued coverage beyond 6 months the patient must meet the following criteria:
1) The patient must be assessed by the physician after the initial 6 months of therapy to determine response.
2) The physician must confirm in writing, that the patient is a 'responder' that meets the following criteria:
-Reduction of at least 50% in the average number of migraine days per month compared to baseline.

Following this assessment, continued coverage may be approved for 120 mg every month for a period of 6 months. Ongoing coverage may be considered if the patient is re-assessed by the physician every 6 months, and is confirmed to be continuing to respond to therapy by maintaining a reduction of at least 50% in the average number of migraine days per month compared to baseline.''

All requests for galcanezumab (including renewal requests) must be completed using the Fremanezumab/Galcanezumab for Migraine Prevention Special Authorization Request Form (ABC 60095).

120 MG / SYR	INJECTION	SYRINGE			
☒ 00002491060	EMGALITY		LIL	$	577.8000
☒ 00002491087	EMGALITY (PEN)		LIL	$	577.8000

GLATIRAMER ACETATE

20 MG / SYR INJECTION SYRINGE

00002460661	GLATECT	PMS	$	32.4000

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.

To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

1) The registered MS Neurologist must confirm a diagnosis of RRMS;

2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of glatiramer acetate per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

1) The patient must be assessed by a registered MS Neurologist;

2) The registered MS Neurologist must confirm a diagnosis of RRMS;

3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more.

Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of glatiramer acetate per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the patient must meet the following criteria:

1) At least one relapse* per 12 month period; or
2) At least two relapses* during the previous 24 month period."

All requests (including renewal requests) for glatiramer acetate must be completed using the Dimethyl Fumarate/Glatiramer Acetate/Interferon Beta-1a/Ocrelizumab/Peginterferon Beta-1a/Teriflunomide for RRMS/Interferon Beta-1b for SPMS or RRMS Special Authorization Request Form (ABC 60001).

GLATIRAMER ACETATE

GLYCEROL PHENYLBUTYRATE

"For chronic management of patients with urea cycle disorders (UCDs) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone.

For coverage, this drug must be prescribed by or in consultation with a metabolic or genetic physician. The diagnosis must be confirmed by blood, enzymatic, biochemical, or genetic testing.

Special authorization may be granted for 12 months."

The following product(s) are eligible for auto-renewal.

1.1 G / ML	**ORAL**	**LIQUID**			
00002453304	RAVICTI		RAP	$	48.0000

GOLIMUMAB

Ankylosing Spondylitis

"Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:
- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg once per month for four doses.
- Patients will be limited to receiving one dose (50 mg) of golimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond four doses the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial four doses to determine response.
2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
- Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for 50 mg once per month for a further 12 month period. Should continued coverage criteria be met, coverage will only be granted for 12 doses per 12 month period. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for golimumab for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

Psoriatic Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant

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to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per month for four doses.
- Patients will be limited to receiving one dose (50 mg) of golimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond four doses, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after four doses to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per month, for a further 12 month period. Should coverage criteria be met, coverage will only be granted for 12 doses per 12-month period. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for golimumab for Psoriatic Arthritis must be

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completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 50 mg per month for a total of four doses.
- Patients will be limited to receiving one dose (50 mg) of golimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond four doses, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after four doses to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 50 mg per month, for a further 12 month period. Should continued coverage criteria be met, coverage will

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only be granted for 12 doses per 12 month period. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for golimumab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Ulcerative Colitis

Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:
- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks; AND
- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:
i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

For coverage, this drug must be prescribed by a Specialist in Gastroenterology as recognized by the College of Physicians and Surgeons and/or the Alberta Medical Association or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross ('Specialist').

Initial coverage may be approved for 200 mg of golimumab administered by subcutaneous injection at Week 0, followed by 100 mg at Week 2. As an interim measure, an additional dose of 50 mg of golimumab will be provided at weeks 6 and 10 to allow time to determine whether the patient meets coverage criteria for maintenance dosing, see below.
- Patients will be limited to receiving a one-month supply of golimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition

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for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by a Specialist between week 12 and week 14 to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for a dose of 50 mg every 4 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist to determine response;
2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of golimumab therapy

Note: For patients who showed a response to induction therapy then experienced secondary loss of response while on maintenance dosing with 50 mg, the maintenance dose may be adjusted from 50 mg to 100 mg by making an additional special authorization request to Alberta Blue Cross for the increased dose.

All requests (including renewal requests) for golimumab for Ulcerative Colitis must be completed using the Adalimumab/Golimumab/Infliximab/Tofacitinib/Vedolizumab for Ulcerative Colitis Special Authorization Request Form (ABC 60008).

50 MG / SYR INJECTION SYRINGE

☒ 00002324776	SIMPONI	JAI	$	1516.0000
☒ 00002324784	SIMPONI (AUTO INJECTOR)	JAI	$	1516.0000

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Ulcerative Colitis

Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:
- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks; AND
- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:
i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

For coverage, this drug must be prescribed by a Specialist in Gastroenterology as recognized by the College of Physicians and Surgeons and/or the Alberta Medical Association or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross ('Specialist').

Initial coverage may be approved for 200 mg of golimumab administered by subcutaneous injection at Week 0, followed by 100 mg at Week 2. As an interim measure, an additional dose of 50 mg of golimumab will be provided at weeks 6 and 10 to allow time to determine whether the patient meets coverage criteria for maintenance dosing, see below.
- Patients will be limited to receiving a one-month supply of golimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by a Specialist between week 12 and week 14 to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for a dose of 50 mg every 4 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist to determine response;
2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of golimumab therapy

Note: For patients who showed a response to induction therapy then experienced

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secondary loss of response while on maintenance dosing with 50 mg, the maintenance dose may be adjusted from 50 mg to 100 mg by making an additional special authorization request to Alberta Blue Cross for the increased dose.

All requests (including renewal requests) for golimumab for Ulcerative Colitis must be completed using the Adalimumab/Golimumab/Infliximab/Tofacitinib/Vedolizumab for Ulcerative Colitis Special Authorization Request Form (ABC 60008).

100 MG / SYR INJECTION SYRINGE				
☒ 00002413175	SIMPONI	JAI	$	1516.0000
☒ 00002413183	SIMPONI (AUTO INJECTOR)	JAI	$	1516.0000

GOSERELIN ACETATE

"When prescribed for non-cancer, non-cosmetic or non-fertility indications.

Special authorization may be granted for 6 months."

Information is required regarding the patient's diagnosis/indication for use of this medication.

The following product(s) are eligible for auto-renewal.

3.6 MG / SYR (BASE) INJECTION SYRINGE				
00002049325	ZOLADEX	TSA	$	422.6778
10.8 MG / SYR (BASE) INJECTION SYRINGE				
00002225905	ZOLADEX LA	TSA	$	1204.7322

HALOBETASOL PROPIONATE/ TAZAROTENE

"Special authorization coverage may be provided for improving the signs and symptoms of moderate to severe plaque psoriasis in adult patients (18 years of age and older) who meet ALL of the following criteria:

1) Patients must have a clinical diagnosis of plaque psoriasis with all of the following characteristics:
- an Investigator's Global Assessment (IGA) score of 3 (moderate) or 4 (severe), and
- an area of plaque psoriasis appropriate for topical treatment covering a body surface area (BSA) of 3% to 12%, and

2) Patients must have not adequately responded to a topical high-potency corticosteroid and for whom the addition of a second topical medication would be appropriate.

Initial coverage may be approved for 12 weeks.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by the prescriber after the initial 8 to 12 weeks of therapy to determine response.
2) The prescriber must confirm, in writing, that the patient is a 'responder' with an IGA score of 'clear' or 'almost clear' (0 or 1).

Continued coverage may be granted for 12 months."

The following product(s) are eligible for auto-renewal after continued coverage criteria have been met.

All requests (including renewal requests) for halobetasol propionate/tazarotene lotion must be completed using the Halobetasol propionate/tazarotene topical lotion Special Authorization Request Form (ABC 60094).

0.01 % * 0.045 %	**TOPICAL**	**LOTION**			
00002499967	DUOBRII		VCL	$	1.9300

ICATIBANT ACETATE

"For the treatment of acute attacks of confirmed Type 1 or Type 2 hereditary angioedema (HAE) in patients with C1-esterase inhibitor deficiency. Icatibant is to be used for:
- acute non-laryngeal attack(s) of at least moderate severity, or
- acute laryngeal attack(s) of any severity

This medication must be prescribed by, or in consultation with, a physician experienced in the treatment of HAE.

Special authorization may be granted for 12 months.

Patients will be limited to a maximum of two doses of icatibant per prescription at their pharmacy."

This product is eligible for auto-renewal.

All requests for icatibant must be completed using the Icatibant/Lanadelumab for HAE Type I or II Special Authorization Request Form (ABC 60083).

30 MG / SYR (BASE)	**INJECTION**			
00002425696	FIRAZYR	TAK	$	2700.0000

IMIQUIMOD

"For the treatment of Actinic Keratosis located on the head and neck in patients who have failed treatment with cryotherapy (where appropriate) and 5-fluorouracil (5-FU).

Special authorization may be granted for 6 months."

All requests for imiquimod must be completed using the Imiquimod Special Authorization Request Form (ABC 60038).

The following product(s) are eligible for auto-renewal.

50 MG/G / G TOPICAL CREAM

00002482983	**TARO-IMIQUIMOD PUMP**	**TAR**	$	**43.4350**
00002239505	ALDARA P	VCL	$	55.5780

INDACATEROL ACETATE/ GLYCOPYRRONIUM BROMIDE/ MOMETASONE FUROATE

"For the maintenance treatment of asthma in adult patients (18 years of age or older) who are not controlled on optimal dual inhaled therapy (i.e., long-acting beta-2 agonist [LABA] and a medium or high dose of an inhaled corticosteroid [ICS]) and have experienced one or more asthma exacerbations in the previous 12 months.

Special authorization may be granted for 24 months."

The following product(s) are eligible for auto-renewal.

All requests for indacaterol acetate + glycopyrronium bromide + mometasone furoate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

150 MCG (BASE) * 50 MCG * 160 MCG INHALATION CAPSULE

00002501244	ENERZAIR BREEZHALER	VLP	$	3.4273

INDACATEROL ACETATE/ MOMETASONE FUROATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): INHALED CORTICOSTEROID (ICS)

"For the treatment of asthma in patients 12 years of age and older uncontrolled on inhaled steroid therapy."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for indacaterol acetate + mometasone furoate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

150 MCG (BASE) * 80 MCG INHALATION CAPSULE

00002498685	ATECTURA BREEZHALER	VLP	$	1.0730

150 MCG (BASE) * 160 MCG INHALATION CAPSULE

00002498707	ATECTURA BREEZHALER	VLP	$	1.3420

INDACATEROL ACETATE/ MOMETASONE FUROATE

150 MCG (BASE) * 320 MCG	INHALATION CAPSULE			
00002498693	ATECTURA BREEZHALER	VLP	$	1.8473

INDACATEROL MALEATE/ GLYCOPYRRONIUM BROMIDE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S): LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])

"For the long-term maintenance treatment of airflow obstruction in patients with moderate to severe (i.e., FEV1 < 80% predicted) chronic obstructive pulmonary disease (COPD), who have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA])."

"For the long-term maintenance treatment of airflow obstruction in patients with severe (i.e., FEV1 < 50% predicted) chronic obstructive pulmonary disease (COPD)."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for indacaterol maleate + glycopyrronium bromide must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

110 MCG (BASE) * 50 MCG (BASE)	INHALATION CAPSULE			
00002418282	ULTIBRO BREEZHALER	COV	$	2.5830

INFANT FORMULA

ORAL POWDER

☒ 00000999543 PURAMINO A+ MJO $ 0.1292

"For the dietary management of infants with:
-cow milk protein allergy OR
-soy protein allergy OR
-multiple food protein intolerance OR
-conditions where an amino acid-based diet is indicated:
-short bowel syndrome
-gastroesophageal reflux disease (GERD)
-eosinophilic esophagitis (EoE)
-malabsorption.

AND

Who have failed or are intolerant to an appropriate trial (1 to 2 week trial is recommended) of an extensively hydrolyzed infant formula.

This product must be prescribed by or in consultation with a general pediatrician, neonatologist, pediatric gastroenterologist or pediatric allergist.

Special authorization may be granted for a maximum of 24 months."

(Refer to Criteria for Special Authorization of Select Drug Products in the Alberta Human Services Drug Benefit Supplement for eligibility in Alberta Human Services clients.)

☒ 00000999568 NEOCATE WITH DHA & ARA NUN $ 0.1660

"For the dietary management of infants with:
-cow milk protein allergy OR
-soy protein allergy OR
-multiple food protein intolerance OR
-conditions where an amino acid-based diet is indicated:
-short bowel syndrome
-gastroesophageal reflux disease (GERD)
-eosinophilic esophagitis (EoE)
-malabsorption.

AND

Who have failed or are intolerant to an appropriate trial (1 to 2 week trial is recommended) of an extensively hydrolyzed infant formula.

This product must be prescribed by or in consultation with a general pediatrician, neonatologist, pediatric gastroenterologist or pediatric allergist.

Special authorization may be granted for a maximum of 24 months."

(Refer to Criteria for Special Authorization of Select Drug Products in the Alberta Human Services Drug Benefit Supplement for eligibility in Alberta Human Services clients.)

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100 MG / VIAL INJECTION

☒ 00002496933 AVSOLA AMG $ 493.0000

Ankylosing Spondylitis

"Special authorization coverage may be provided for the reduction in the signs and symptoms and improvement in physical function of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for three doses as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
- Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for one 5 mg/kg dose of infliximab every 6 to 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for infliximab for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease

"Special authorization coverage may be approved for coverage of infliximab for the reduction in signs and symptoms and induction and maintenance of clinical remission of Moderately to Severely Active Crohn's Disease and/or treatment of Fistulizing Crohn's Disease in patients who meet the following criteria:

- Infliximab must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross for infliximab for coverage for the treatment of Moderately to Severely Active Crohn's Disease and/or Fistulizing Crohn's Disease patients (`Specialist').
- Patients must be 18 years of age or older to be considered for coverage of infliximab.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients may be allowed to switch from one biologic agent to another following an adequate trial

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of the first biologic agent if unresponsive to therapy (both primary loss of response and secondary loss of response) or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

Prior to initiation of infliximab therapy for New Patients:

'New Patients' are patients who have never been treated with infliximab by any health care provider.

Moderately to Severely Active Crohn's Disease:

Prior to initiation of infliximab therapy, New Patients must have a current Modified (without the physical exam) Harvey Bradshaw Index score of greater than or equal to 7 (New Patient's Baseline Score), AND be Refractory.

Refractory is defined as one or more of the following:
1) Serious adverse effects or reactions to the treatments specified below; OR
2) Contraindications (as defined in product monographs) to the treatments specified below; OR
3) Previous documented lack of effect at doses and for duration of all treatments specified below:
a) mesalamine: minimum of 3 grams/day for a minimum of 6 weeks; AND refractory to, or dependent on, glucocorticoids:
following at least one tapering dosing schedule of 40 mg/day, tapering by 5 mg each week to 20 mg, then tapering by 2.5 mg each week to zero, or similar;

[Note: Patients who have used the above treatments in combination will not be required to be challenged with individual treatments as monotherapy]

AND
b) Immunosuppressive therapy as follows:
- Azathioprine: minimum of 2 mg/kg/day for a minimum of 3 months; OR
- 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 3 months; OR
- Methotrexate: minimum or 15 mg/week for a minimum of 3 months.
OR
- Immunosuppressive therapy discontinued at less than 3 months due to serious adverse effects or reactions.

Applications for coverage must include information regarding the dosages and duration of trial of each treatment the patient received, a description of any adverse effects, reactions, contraindications and/or lack of effect, as well as any other information requested by Alberta Blue Cross.

Fistulizing Crohn's Disease:

Prior to initiation of infliximab therapy, New Patients must have actively draining perianal or enterocutaneous fistula(s) that have recurred or persisted despite:

a) A course of an appropriate dose of antibiotic therapy (e.g. ciprofloxacin or metronidazole) for a minimum of 3 weeks; AND
b) Immunosuppressive therapy:
- Azathioprine: minimum of 2 mg/kg/day for a minimum of 6 weeks; OR
- 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 6 weeks; OR
- Immunosuppressive therapy discontinued at less than 6 weeks due to serious adverse effects or reactions.

[Note: Patients who have used the above treatments in combination for the treatment of Fistulizing Crohn's will not be required to be challenged with individual treatments as monotherapy]

Applications for coverage must include information regarding the dosages and duration of trial of each treatment the patient received, a description of any adverse effects, reactions, contraindications and/or lack of effect, as well as any other information requested by Alberta Blue Cross.

Coverage Criteria for Moderately to Severely Active Crohn's Disease AND/OR Fistulizing Crohn's

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- New Patients must meet the criteria above prior to being considered for approval.
- All approvals are also subject to the following applicable criteria.

Induction Dosing for New Patients:

- Coverage for Induction Dosing may only be approved for New Patients (those who have never been treated with infliximab by any health care provider).
- 'Induction Dosing' means a maximum of one 5 mg/kg dose of infliximab per New Patient at each 0, 2 and 6 weeks (for a maximum total of three doses).
- New Patients are eligible to receive Induction Dosing only once, after which time the Maintenance Dosing for New Patients and Continued Coverage for Maintenance Dosing criteria will apply.

Maintenance Dosing:

'Maintenance Dosing' means one 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks for a period of 12 months to:
- New Patients following the completion of Induction Dosing; OR
- Existing Patients, who are patients that are being treated, or have previously been treated, with infliximab.

Maintenance Dosing for New Patients after Completion of Induction Dosing:

- The New Patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of Induction Dosing to determine response by obtaining a Modified Harvey Bradshaw Index score for patients with Moderately to Severely Active Crohn's Disease and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND
- The Specialist must confirm the Modified Harvey Bradshaw Index score shows a decrease from the New Patient's Baseline Score of greater than or equal to 3 points for patients with Moderately to Severely Active Crohn's and/or confirm closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

Maintenance Dosing for Existing Patients:

- The patient must be assessed by a Specialist at least 4 to 8 weeks after the day the last dose of infliximab was administered to the patient and prior to administration of the next dose to obtain: a Modified Harvey Bradshaw Index Score (Existing Patient's Baseline Score) for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND

- these measures must be provided to Alberta Blue Cross for assessment for continued coverage for maintenance dosing.

(For existing patients with Moderately to Severely Active Crohn's Disease with an incomplete response or for existing patients with Fistulizing Crohn's who respond then lose their response, the dose may be adjusted to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.)

Continued Coverage for Maintenance Dosing:

Continued coverage may be considered for one 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks for a period of 12 months, if the following criteria are met at the end of each 12 month period:

- The New Patient or the Existing Patient must be assessed by a Specialist at least 4 to 6 weeks after the day the last dose of infliximab was administered to the patient and prior to the administration of the next dose to obtain a Modified Harvey Bradshaw Index Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND
- For New Patients: The Specialist must confirm that the patient has maintained a greater than or equal to 3 point decrease from the New Patient's Baseline Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite

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gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; OR
- For Existing Patients: The Specialist must confirm that the patient has maintained the Existing Patient's Baseline Score and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

(For new and existing patients with Moderately to Severely Active Crohn's Disease with an incomplete response or for new and existing patients with Fistulizing Crohn's who respond then lose their response, the maintenance dose may be adjusted to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.)"

All requests (including renewal requests) for infliximab for Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease must be completed using the Adalimumab/Vedolizumab for Crohn's/Infliximab for Crohn's/Fistulizing Crohn's Disease Special Authorization Request Form (ABC 60031).

Plaque Psoriasis

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:
- Have a total PASI of 10 or more and a DLQI of more than 10, OR
- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
- Cyclosporine (6 weeks treatment); AND
- Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

- Initial coverage may be approved as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet all of the following criteria:
1) The patient must be assessed by a Dermatology Specialist after the initial three doses to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Greater than or equal to 75% reduction in PASI score, or
- Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for one 5 mg/kg dose of infliximab every 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be

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continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for infliximab for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Tildrakizumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

Psoriatic Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for three doses as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for one 5 mg/kg dose every 8 weeks, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

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It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for infliximab for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial) [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for three doses as follows: An initial dose of 3 mg/kg, followed by additional 3 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for one 3 mg/kg dose every 8 weeks for a period of 12 months [Note: For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg and/or treating as often as every 4 weeks]. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- confirmation of maintenance of ACR20, OR
- maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to

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the correct number of decimal places as indicated above."

All requests (including renewal requests) for infliximab for Rheumatoid Arthritis must be completed using the
Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Ulcerative Colitis

"Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:
- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks
AND
- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:
i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

For coverage, this drug must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross ('Specialist').

Initial coverage may be approved for three doses of 5 mg/kg of infliximab at 0, 2 and 6 weeks.

- Patients will be limited to receiving a one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of therapy to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for dose of 5 mg/kg every 8 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist in Gastroenterology to determine response;
2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of infliximab therapy

Note: For patients who showed a response to induction therapy then experienced secondary loss of response while on maintenance dosing with 5 mg/kg, the maintenance dose may be adjusted from 5 mg/kg to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose."

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All requests (including renewal requests) for infliximab for Ulcerative Colitis must be completed using the Adalimumab/Golimumab/Infliximab/Tofacitinib/Vedolizumab for Ulcerative Colitis Special Authorization Request Form (ABC 60008).

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Ankylosing Spondylitis

"Special authorization coverage may be provided for the reduction in the signs and symptoms and improvement in physical function of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for three doses as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
- Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for one 5 mg/kg dose of infliximab every 6 to 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for infliximab for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease

"Special authorization coverage may be approved for coverage of infliximab for the reduction in signs and symptoms and induction and maintenance of clinical remission of Moderately to Severely Active Crohn's Disease and/or treatment of Fistulizing Crohn's Disease in patients who meet the following criteria:

- Infliximab must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross for infliximab for coverage for the treatment of Moderately to Severely Active

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Crohn's Disease and/or Fistulizing Crohn's Disease patients (`Specialist').
- Patients must be 18 years of age or older to be considered for coverage of infliximab.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients may be allowed to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy (both primary loss of response and secondary loss of response) or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

Prior to initiation of infliximab therapy for New Patients:

'New Patients' are patients who have never been treated with infliximab by any health care provider.

Moderately to Severely Active Crohn's Disease:

Prior to initiation of infliximab therapy, New Patients must have a current Modified (without the physical exam) Harvey Bradshaw Index score of greater than or equal to 7 (New Patient's Baseline Score), AND be Refractory.

Refractory is defined as one or more of the following:
1) Serious adverse effects or reactions to the treatments specified below; OR
2) Contraindications (as defined in product monographs) to the treatments specified below; OR
3) Previous documented lack of effect at doses and for duration of all treatments specified below:
a) mesalamine: minimum of 3 grams/day for a minimum of 6 weeks; AND refractory to, or dependent on, glucocorticoids:
following at least one tapering dosing schedule of 40 mg/day, tapering by 5 mg each week to 20 mg, then tapering by 2.5 mg each week to zero, or similar;

[Note: Patients who have used the above treatments in combination will not be required to be challenged with individual treatments as monotherapy]

AND
b) Immunosuppressive therapy as follows:
- Azathioprine: minimum of 2 mg/kg/day for a minimum of 3 months; OR
- 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 3 months; OR
- Methotrexate: minimum or 15 mg/week for a minimum of 3 months.
OR
- Immunosuppressive therapy discontinued at less than 3 months due to serious adverse effects or reactions.

Applications for coverage must include information regarding the dosages and duration of trial of each treatment the patient received, a description of any adverse effects, reactions, contraindications and/or lack of effect, as well as any other information requested by Alberta Blue Cross.

Fistulizing Crohn's Disease:

Prior to initiation of infliximab therapy, New Patients must have actively draining perianal or enterocutaneous fistula(s) that have recurred or persisted despite:

a) A course of an appropriate dose of antibiotic therapy (e.g. ciprofloxacin or metronidazole) for a minimum of 3 weeks; AND
b) Immunosuppressive therapy:
- Azathioprine: minimum of 2 mg/kg/day for a minimum of 6 weeks; OR
- 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 6 weeks; OR
- Immunosuppressive therapy discontinued at less than 6 weeks due to serious adverse effects or reactions.

[Note: Patients who have used the above treatments in combination for the treatment of Fistulizing Crohn's will not be required to be challenged with individual treatments as monotherapy]

Applications for coverage must include information regarding the dosages and duration of trial of each treatment the patient received, a description of any adverse effects, reactions,

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contraindications and/or lack of effect, as well as any other information requested by Alberta Blue Cross.

Coverage Criteria for Moderately to Severely Active Crohn's Disease AND/OR Fistulizing Crohn's Disease

- New Patients must meet the criteria above prior to being considered for approval.
- All approvals are also subject to the following applicable criteria.

Induction Dosing for New Patients:

- Coverage for Induction Dosing may only be approved for New Patients (those who have never been treated with infliximab by any health care provider).
- 'Induction Dosing' means a maximum of one 5 mg/kg dose of infliximab per New Patient at each 0, 2 and 6 weeks (for a maximum total of three doses).
- New Patients are eligible to receive Induction Dosing only once, after which time the Maintenance Dosing for New Patients and Continued Coverage for Maintenance Dosing criteria will apply.

Maintenance Dosing:

'Maintenance Dosing' means one 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks for a period of 12 months to:
- New Patients following the completion of Induction Dosing; OR
- Existing Patients, who are patients that are being treated, or have previously been treated, with infliximab.

Maintenance Dosing for New Patients after Completion of Induction Dosing:

- The New Patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of Induction Dosing to determine response by obtaining a Modified Harvey Bradshaw Index score for patients with Moderately to Severely Active Crohn's Disease and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND
- The Specialist must confirm the Modified Harvey Bradshaw Index score shows a decrease from the New Patient's Baseline Score of greater than or equal to 3 points for patients with Moderately to Severely Active Crohn's and/or confirm closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

Maintenance Dosing for Existing Patients:

- The patient must be assessed by a Specialist at least 4 to 8 weeks after the day the last dose of infliximab was administered to the patient and prior to administration of the next dose to obtain: a Modified Harvey Bradshaw Index Score (Existing Patient's Baseline Score) for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND

- these measures must be provided to Alberta Blue Cross for assessment for continued coverage for maintenance dosing.

(For existing patients with Moderately to Severely Active Crohn's Disease with an incomplete response or for existing patients with Fistulizing Crohn's who respond then lose their response, the dose may be adjusted to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.)

Continued Coverage for Maintenance Dosing:

Continued coverage may be considered for one 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks for a period of 12 months, if the following criteria are met at the end of each 12 month period:

- The New Patient or the Existing Patient must be assessed by a Specialist at least 4 to 6 weeks after the day the last dose of infliximab was administered to the patient and prior to the administration of the next dose to obtain a Modified Harvey Bradshaw Index Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for

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Fistulizing Crohn's; AND
- For New Patients: The Specialist must confirm that the patient has maintained a greater than or equal to 3 point decrease from the New Patient's Baseline Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; OR
- For Existing Patients: The Specialist must confirm that the patient has maintained the Existing Patient's Baseline Score and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

(For new and existing patients with Moderately to Severely Active Crohn's Disease with an incomplete response or for new and existing patients with Fistulizing Crohn's who respond then lose their response, the maintenance dose may be adjusted to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.)"

All requests (including renewal requests) for infliximab for Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease must be completed using the Adalimumab/Vedolizumab for Crohn's/Infliximab for Crohn's/Fistulizing Crohn's Disease Special Authorization Request Form (ABC 60031).

Plaque Psoriasis

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:
- Have a total PASI of 10 or more and a DLQI of more than 10, OR
- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
- Cyclosporine (6 weeks treatment); AND
- Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

- Initial coverage may be approved as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet all of the following criteria:
1) The patient must be assessed by a Dermatology Specialist after the initial three doses to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Greater than or equal to 75% reduction in PASI score, or
- Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.

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Following this assessment, continued coverage may be considered for one 5 mg/kg dose of infliximab every 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for infliximab for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Tildrakizumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

Psoriatic Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for three doses as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for one 5 mg/kg dose every 8 weeks, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal

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place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for infliximab for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial) [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for three doses as follows: An initial dose of 3 mg/kg, followed by additional 3 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for one 3 mg/kg dose every 8 weeks for a period of 12 months [Note: For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg and/or treating as often as every 4 weeks]. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- confirmation of maintenance of ACR20, OR
- maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.

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3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for infliximab for Rheumatoid Arthritis must be completed using the
Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Ulcerative Colitis

"Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:
- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks
AND
- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:
i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

For coverage, this drug must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross ('Specialist').

Initial coverage may be approved for three doses of 5 mg/kg of infliximab at 0, 2 and 6 weeks.

- Patients will be limited to receiving a one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of therapy to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for dose of 5 mg/kg every 8 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist in Gastroenterology to determine response;
2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of infliximab therapy

Note: For patients who showed a response to induction therapy then experienced secondary loss of response while on maintenance dosing with 5 mg/kg, the maintenance dose may be adjusted

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from 5 mg/kg to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose."

All requests (including renewal requests) for infliximab for Ulcerative Colitis must be completed using the Adalimumab/Golimumab/Infliximab/Tofacitinib/Vedolizumab for Ulcerative Colitis Special Authorization Request Form (ABC 60008).

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100 MG / VIAL INJECTION

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Ankylosing Spondylitis

"Special authorization coverage may be provided for the reduction in the signs and symptoms and improvement in physical function of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for three doses as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from another biologic agent to infliximab following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to infliximab if previously trialed and deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
- Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for one 5 mg/kg dose of infliximab every 6 to 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for infliximab for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

Moderately to Severely Active Crohn's and Fistulizing Crohn's Disease

"Special authorization coverage may be approved for coverage of infliximab for the reduction in signs and symptoms and induction and maintenance of clinical remission of Moderately to Severely Active Crohn's Disease and/or treatment of Fistulizing Crohn's Disease in patients who meet the following criteria:

- Infliximab must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross for infliximab for coverage for the treatment of Moderately to Severely Active Crohn's Disease and/or Fistulizing Crohn's Disease patients (`Specialist').
- Patients must be 18 years of age or older to be considered for coverage of infliximab.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from another biologic to infliximab following an adequate trial

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of the first biologic agent if unresponsive to therapy (both primary loss of response and secondary loss of response) or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to infliximab if previously trialed and deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

Prior to initiation of infliximab therapy for New Patients:

'New Patients' are patients who have never been treated with infliximab by any health care provider.

Moderately to Severely Active Crohn's Disease:

Prior to initiation of infliximab therapy, New Patients must have a current Modified (without the physical exam) Harvey Bradshaw Index score of greater than or equal to 7 (New Patient's Baseline Score), AND be Refractory.

Refractory is defined as one or more of the following:
1) Serious adverse effects or reactions to the treatments specified below; OR
2) Contraindications (as defined in product monographs) to the treatments specified below; OR
3) Previous documented lack of effect at doses and for duration of all treatments specified below:
a) mesalamine: minimum of 3 grams/day for a minimum of 6 weeks; AND refractory to, or dependent on, glucocorticoids:
following at least one tapering dosing schedule of 40 mg/day, tapering by 5 mg each week to 20 mg, then tapering by 2.5 mg each week to zero, or similar;

[Note: Patients who have used the above treatments in combination will not be required to be challenged with individual treatments as monotherapy]

AND
b) Immunosuppressive therapy as follows:
- Azathioprine: minimum of 2 mg/kg/day for a minimum of 3 months; OR
- 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 3 months; OR
- Methotrexate: minimum or 15 mg/week for a minimum of 3 months.
OR
- Immunosuppressive therapy discontinued at less than 3 months due to serious adverse effects or reactions.

Applications for coverage must include information regarding the dosages and duration of trial of each treatment the patient received, a description of any adverse effects, reactions, contraindications and/or lack of effect, as well as any other information requested by Alberta Blue Cross.

Fistulizing Crohn's Disease:

Prior to initiation of infliximab therapy, New Patients must have actively draining perianal or enterocutaneous fistula(s) that have recurred or persisted despite:

a) A course of an appropriate dose of antibiotic therapy (e.g. ciprofloxacin or metronidazole) for a minimum of 3 weeks; AND
b) Immunosuppressive therapy:
- Azathioprine: minimum of 2 mg/kg/day for a minimum of 6 weeks; OR
- 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 6 weeks; OR
- Immunosuppressive therapy discontinued at less than 6 weeks due to serious adverse effects or reactions.

[Note: Patients who have used the above treatments in combination for the treatment of Fistulizing Crohn's will not be required to be challenged with individual treatments as monotherapy]

Applications for coverage must include information regarding the dosages and duration of trial of each treatment the patient received, a description of any adverse effects, reactions, contraindications and/or lack of effect, as well as any other information requested by Alberta Blue Cross.

Coverage Criteria for Moderately to Severely Active Crohn's Disease AND/OR Fistulizing Crohn's

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Disease

- New Patients must meet the criteria above prior to being considered for approval.
- All approvals are also subject to the following applicable criteria.

Induction Dosing for New Patients:

- Coverage for Induction Dosing may only be approved for New Patients (those who have never been treated with infliximab by any health care provider).
- 'Induction Dosing' means a maximum of one 5 mg/kg dose of infliximab per New Patient at each 0, 2 and 6 weeks (for a maximum total of three doses).
- New Patients are eligible to receive Induction Dosing only once, after which time the Maintenance Dosing for New Patients and Continued Coverage for Maintenance Dosing criteria will apply.

Maintenance Dosing:

'Maintenance Dosing' means one 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks for a period of 12 months to:
- New Patients following the completion of Induction Dosing; OR
- Existing Patients, who are patients that are being treated, or have previously been treated, with infliximab.

Maintenance Dosing for New Patients after Completion of Induction Dosing:

- The New Patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of Induction Dosing to determine response by obtaining a Modified Harvey Bradshaw Index score for patients with Moderately to Severely Active Crohn's Disease and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND
- The Specialist must confirm the Modified Harvey Bradshaw Index score shows a decrease from the New Patient's Baseline Score of greater than or equal to 3 points for patients with Moderately to Severely Active Crohn's and/or confirm closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

Maintenance Dosing for Existing Patients:

- The patient must be assessed by a Specialist at least 4 to 8 weeks after the day the last dose of infliximab was administered to the patient and prior to administration of the next dose to obtain: a Modified Harvey Bradshaw Index Score (Existing Patient's Baseline Score) for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND

- these measures must be provided to Alberta Blue Cross for assessment for continued coverage for maintenance dosing.

(For existing patients with Moderately to Severely Active Crohn's Disease with an incomplete response or for existing patients with Fistulizing Crohn's who respond then lose their response, the dose may be adjusted to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.)

Continued Coverage for Maintenance Dosing:

Continued coverage may be considered for one 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks for a period of 12 months, if the following criteria are met at the end of each 12 month period:

- The New Patient or the Existing Patient must be assessed by a Specialist at least 4 to 6 weeks after the day the last dose of infliximab was administered to the patient and prior to the administration of the next dose to obtain a Modified Harvey Bradshaw Index Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND
- For New Patients: The Specialist must confirm that the patient has maintained a greater than or equal to 3 point decrease from the New Patient's Baseline Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite

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gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; OR
- For Existing Patients: The Specialist must confirm that the patient has maintained the Existing Patient's Baseline Score and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

(For new and existing patients with Moderately to Severely Active Crohn's Disease with an incomplete response or for new and existing patients with Fistulizing Crohn's who respond then lose their response, the maintenance dose may be adjusted to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.)"

All requests (including renewal requests) for infliximab for Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease must be completed using the Adalimumab/Vedolizumab for Crohn's/Infliximab for Crohn's/Fistulizing Crohn's Disease Special Authorization Request Form (ABC 60031).

Plaque Psoriasis

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:
- Have a total PASI of 10 or more and a DLQI of more than 10, OR
- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
- Cyclosporine (6 weeks treatment); AND
- Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

- Initial coverage may be approved as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from another biologic agent to infliximab following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to infliximab if previously trialed and deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet all of the following criteria:
1) The patient must be assessed by a Dermatology Specialist after the initial three doses to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Greater than or equal to 75% reduction in PASI score, or
- Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for one 5 mg/kg dose of infliximab every 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be

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continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for infliximab for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Tildrakizumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

Psoriatic Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for three doses as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from another biologic agent to infliximab following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to infliximab if previously trialed and deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.
Following this assessment, continued coverage may be approved for one 5 mg/kg dose every 8 weeks, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to

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the correct number of decimal places as indicated above."

All requests (including renewal requests) for infliximab for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial) [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology (''RA Specialist'').

- Initial coverage may be approved for three doses as follows: An initial dose of 3 mg/kg, followed by additional 3 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from another biologic agent (with the exception of anakinra) to infliximab following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to infliximab if previously trialed and deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial three doses, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Continued coverage may be approved for one 3 mg/kg dose every 8 weeks for a period of 12 months [Note: For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg and/or treating as often as every 4 weeks]. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- confirmation of maintenance of ACR20, OR
- maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

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All requests (including renewal requests) for infliximab for Rheumatoid Arthritis must be completed using the
Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Ulcerative Colitis

"Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:
- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks
AND
- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:
i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

For coverage, this drug must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross ('Specialist').

Initial coverage may be approved for three doses of 5 mg/kg of infliximab at 0, 2 and 6 weeks.

- Patients will be limited to receiving a one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from another biologic agent to infliximab following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to infliximab if previously trialed and deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of therapy to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for dose of 5 mg/kg every 8 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist in Gastroenterology to determine response;
2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of infliximab therapy

Note: For patients who showed a response to induction therapy then experienced secondary loss of response while on maintenance dosing with 5 mg/kg, the maintenance dose may be adjusted from 5 mg/kg to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose."

All requests (including renewal requests) for infliximab for Ulcerative Colitis must be completed using the Adalimumab/Golimumab/Infliximab/Tofacitinib/Vedolizumab for Ulcerative Colitis Special

INFLIXIMAB

Authorization Request Form (ABC 60008).

INOTERSEN SODIUM

"For the treatment of polyneuropathy in adult patients with a confirmed genetic diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in patients who meet the following criteria:

- Are symptomatic with early-stage neuropathy, defined as polyneuropathy disability [PND] stage I to less than or equal to IIIB or familial amyloidotic polyneuropathy [FAP] stage I or II
And
- do not exhibit severe heart failure symptoms (defined as New York Heart Association [NYHA] class III or IV)
And
-have not previously undergone a liver transplant.

For coverage, this drug must be prescribed by a specialist with experience in the diagnosis and management of hATTR.

Initial coverage may be approved for 284 mg adminstered subcutaneously once weekly for a period of nine months.

Patients will be limited to receiving a four-week supply of inotersen per prescription at their pharmacy.

For renewal of coverage, patients must show continued benefit from treatment with inotersen and must NOT be:
- permanently bedridden and dependent on assistance for basic activities of daily living, NOR
- receiving end-of-life care.

Continued coverage may be approved for 284 mg weekly for a period of six months.

Coverage cannot be provided for use in combination with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat hATTR."

All requests (including renewal requests) for inotersen must be completed using the Inotersen/Patisiran for HATTR-PN Special Authorization Request Form (ABC 60084).

284 MG / SYR (BASE)	INJECTION	SYRINGE		
00002481383	TEGSEDI		AKC	$ 8043.4874

INSULIN HUMAN BIOSYNTHETIC (REGULAR)

"Special authorization coverage may be provided for improvement of glycemic control in patients with diabetes mellitus with the following criteria:

Patients require more than 200 units of insulin per day, with or without other therapies.

For coverage, this drug product must be initiated by a specialist in Endocrinology (or by an internal medicine specialist with an interest in Endocrinology on a case-by-case basis, in geographic areas where access to this specialty is not available).

Special authorization may be granted for 6 months."

This product is eligible for auto-renewal.

500 UNIT / ML	**INJECTION**			
00002466864	ENTUZITY KWIKPEN	LIL	$	16.3350

INTERFERON BETA-1A

Relapsing Remitting Multiple Sclerosis (RRMS):

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.

To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

1) The registered MS Neurologist must confirm a diagnosis of RRMS;

2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of interferon beta-1a per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

1) The patient must be assessed by a registered MS Neurologist;

2) The registered MS Neurologist must confirm a diagnosis of RRMS;

3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more.
Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of interferon beta-1a per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the patient must meet the following criteria:

INTERFERON BETA-1A

1) At least one relapse* per 12 month period; or
2) At least two relapses* during the previous 24 month period."

All requests (including renewal requests) for interferon beta-1a must be completed using the Dimethyl Fumarate/Glatiramer Acetate/Interferon Beta-1a/Ocrelizumab/Peginterferon Beta-1a/Teriflunomide for RRMS/Interferon Beta-1b for SPMS or RRMS Special Authorization Request Form (ABC 60001).

44 MCG / ML INJECTION CARTRIDGE				
00002318253	REBIF (1.5 ML CARTRIDGE)	SRO	$	280.3900
88 MCG / ML INJECTION CARTRIDGE				
00002318261	REBIF (1.5 ML CARTRIDGE)	SRO	$	341.3400
6 MIU / SYR INJECTION SYRINGE				
00002269201	AVONEX PS/PEN (30 MCG/0.5 ML)	BIO	$	440.7949
22 MCG / SYR INJECTION SYRINGE				
00002237319	REBIF (0.5 ML SYRINGE)	SRO	$	140.1900
44 MCG / SYR INJECTION SYRINGE				
00002237320	REBIF (0.5 ML SYRINGE)	SRO	$	170.6700

INTERFERON BETA-1B

Relapsing Remitting Multiple Sclerosis (RRMS):

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.
To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

1) The registered MS Neurologist must confirm a diagnosis of RRMS;

2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of interferon beta-1b per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

1) The patient must be assessed by a registered MS Neurologist;

2) The registered MS Neurologist must confirm a diagnosis of RRMS;

3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more.

Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of interferon beta-1b per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the patient must meet the following criteria:

INTERFERON BETA-1B

1) At least one relapse* per 12 month period; or
2) At least two relapses* during the previous 24 month period."

All requests (including renewal requests) for interferon beta-1b must be completed using the Dimethyl Fumarate/Glatiramer Acetate/ Interferon Beta-1a/ Interferon Beta-1b/ Teriflunomide Special Authorization Request Form (ABC 60001).

Secondary Progressive Multiple Sclerosis with Relapses (SPMS with relapses):

"Special authorization coverage may be provided for the slowing of progression in disability and the reduction of the frequency of clinical relapses in patients with secondary progressive multiple sclerosis with relapses.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.

To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

1) The registered MS Neurologist must confirm a diagnosis of SPMS with relapses;

2) The patient must have active disease which is defined as two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms (documented by a physician), lasting at least 72 hours in the absence of fever, not associated with withdrawal from steroids, and preceded by stability for at least one month. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

3) The patient must be ambulatory to 100m without an aid (The registered MS Neurologist must provide an updated Expanded Disability Status Scale (EDSS) score of less than or equal to 5.5).

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of interferon beta-1b per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

1) The patient must be assessed by a registered MS Neurologist;

2) The registered MS Neurologist must confirm a diagnosis of SPMS with relapses;

3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more.

Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.

INTERFERON BETA-1B

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of interferon beta-1b per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the patient must meet the following criteria:

1) At least one relapse* per 12 month period; or
2) At least two relapses* during the previous 24 month period."

All requests (including renewal requests) for interferon beta-1b must be completed using the Dimethyl Fumarate/Glatiramer Acetate/Interferon Beta-1a/Ocrelizumab/Peginterferon Beta-1a/Teriflunomide for RRMS/Interferon Beta-1b for SPMS or RRMS Special Authorization Request Form (ABC 60001).

9.6 MIU / VIAL INJECTION				
00002169649	BETASERON (0.3 MG)	BAI	$	99.3593

IPRATROPIUM BROMIDE

"For use in patients with manual dexterity problems or visual limitations who are unable to prepare a dose of the drug using the multi-dose solution."

"For use in patients who are hypersensitive to preservatives contained in multi-dose solutions."

"Special authorization for both criteria may be granted for 24 months."

Information is required regarding the nature of the difficulties experienced by the patient in preparing a dose using the multi-dose preparation; or the nature of the patient's hypersensitivity to the preservatives contained in the multi-dose solution.

The following product(s) are eligible for auto-renewal.

125 MCG / ML INHALATION UNIT DOSE SOLUTION				
00002231135	PMS-IPRATROPIUM	PMS	$	1.1505
250 MCG / ML INHALATION UNIT DOSE SOLUTION				
00002231244	**PMS-IPRATROPIUM (1ML)**	**PMS**	$	**0.6590**
00002231245	**PMS-IPRATROPIUM (2ML)**	**PMS**	$	**0.6590**
00002216221	**TEVA-IPRATROPIUM STERINEBS**	**TEV**	$	**0.6590**

ISAVUCONAZONIUM SULFATE

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For the treatment of invasive aspergillosis in adult patients who are refractory to or intolerant of voriconazole and caspofungin."*

"For the treatment of invasive mucormycosis."*

"This medication must be prescribed in consultation with a specialist in Infectious Diseases."

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

100 MG ORAL CAPSULE				
00002483971	CRESEMBA	AVP	$	78.8300
200 MG / VIAL INJECTION				
00002483998	CRESEMBA	AVP	$	400.0000

ITRACONAZOLE

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For the treatment of oral and/or esophageal candidiasis in immunocompromised patients who are intolerant to fluconazole, or who have failed fluconazole as evidenced by significant clinical deterioration due to the fungal infection during a course of therapy or no resolution after a full course of therapy."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

10 MG / ML ORAL SOLUTION				
00002484315	**JAMP ITRACONAZOLE**	**JPC**	$	**0.4111**
00002495988	**ODAN ITRACONAZOLE**	**ODN**	$	**0.4111**
00002231347	SPORANOX	JAI	$	0.9512

IVABRADINE HYDROCHLORIDE

"For the treatment of heart failure (HF) in patients with the following criteria:

1) Reduced left ventricular ejection fraction (LVEF) (less than or equal to 35%)
And
2) New York Heart Association (NYHA) class II or III HF symptoms despite at least FOUR weeks of optimal treatment with:
- a stable dose of an angiotensin converting enzyme inhibitor (ACEI) or an angiotensin II receptor antagonist (ARB)
- in combination with a beta-blocker and, if tolerated, a mineralocorticoid receptor antagonist (MRA)
And
3) Who are in sinus rhythm with a resting heart rate greater than or equal to 77 beats per minute (bpm) on average using either an ECG on at least three separate visits or by continuous monitoring
And
4) Who had at least one hospitalization due to HF in the last year

For coverage, this drug must be initiated by a Specialist in Cardiology or Internal Medicine, and the initial request must be completed by the Specialist.

Special authorization may be granted for six months."

This product is eligible for auto-renewal.

All requests (including renewal requests) for ivabradine hydrochloride must be completed using the Eplerenone/Ivabradine/Sacubitril+Valsartan Special Authorization Request Form (ABC 60050).

5 MG (BASE) ORAL TABLET				
00002459973	LANCORA	SEV	$	0.8930
7.5 MG (BASE) ORAL TABLET				
00002459981	LANCORA	SEV	$	1.6339

IVACAFTOR

"For the treatment of cystic fibrosis (CF) in patients age six (6) years and older who have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R; and

For the treatment of cystic fibrosis (CF) in patients aged 18 and older with an R117H mutation in the CFTR gene.

For coverage, this drug must be prescribed by a prescriber affiliated with one of the following Alberta Cystic Fibrosis Clinics:
- Cystic Fibrosis Clinic, Adult: Kaye Edmonton Clinic
- Cystic Fibrosis Services - Adult Outpatient: Foothills Medical Centre
- Cystic Fibrosis Clinic, Pediatric: Stollery Children's Hospital
- Pediatric Cystic Fibrosis Clinic: Alberta Children's Hospital

Initial coverage may be approved for up to 150 mg every 12 hours for 6 months. Patients will be limited to receiving a one-month supply per prescription at their pharmacy.

Coverage cannot be provided when intended for use in combination with other CFTR modulators.

Renewal Criteria

The sweat chloride test will be repeated at the next routine review appointment after starting ivacaftor to determine whether sweat chloride levels are reducing and to check compliance with the drug regimen. The sweat chloride level will then be re-checked 6 months after starting treatment to determine whether the full reduction (as detailed below) has been achieved. Thereafter sweat chloride levels will be checked annually.

For continued coverage of up to 150mg every 12 hours beyond the initial 6-month authorization, the patient will be considered to have responded to treatment if either:

a) The patient's sweat chloride test falls below 60mmoL/L; OR
b) The patient's sweat chloride test falls by at least 30%

In cases where the baseline sweat chloride test is already below 60mmoL/L, the patient will be considered to have responded to treatment if either:

c) The patient's sweat chloride test falls by at least 30%; OR
d) The patient demonstrates a sustained absolute improvement in FEV1 of at least 5%. In this instance FEV1 will be compared with the baseline pre-treatment level one month and three months after starting treatment.

Following this assessment, continued coverage of up to 150 mg every 12 hours may be approved for a period of 12 months. Patients will be limited to receiving a one-month supply per prescription at their pharmacy.

If the expected reduction in sweat chloride does not occur, the patient's CF clinician will first explore any challenges in following the recommended dosing schedule for ivacaftor. The patient's sweat chloride will then be retested around one week later and funding discontinued if the patient does not meet the above criteria."

All requests (including renewal requests) for ivacaftor must be completed using the Ivacaftor Special Authorization Request Form (ABC 60004).

150 MG ORAL TABLET

00002397412	KALYDECO	VER	$	420.0000

IVACAFTOR/ LUMACAFTOR

"For the treatment of cystic fibrosis (CF) in patients age two (2) years and older who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene who have demonstrated adherence to their prescribed cystic fibrosis therapeutic regimen and who have ONE or more of the following:

Experienced one (1) or more pulmonary exacerbation(s) per year requiring IV antibiotics; OR
Experienced three (3) or more pulmonary exacerbations per year requiring therapy with oral antibiotics; OR
For patients 6 -11 years of age: the patient has a decline of absolute FEV1 % predicted of greater than or equal to 5 percentage points within a 12 month period, sustained over at least 4 months, in spite of optimized medical therapies; OR
For patient 12 years of age and older: the patient has a baseline FEV1 of less than 70% predicted, who has an absolute decline in FEV1 of greater than or equal to 5%, within a 12 month period, sustained over at least 4 months, in spite of optimized medical therapies; OR
For patient 12 years of age and older: the patient has a baseline FEV1 of greater than or equal to 70% predicted who have an absolute decline in FEV1 of greater than or equal to 10% predicted within a 12 month period, sustained over at least 4 months, in spite of optimized medical therapies.

For initial coverage, the following pre-treatment information must be provided:
1) Number of days treated with oral and IV antibiotics for pulmonary exacerbations in the previous 6 months; AND/OR number of pulmonary exacerbations requiring oral and IV antibiotics in the previous 6 months; AND
2) Number of CF related hospitalizations in the previous 6 months; AND
3) Baseline Body Mass Index (BMI); AND
For patients aged 6 years and older:
4) Baseline measurement of FEV1 % predicted (within the last 30 days), AND
5) Change in FEV1 demonstrating decline in FEV1 % predicted prior to starting therapy (as defined above);

This drug must be prescribed by a prescriber affiliated with one of the following Alberta Cystic Fibrosis Clinics:
- Cystic Fibrosis Clinic, Adult: Kaye Edmonton Clinic
- Cystic Fibrosis Services - Adult Outpatient: Foothills Medical Centre
- Cystic Fibrosis Clinic, Pediatric: Stollery Children's Hospital
- Pediatric Cystic Fibrosis Clinic: Alberta Children's Hospital

For coverage, dosing will be approved as follows:
Patients 2-5 years of age: up to one packet of granules (containing lumacaftor 150 mg and ivacaftor 188 mg) every 12 hours.
Patients 6-11 years of age: 2 tablets (each containing lumacaftor 100 mg and ivacaftor 125 mg) every 12 hours.
Patients 12 years of age and older: 2 tablets (each containing lumacaftor 200 mg and ivacaftor 125 mg) every 12 hours.
Patients will be limited to receiving a one-month supply per prescription at their pharmacy.

Initial coverage may be approved for 6 months.
Subsequent renewal of coverage may be approved for 12 months.

For continued coverage, the patient must meet the following criteria:
1) Patient continues to adhere to their prescribed cystic fibrosis therapeutic regimen; AND
2) Patient has demonstrated at least ONE of the following:
-Reduction in the total number of days for which the patient received treatment with oral and/or IV antibiotics for pulmonary exacerbations compared with the 6 month period prior to initiating treatment; OR
-Reduction in the total number of pulmonary exacerbations requiring oral and IV antibiotics compared with the 6 month period prior to initiating treatment; OR
-Reduction in the number of CF related hospitalizations compared with the 6 month period prior to initiating treatment; OR
-Maintenance or increase in BMI compared with the baseline BMI assessment; OR

IVACAFTOR/ LUMACAFTOR

-For patients aged 6 years and older: No decline in FEV1 % predicted compared with the baseline FEV1 assessment.

Coverage cannot be provided for lumacaftor/ivacaftor for the following:
1) When intended for use in combination with other CFTR modulators; OR
2) Patient is currently receiving invasive mechanical ventilation via endotracheal tube or tracheostomy tube; OR
3) Patient is the previous recipient of a double lung transplant."

All requests (including renewal requests) for lumacaftor/ivacaftor must be completed using the Combination CFTR Modulators Special Authorization Request From (ABC 60090).

125 MG * 100 MG ORAL TABLET				
00002463040	ORKAMBI	VER	$	170.5357
125 MG * 200 MG ORAL TABLET				
00002451379	ORKAMBI	VER	$	170.5357
125 MG * 100 MG ORAL GRANULE				
00002483831	ORKAMBI	VER	$	341.0700
188 MG * 150 MG ORAL GRANULE				
00002483858	ORKAMBI	VER	$	341.0700

IXEKIZUMAB

Plaque Psoriasis

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:

- Have a total PASI of 10 or more and a DLQI of more than 10, OR
- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory to or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
- Cyclosporine (6 weeks treatment); AND
- Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").
- Initial coverage may be approved for one 160 mg dose (two 80 mg injections) at weeks 0, followed by 80 mg (one injection) at Weeks 2, 4, 6, 8, 10, and 12.
- Patients will be limited to receiving a one-month supply of ixekizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage, the patient must meet all of the following criteria:

1) The patient must be assessed by a Dermatology Specialist after the initial 12 weeks of therapy to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Greater than or equal to 75% reduction in PASI score, OR
- Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for 80 mg every 4 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for ixekizumab for Plaque Psoriasis must be completed

IXEKIZUMAB

using the
Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Tildrakizumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

Psoriatic Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

Initial coverage may be approved for one 160 mg dose (two 80 mg injections) at week 0, followed by 80 mg (one injection) at weeks 4, 8, 12, 16, 20 & 24.

- Patients will be limited to receiving a one-month supply of ixekizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 24 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial 24 weeks to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be considered for 80 mg every 4 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;

IXEKIZUMAB

2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.

3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for ixekizumab for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

80 MG / SYR INJECTION SYRINGE			
☒ 00002455110	TALTZ	LIL	$ 1702.8700
☒ 00002455102	TALTZ AUTOINJECTOR	LIL	$ 1702.8700

LACOSAMIDE

"For adjunctive therapy in patients with refractory partial-onset seizures who meet all of the following criteria:
- Are currently receiving two or more antiepileptic medications, AND
- Have failed or demonstrated intolerance to three other antiepileptic medications, AND
- Therapy must be initiated by a Neurologist.

For the purpose of administering these criteria failure is defined as inability to achieve satisfactory seizure control.

Special authorization may be granted for six months.

Coverage cannot be provided for brivaracetam, eslicarbazepine, lacosamide or perampanel when these medications are intended for use in combination."

Each of these products is eligible for auto-renewal.

50 MG ORAL TABLET

00002489287	**ACH-LACOSAMIDE**	**AHI**	$	**0.6313**
00002475332	**AURO-LACOSAMIDE**	**AUR**	$	**0.6313**
00002488388	**JAMP-LACOSAMIDE**	**JPC**	$	**0.6313**
00002512874	**LACOSAMIDE**	**SNS**	$	**0.6313**
00002487802	**MAR-LACOSAMIDE**	**MAR**	$	**0.6313**
00002490544	**MINT-LACOSAMIDE**	**MPI**	$	**0.6313**
00002499568	**NRA-LACOSAMIDE**	**NRA**	$	**0.6313**
00002478196	**PHARMA-LACOSAMIDE**	**PMS**	$	**0.6313**
00002474670	**SANDOZ LACOSAMIDE**	**SDZ**	$	**0.6313**
00002472902	**TEVA-LACOSAMIDE**	**TEV**	$	**0.6313**
00002357615	VIMPAT	UCB	$	2.4093

100 MG ORAL TABLET

00002489295	**ACH-LACOSAMIDE**	**AHI**	$	**0.8750**
00002475340	**AURO-LACOSAMIDE**	**AUR**	$	**0.8750**
00002488396	**JAMP-LACOSAMIDE**	**JPC**	$	**0.8750**
00002512882	**LACOSAMIDE**	**SNS**	$	**0.8750**
00002487810	**MAR-LACOSAMIDE**	**MAR**	$	**0.8750**
00002490552	**MINT-LACOSAMIDE**	**MPI**	$	**0.8750**
00002499576	**NRA-LACOSAMIDE**	**NRA**	$	**0.8750**
00002478218	**PHARMA-LACOSAMIDE**	**PMS**	$	**0.8750**
00002474689	**SANDOZ LACOSAMIDE**	**SDZ**	$	**0.8750**
00002472910	**TEVA-LACOSAMIDE**	**TEV**	$	**0.8750**
00002357623	VIMPAT	UCB	$	3.4477

150 MG ORAL TABLET

00002489309	**ACH-LACOSAMIDE**	**AHI**	$	**1.1763**
00002475359	**AURO-LACOSAMIDE**	**AUR**	$	**1.1763**
00002488418	**JAMP-LACOSAMIDE**	**JPC**	$	**1.1763**
00002512890	**LACOSAMIDE**	**SNS**	$	**1.1763**
00002487829	**MAR-LACOSAMIDE**	**MAR**	$	**1.1763**
00002490560	**MINT-LACOSAMIDE**	**MPI**	$	**1.1763**
00002499584	**NRA-LACOSAMIDE**	**NRA**	$	**1.1763**
00002478226	**PHARMA-LACOSAMIDE**	**PMS**	$	**1.1763**
00002474697	**SANDOZ LACOSAMIDE**	**SDZ**	$	**1.1763**
00002472929	**TEVA-LACOSAMIDE**	**TEV**	$	**1.1763**
00002357631	VIMPAT	UCB	$	4.4862

LACOSAMIDE

200 MG ORAL TABLET

00002489317	**ACH-LACOSAMIDE**	**AHI**	$	**1.4500**
00002475367	**AURO-LACOSAMIDE**	**AUR**	$	**1.4500**
00002488426	**JAMP-LACOSAMIDE**	**JPC**	$	**1.4500**
00002512904	**LACOSAMIDE**	**SNS**	$	**1.4500**
00002487837	**MAR-LACOSAMIDE**	**MAR**	$	**1.4500**
00002490579	**MINT-LACOSAMIDE**	**MPI**	$	**1.4500**
00002499592	**NRA-LACOSAMIDE**	**NRA**	$	**1.4500**
00002478234	**PHARMA-LACOSAMIDE**	**PMS**	$	**1.4500**
00002474700	**SANDOZ LACOSAMIDE**	**SDZ**	$	**1.4500**
00002472937	**TEVA-LACOSAMIDE**	**TEV**	$	**1.4500**
00002357658	VIMPAT	UCB	$	5.5247

LANADELUMAB

"For the routine prevention of attacks of confirmed Type 1 or Type 2 hereditary angioedema (HAE) in patients 12 years of age or older who have had at least three HAE attacks that required the use of an acute injectable treatment within any four-week period in the three months before initiating lanadelumab therapy.

This medication must be prescribed by, or in consultation with, a physician experienced in the treatment of HAE. A record of the baseline total of HAE attacks requiring use of an acute injectable treatment in the three months prior to initiating lanadelumab is required.

Initial coverage may be approved for 3 months. The patient must be assessed after the initial three months to determine response. Patients who have a response to initial treatment* may receive continued coverage with lanadelumab for six months, and should be assessed for continued response** every six months.

*Response to initial lanadelumab treatment is defined as:
- at least a 50% reduction in the number of HAE attacks requiring use of an acute injectable treatment compared to the three month baseline number of attacks prior to initiation of lanadelumab.

**Continued response is defined as:
- maintenance of a minimum improvement of a 50% reduction in the number of HAE attacks requiring use of an acute injectable treatment compared to the baseline number of attacks observed before initiating treatment with lanadelumab.

Coverage cannot be provided for lanadelumab when used in combination with other medications used for long-term prophylactic treatment of angioedema (e.g., C1-INH).

Coverage may be approved for a dosage of up to 300 mg every two weeks. Patients will be limited to receiving a one-month supply per prescription at their pharmacy."

All requests for lanadelumab must be completed using the Icatibant/Lanadelumab for HAE Type I or II Special Authorization Request Form (ABC 60083).

150 MG / ML INJECTION

☒ 00002480948	TAKHZYRO	TAK	$	10269.0000
☒ 00002505614	TAKHZYRO (SYRINGE)	TAK	$	10269.0000

LANREOTIDE ACETATE

"For the treatment of acromegaly when prescribed by or in consultation with a Specialist in Internal Medicine.

For control of symptoms in patients with metastatic carcinoid tumors when prescribed by or in consultation with a Specialist in Internal Medicine, Palliative Care or General Surgery.

Special authorization may be granted for 12 months."

The following product(s) are eligible for auto-renewal.

60 MG / SYR INJECTION SYRINGE				
00002283395	SOMATULINE AUTOGEL (0.2 ML SYRINGE)	ISP	$	1233.1722
90 MG / SYR INJECTION SYRINGE				
00002283409	SOMATULINE AUTOGEL (0.3 ML SYRINGE)	ISP	$	1644.9748
120 MG / SYR INJECTION SYRINGE				
00002283417	SOMATULINE AUTOGEL (0.5 ML SYRINGE)	ISP	$	2059.0129

LETERMOVIR

"For the prophylaxis therapy of cytomegalovirus (CMV) infection in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT), in patients with undetectable CMV viremia at baseline, and who meet the following criteria:

- is a recipient of umbilical cord blood as stem cell source, or
- a haploidentical recipient, or
- a recipient of T-cell depleted grafts, or
- a recipient treated with antithymocyte globulin (ATG) for conditioning, or
- a recipient requiring high-dose steroids (defined as the use of greater than or equal to 1 mg/kg/day of prednisone or equivalent dose of another corticosteroid) or other immunosuppression for acute graft versus host disease (GVHD), or
- a recipient treated with ATG for steroid-refractory acute GVHD treatment, or
- a recipient with documented history of CMV disease prior to transplantation.

For coverage, this drug must be prescribed by the Director of the Alberta Blood & Marrow Transplant Program, or their designates.

Coverage may be approved at a dosage of up to 480 mg per day administered orally or intravenously.
Duration of therapy will be limited to 100 days, per patient, per HSCT procedure.
Patients will be limited to 14 days supply of letermovir per prescription at their pharmacy."

240 MG ORAL TABLET				
00002469375	PREVYMIS	MFC	$	238.7160
480 MG ORAL TABLET				
00002469383	PREVYMIS	MFC	$	238.7160
20 MG / ML INJECTION				
☒ 00002469405	PREVYMIS (24 ML)	MFC	$	19.5454
☒ 00002469367	PREVYMIS (12 ML)	MFC	$	19.8933

LEUPROLIDE ACETATE

"When prescribed for non-cancer, non-cosmetic or non-fertility indications.

Special authorization may be granted for 6 months."

Information is required regarding the patient's diagnosis/indication for use of this medication.

The following product(s) are eligible for auto-renewal.

3.75 MG / VIAL INJECTION				
00000884502	LUPRON DEPOT	ABV	$	375.6897
7.5 MG / VIAL INJECTION				
00000836273	LUPRON DEPOT	ABV	$	387.9700
11.25 MG / VIAL INJECTION				
00002239834	LUPRON DEPOT	ABV	$	1119.3367
22.5 MG / VIAL INJECTION				
00002230248	LUPRON DEPOT	ABV	$	1071.0000

LEVOCARNITINE

"For the treatment of primary carnitine deficiency. Information is required regarding the total plasma carnitine levels."

"For the treatment of patients with an inborn error of metabolism that results in secondary carnitine deficiency. Information is required regarding the patient's diagnosis."

"Special authorization may be granted for 6 months."

In order to comply with the first criteria: Information is required regarding pre-treatment total plasma carnitine levels.

The following product(s) are eligible for auto-renewal.

330 MG ORAL TABLET				
00002144328	CARNITOR	SGM	$	3.5244
100 MG / ML ORAL SOLUTION				
00002144336	**CARNITOR**	**SGM**	$	**0.3809**
00002492105	**ODAN LEVOCARNITINE**	**ODN**	$	**0.3809**
200 MG / ML INJECTION				
00002144344	CARNITOR	SGM	$	16.3748

LEVODOPA/ CARBIDOPA

Special authorization coverage may be provided for the treatment of patients with advanced levodopa-responsive Parkinson's disease, who meet the following criteria:

1) The patient experiences severe disability associated with at least 25% of the waking day in the off state and/or ongoing, bothersome levodopa-induced dyskinesias, despite having tried frequent dosing of levodopa (at least five doses per day). Time in the off state, frequency of motor fluctuations, and severity of associated disability should be assessed by a movement disorder subspecialist and be based on an adequate and reliable account from longitudinal specialist care, clinical interview of a patient and/or care partner, or motor symptom diary.
2) The patient has received an adequate trial of maximally tolerated doses of levodopa, with demonstrated clinical response.
3) The patient has failed or is intolerant to adequate trials of each of the following adjunctive medications, if not contraindicated: a catechol-O-methyl transferase (COMT) inhibitor, a dopamine agonist, a monoamine oxidase (MAO-B) inhibitor, and amantadine.
4) The patient is able to administer the medication and care for the administration port and infusion pump. Alternatively, trained personnel or a care partner must be available to perform these tasks reliably.
5) The patient does not have a contraindication to the insertion of a percutaneous endoscopic gastrostomy-jejunostomy (PEG-J) tube.
6) The patient does not have severe psychosis or dementia.
7) Levodopa/carbidopa intestinal gel is initiated by a movement disorder subspecialist who has appropriate training in its use and is practising in a movement disorder clinic that provides ongoing management and support for patients receiving treatment.

Initial coverage may be approved for a period of 12 months.

Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
- The patient demonstrates a significant reduction in the time spent in the off state and/or in ongoing, bothersome levodopa-induced dyskinesias, along with an improvement in the related disability.

All requests for levodopa/carbidopa intestinal gel must be completed using the Levodopa/Carbidopa Intestinal Gel Special Authorization Request Form (ABC 60068).

2,000 MG * 500 MG	**INTRAINTESTINAL**	**GEL**			
00002292165	DUODOPA		ABV	$	169.8100

LEVOFLOXACIN

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): TOBRAMYCIN INHALATION SOLUTION

"For the treatment of chronic pulmonary Pseudomonas aeruginosa infections when used as cyclic treatment (28-day cycles) in patients 18 years of age and older with moderate to severe cystic fibrosis (CF) and deteriorating clinical condition despite treatment with inhaled tobramycin."

"Coverage will not be considered when inhaled levofloxacin and other inhaled antibiotic(s) (e.g. tobramycin, aztreonam) are intended for use in combination, either concurrently or for antibiotic cycling during off-treatment periods."

"Special authorization may be granted for 6 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

100 MG / ML	**INHALATION**	**SOLUTION**			
00002442302	QUINSAIR		RAP	$	26.8703

LINAGLIPTIN

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): METFORMIN
SECOND-LINE DRUG PRODUCT(S): SULFONYLUREAS
AND WHERE INSULIN IS NOT AN OPTION

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:
- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated
CA - Prior adverse reaction
CB - Previous treatment failure
CJ - Product is not effective

All requests for linagliptin must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

5 MG ORAL TABLET

00002370921	TRAJENTA	BOE	$	2.6863

LINAGLIPTIN/ METFORMIN HCL

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): METFORMIN
SECOND-LINE DRUG PRODUCT(S): SULFONYLUREAS
AND WHERE INSULIN IS NOT AN OPTION

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:
- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated
CA - Prior adverse reaction
CB - Previous treatment failure
CJ - Product is not effective

All requests for linagliptin+metformin must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

2.5 MG * 500 MG ORAL TABLET				
00002403250	JENTADUETO	BOE	$	1.4050
2.5 MG * 850 MG ORAL TABLET				
00002403269	JENTADUETO	BOE	$	1.4050
2.5 MG * 1,000 MG ORAL TABLET				
00002403277	JENTADUETO	BOE	$	1.4050

LINEZOLID

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For the treatment of:

1) Vancomycin-resistant enterococcus infections or

2) Methicillin-resistant Staphylococcus aureus (MRSA)/methicillin-resistant coagulase-negative Staphylococcus infections in patients who are unresponsive to or intolerant of vancomycin or

3) Susceptible organisms in patients severely intolerant or allergic to all other appropriate alternatives (e.g. beta-lactam antibiotics, clindamycin, trimethoprim/sulfamethoxazole and vancomycin) or to facilitate patient discharge from hospital where it otherwise would not be possible.

This product must be prescribed in consultation with a specialist in Infectious Diseases in all instances."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

In order to comply with the above criteria, information is required regarding the type of infection and organisms involved. Information is also required regarding previous antibiotic therapy that has been utilized and the patient's response to therapy and the first line agents the organism is resistant to or why other first-line therapies cannot be used in this patient. The specialist in Infectious Diseases that recommended this drug is also required.

600 MG ORAL TABLET

00002426552	**APO-LINEZOLID**	**APX**	$	**19.3041**
00002520354	**JAMP LINEZOLID**	**JPC**	$	**19.3041**
00002422689	**SANDOZ LINEZOLID**	**SDZ**	$	**19.3041**

LIXISENATIDE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): METFORMIN
SECOND-LINE DRUG PRODUCT(S): SULFONYLUREAS
AND INSULIN

"As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:
- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- insulin

Or, for whom these products are contraindicated."

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated
CA - Prior adverse reaction
CB - Previous treatment failure
CJ - Product is not effective

All requests for lixisenatide must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

0.05 MG / ML INJECTION				
00002464276	ADLYXINE	SAV	$	18.9933
0.1 MG / ML INJECTION				
00002464284	ADLYXINE	SAV	$	18.9933

LUSPATERCEPT

BETA-THALASSEMIA ANEMIA

"For the treatment of adult patients with red blood cell (RBC) transfusion-dependent anemia associated with beta-thalassemia who meet the following criteria:

-Patients must be receiving regular transfusions, defined as the following in the previous 24 weeks:
1. Receiving 6 to 20 RBC units, and
2. No transfusion free-period greater than 35 days

Information must be provided regarding the patient's transfusion burden (RBC units/time) in the previous 24 weeks prior to initiating luspatercept.

For coverage, this drug must be prescribed by a Specialist in Hematology.

Initial coverage may be approved for a period of six months at a dosage maximum of 1.25 mg/kg (not exceeding 120 mg total dose) administered once every three weeks.

Patients will be limited to receiving one dose of luspatercept per prescription at their pharmacy.

The patient must be assessed after the initial treatment period to determine response*. Patients who have a response to initial treatment may receive continued coverage with luspatercept and should be assessed for continued response** every six months.

*Response to initial luspatercept treatment is defined as:
-a 33% or greater reduction in RBC transfusion burden compared to the 24 weeks pre-treatment baseline RBC transfusion burden before initiating treatment with luspatercept.

**Continued response is defined as:
-maintenance of a 33% or greater reduction in RBC transfusion burden compared to the 24 weeks pre-treatment baseline RBC transfusion burden before initiating treatment with luspatercept.

Continued coverage may be approved for up to 1.25 mg/kg not exceeding 120 mg total dose administered every three weeks for a period of six months."

All requests (including renewal requests) for luspatercept must be completed using the Luspatercept Special Authorization Request Form (ABC 60106).

MYELODYSPLASTIC SYNDROME ASSOCIATED ANEMIA

"For the treatment of adult patients with red blood cell (RBC) transfusion-dependent anemia associated with very low- to intermediate-risk myelodysplastic syndromes (MDS) who have ring sideroblasts and who have failed or are not suitable for erythropoietin-based therapy.

For coverage, the drug must be prescribed by a Specialist in Hematology or Oncology.

Initial coverage may be approved for a period of six months at a dosage maximum of 1.75 mg/kg administered once every three weeks.

For continued coverage:
-For first renewal assessment: Patients should be RBC transfusion independent over a minimum of 16 consecutive weeks within the first 24 weeks of treatment initiation.
-For subsequent renewals: Patients should be RBC transfusion independent over a minimum of 16 consecutive weeks within the previous authorization period.

Continued coverage may be approved for a period of six months at a dosage maximum of 1.75 mg/kg administered once every three weeks.

Patients will be limited to receiving one dose of luspatercept per prescription at their pharmacy."

LUSPATERCEPT

All requests (including renewal requests) for luspatercept must be completed using the Luspatercept Special Authorization Request Form (ABC 60106).

25 MG / VIAL INJECTION				
00002505541	REBLOZYL	CLG	$	2189.0000
75 MG / VIAL INJECTION				
00002505568	REBLOZYL	CLG	$	6567.0000

MEGESTROL ACETATE

"For the treatment of non-cancer indications (e.g. cachexia in HIV/AIDS patients and cancer patients).

Special authorization may be granted for 6 months."

(Please note: The above megestrol acetate products are benefits not requiring special authorization for individuals approved by Alberta Health for Palliative Coverage. Refer to the Palliative Coverage Drug Benefit Supplement for additional information on this coverage.)

The following product(s) are eligible for auto-renewal.

40 MG ORAL TABLET				
00002195917	MEGESTROL	AAP	$	1.5184
160 MG ORAL TABLET				
00002195925	MEGESTROL	AAP	$	6.6190

MEPOLIZUMAB

"Special authorization coverage may be provided for add-on maintenance treatment of adult patients with severe eosinophilic asthma if the following clinical criteria and conditions are met:

Patient is inadequately controlled with high-dose inhaled corticosteroids (ICS) and one or more additional asthma controller(s) (e.g., a long-acting beta-agonist [LABA]).

AND

Patient has a blood eosinophil count of greater than or equal to 300 cells/mcL AND has experienced two or more clinically significant asthma exacerbations* in the 12 months prior to treatment initiation with mepolizumab;
OR

Patient has a blood eosinophil count of greater than or equal to 150 cells/mcL AND is receiving daily maintenance treatment with oral corticosteroids (OCS).

For coverage, the drug must be initiated and monitored by a respirologist or clinical immunologist or allergist.

Initial coverage may be approved for 12 months of 100 mg administered every 4 weeks.

-Patients will be limited to receiving a one-month supply of mepolizumab per prescription at their pharmacy.
-Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
-Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
-Coverage cannot be provided for mepolizumab when this medication is intended for use in combination with other biologics for the treatment of asthma.

If ALL the following criteria are met, special authorization may be approved for 100 mg administered every 4 weeks for a further 12-month period.

1) An improvement in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 when compared to pre-treatment baseline or an ACQ-5 score of less than or equal to 1; AND
2) Maintenance or reduction in the number of clinically significant exacerbations* compared to the 12 months prior to initiation of treatment with mepolizumab; AND
3) For patients on daily maintenance therapy with OCS prior to initiating mepolizumab, a decrease in the OCS dose.

Continued coverage may be considered for 100 mg administered every 4 weeks if ALL of the following criteria are met at the end of each additional 12-month period:
1) The ACQ-5 score achieved during the first 12 months of therapy is at least maintained throughout treatment or the ACQ-5 score is less than or equal to 1; AND
2) Maintenance or reduction in the number of clinically significant exacerbations* compared to the previous 12-month period; AND

3) For patients on daily maintenance therapy with OCS prior to initiating mepolizumab, the reduction in the OCS dose achieved after the first 12 months of therapy is at least maintained throughout treatment.

* Clinically significant asthma exacerbation is defined as worsening of asthma such that the treating physician elected to administer systemic glucocorticoids for at least 3 days or the patient visited an emergency department or was hospitalized."

All requests (including renewal requests) for mepolizumab must be completed using the Benralizumab/Mepolizumab Special Authorization Request Form (ABC 60061).

MEPOLIZUMAB

100 MG / VIAL INJECTION				
00002449781	NUCALA	GSK	$	2035.3800
100 MG / SYR INJECTION SYRINGE				
☒ 00002492997	NUCALA	GSK	$	2035.3800
☒ 00002492989	NUCALA (AUTOINJECTOR)	GSK	$	2035.3800

MEROPENEM

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or Hematology, or a designated prescriber.)

"1) For second-line therapy of infections due to gram-negative organisms producing inducible beta-lactamases or extended spectrum beta-lactamases where there is resistance to first-line agents or

2) For therapy for infections involving multi-resistant Pseudomonas aeruginosa, where there is documented susceptibility to meropenem or

3) For use in other Health Canada approved indications, in consultation with a specialist in Infectious Diseases."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or Hematology, or a designated prescriber.

In order to comply with all of the above criteria, information is required regarding the type of infection and organisms involved. Also, where the criteria restrict coverage of the requested drug to non-first line therapy, information is required regarding previous first-line antibiotic therapy that has been utilized, the patient's response to therapy, and the first line agents the organism is resistant to or why other first-line therapies cannot be used in this patient. Also, where applicable, the specialist in Infectious Diseases that recommended this drug is required.

500 MG / VIAL INJECTION				
00002378787	**MEROPENEM**	**SDZ**	$	**9.2225**
00002493330	**MEROPENEM**	**STM**	$	**9.2225**
00002421518	**TARO-MEROPENEM**	**SPG**	$	**9.2225**
1 G / VIAL INJECTION				
00002378795	**MEROPENEM**	**SDZ**	$	**18.4450**
00002493349	**MEROPENEM FOR INJECTION**	**STM**	$	**18.4450**
00002421526	**TARO-MEROPENEM**	**SPG**	$	**18.4450**

MIGALASTAT HYDROCHLORIDE

"For treatment of adults (18 years of age or older) with laboratory-confirmed diagnosis of Fabry Disease (a deficiency of alpha-galactosidase [alpha-Gal A]) who have an alpha-Gal A mutation that is determined to be amenable by an in vitro assay.

The patient must also be otherwise eligible for enzyme replacement therapy (ERT) for the treatment of Fabry Disease as determined and assessed through the Canadian Fabry Disease Initiative (CFDI).

For coverage, this drug must be prescribed by a physician affiliated with the Canadian Fabry Disease Initiative (CFDI).
Coverage cannot be provided for use in combination with any ERT.

Initial coverage may be approved up to 12 months.

For continued coverage beyond 12 months, confirmation of continued response is required. Continued coverage may be approved for a period of 12 months."

All requests (including renewal requests) for migalastat must be completed using the Migalastat Special Authorization Request Form (ABC 60071).

123 MG (BASE) ORAL CAPSULE				
00002468042	GALAFOLD	AMI	$	1700.0000

MIRABEGRON

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): SOLIFENACIN OR TOLTERODINE LA

"For patients who have failed on or are intolerant to solifenacin or tolterodine LA.

Special authorization may be granted for 24 months.

Coverage cannot be provided for mirabegron when this medication is intended for use in combination with other overactive bladder agents."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

All requests for mirabegron must be completed using the darifenacin hydrobromide/Fesoterodine fumarate/Mirabegron/Trospium chloride Special Authorization Request Form (ABC 60088).

25 MG ORAL EXTENDED-RELEASE TABLET				
00002402874	MYRBETRIQ	ASP	$	1.4600
50 MG ORAL EXTENDED-RELEASE TABLET				
00002402882	MYRBETRIQ	ASP	$	1.4600

MODAFINIL

"For the treatment of documented narcolepsy. This drug product must be prescribed by a specialist in Neurology or Psychiatry, or a sleep specialist affiliated with a recognized level 1 lab.

Special authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

100 MG ORAL TABLET

00002285398	**APO-MODAFINIL**	**APX**	$	**0.3427**
00002430487	**AURO-MODAFINIL**	**AUR**	$	**0.3427**
00002503727	**JAMP MODAFINIL**	**JPC**	$	**0.3427**
00002432560	**MAR-MODAFINIL**	**MAR**	$	**0.3427**
00002420260	**TEVA-MODAFINIL**	**TEV**	$	**0.3427**
00002239665	ALERTEC	TMP	$	1.5123

MONTELUKAST SODIUM

(Refer to 48:10.24 of the Alberta Drug Benefit List for coverage of patients 6 to 18 years of age inclusive).

"For the prophylaxis and chronic treatment of asthma in patients over the age of 18 who meet one of the following criteria:
a) when used as adjunctive therapy in patients who do not respond adequately to high doses of inhaled glucocorticosteroids and long-acting beta 2 agonists. Patients must be unable to use long-acting beta 2 agonists or have demonstrated persistent symptoms while on long-acting beta 2 agonists, or
b) cannot operate inhaler devices."

"For the prophylaxis of exercise-induced bronchoconstriction in patients over the age of 18 where tachyphylaxis exists for long-acting beta 2 agonists."

"Special authorization for both criteria may be granted for 6 months."

In order to comply with the first criteria, information should indicate either
a) current use of inhaled steroids and contraindications or poor response to long-acting beta 2 agonists (e.g. salmeterol or formoterol) or,
b) the nature of the patient's difficulties with using inhaler devices.

In order to comply with the second criteria, information should include the nature of the patient's response to long-acting beta 2 agonists (e.g. salmeterol or formoterol).

All requests (including renewal requests) for montelukast 5 mg & 10 mg must be completed using the Montelukast Special Authorization Request Form (ABC 60039).

The following product(s) are eligible for auto-renewal.

10 MG (BASE) ORAL TABLET				
00002379236	**ACH-MONTELUKAST**	**AHI**	$	**0.4231**
00002374609	**APO-MONTELUKAST**	**APX**	$	**0.4231**
00002401274	**AURO-MONTELUKAST**	**AUR**	$	**0.4231**
00002391422	**JAMP-MONTELUKAST**	**JPC**	$	**0.4231**
00002488183	**M-MONTELUKAST**	**MTR**	$	**0.4231**
00002399997	**MAR-MONTELUKAST**	**MAR**	$	**0.4231**
00002408643	**MINT-MONTELUKAST**	**MPI**	$	**0.4231**
00002379333	**MONTELUKAST**	**SNS**	$	**0.4231**
00002382474	**MONTELUKAST**	**SIV**	$	**0.4231**
00002522136	**NAT-MONTELUKAST**	**NTP**	$	**0.4231**
00002489821	**NRA-MONTELUKAST**	**NRA**	$	**0.4231**
00002373947	**PMS-MONTELUKAST FC**	**PMS**	$	**0.4231**
00002389517	**RAN-MONTELUKAST**	**RAN**	$	**0.4231**
00002328593	**SANDOZ MONTELUKAST**	**SDZ**	$	**0.4231**
00002355523	**TEVA-MONTELUKAST**	**TEV**	$	**0.4231**
00002238217	SINGULAIR	ORC	$	2.6060
5 MG (BASE) ORAL CHEWABLE TABLET				
00002377616	**APO-MONTELUKAST**	**APX**	$	**0.3082**
00002514885	**JAMP MONTELUKAST**	**JPC**	$	**0.3082**
00002442361	**JAMP-MONTELUKAST**	**JPC**	$	**0.3082**
00002399873	**MAR-MONTELUKAST**	**MAR**	$	**0.3082**
00002408635	**MINT-MONTELUKAST**	**MPI**	$	**0.3082**
00002379325	**MONTELUKAST**	**SNS**	$	**0.3082**
00002382466	**MONTELUKAST**	**SIV**	$	**0.3082**
00002522128	**NAT-MONTELUKAST**	**NTP**	$	**0.3082**
00002354985	**PMS-MONTELUKAST**	**PMS**	$	**0.3082**
00002330393	**SANDOZ MONTELUKAST**	**SDZ**	$	**0.3082**
00002355515	**TEVA-MONTELUKAST**	**TEV**	$	**0.3082**
00002238216	SINGULAIR	ORC	$	1.7744

NARATRIPTAN HCL

(Refer to 28:32.28 of the Alberta Drug Benefit List for coverage of patients 18 to 64 years of age inclusive.)

"For the treatment of acute migraine attacks in patients 65 years of age and older where other standard therapy has failed."

"For the treatment of acute migraine attacks in patients 65 years of age and older who have been using naratriptan hydrochloride prior to turning 65."

"Special authorization for both criteria may be granted for 24 months."

In order to comply with the first criteria, information is required regarding previous medications utilized and the patient's response to therapy.

The following product(s) are eligible for auto-renewal.

1 MG (BASE) ORAL TABLET				
00002314290	TEVA-NARATRIPTAN	TEV	$	12.4993
2.5 MG (BASE) ORAL TABLET				
00002322323	**SANDOZ NARATRIPTAN**	**SDZ**	$	**6.1436**
00002314304	**TEVA-NARATRIPTAN**	**TEV**	$	**6.1436**

NATALIZUMAB

Relapsing Remitting Multiple Sclerosis (RRMS)

"Special authorization coverage may be provided for the treatment of relapsing remitting multiple sclerosis (RRMS) to reduce the frequency of clinical relapses, to decrease the number and volume of active brain lesions identified on magnetic resonance imaging (MRI) scans and to delay the progression of physical disability, in adult patients (18 years of age or older) who are refractory or intolerant to at least ONE of the following:

- dimethyl fumarate
- glatiramer acetate
- interferon beta
- ocrelizumab
- ofatumumab
- peginterferon beta
- teriflunomide

Definition of 'intolerant'
Demonstrating serious adverse effects or contraindications to treatments as defined in the product monograph, or a persisting adverse event that is unresponsive to recommended management techniques and which is incompatible with further use of that class of MS disease modifying therapy (DMT).

Definition of 'refractory'
-Development of neutralizing antibodies to interferon beta.

-When the above MS DMTs are taken at the recommended doses for a full and adequate course of treatment, within a consecutive 12-month period while the patient was on the MS DMT, the patient has:

1) Been adherent to the MS DMT (greater than 80% of approved doses have been administered);

2) Experienced at least two relapses* of MS confirmed by the presence of neurologic deficits on examination.
i. The first qualifying clinical relapse must have begun at least one month after treatment initiation.
ii. Both qualifying relapses must be classified with a relapse severity of moderate, severe or very severe**.

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

**Relapse severity: with moderate relapses modification or more time is required to carry out activities of daily living; with severe relapses there is inability to carry out some activities of daily living; with very severe relapses activities of daily living must be completed by others.
Coverage
For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.
To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).
Initial Coverage
1) The registered MS Neurologist must confirm a diagnosis of RRMS;
2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS DMT. In most cases this will be satisfied by the 'refractory' to treatment criterion but if a patient failed an MS DMT more than one year earlier, ongoing active disease must be confirmed.

NATALIZUMAB

3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).
Coverage will not be approved when any MS DMT or other immunosuppressive therapy is to be used in combination with natalizumab.
Coverage of natalizumab will not be approved if the patient was deemed to be refractory to natalizumab in the past, i.e., has not met the 'responder' criteria below in 'Continued Coverage'.
Following assessment of the request, coverage may be approved for up to 13 doses of 300 mg (i.e., one dose administered every 4 weeks for a period up to 12 months). Patients will be limited to receiving one dose (4 weeks supply) of natalizumab per prescription at their pharmacy.
Continued Coverage
For continued coverage beyond the initial coverage period, the patient must meet the following criteria:
1) The patient must be assessed by a registered MS Neurologist;
2) The registered MS Neurologist must confirm a diagnosis of RRMS;
3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more;
Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.
4) At the first renewal there must be evidence that neutralizing antibodies to natalizumab are absent.
5) The registered MS Neurologist must confirm in writing that the patient is a 'responder' who has experienced no more than one inflammatory event in the last year (defined as either a clinical relapse or new T2 lesion or gadolinium-enhancing lesion). In instances where a patient has had four or more clinical relapses in the year prior to starting treatment, there must be at least a 50% reduction in relapse rate over the entire treatment period.
Following assessment of the request, continued coverage may be approved for maintenance therapy of 300 mg every 4 weeks for a period up to 12 months. Patients will be limited to receiving one dose of natalizumab per prescription at their pharmacy.
Restarting After an Interruption in Therapy Greater Than 12 Months
In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the patient must meet the following criteria:
1) At least one relapse* per 12 month period; or
2) At least two relapses* during the previous 24 month period."

All requests (including renewal requests) for fingolimod must be completed using the Cladribine/Fingolimod/Natalizumab For Multiple Sclerosis Special Authorization Request Form (ABC 60000).

20 MG / ML INJECTION

00002286386	TYSABRI	BIO	$	181.4455

NINTEDANIB ESILATE

Chronic Fibrosing Interstitial Lung Disease (ILD)

"Initial approval criteria:
Adult patients with a diagnosis of chronic fibrosing interstitial lung disease with a progressive phenotype:
- Diagnosis confirmed by a respirologist.
- Patient has a forced vital capacity (FVC) greater than or equal to 45% of predicted.
- Patient is under the care of a physician with experience in interstitial lung diseases.

Special authorization may be granted for 12 months.

For renewal of coverage:
Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of greater than or equal to 10% during the preceding year of treatment with nintedanib. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Exclusion Criteria:
Combination use of pirfenidone and nintedanib will not be funded."

All requests for nintedanib must be completed using the Nintedanib/Pirfenidone Special Authorization Request Form (ABC 60051).

Mild to Moderate Idiopathic Pulmonary Fibrosis (IPF)

"Initial approval criteria:

Adult patients with a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF):
- Diagnosis confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.
- All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded.
- Mild to moderate IPF is defined as forced vital capacity (FVC) greater than or equal to 50% of predicted.
- Patient is under the care of a physician with experience in IPF.

Initial approval period: 7 months (allow 4 weeks for repeat pulmonary function tests)

Initial renewal criteria (at 6 months):

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of greater than or equal to 10% from initiation of therapy until renewal (initial 6 month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Approval period: 6 months

Second and subsequent renewals (at 12 months and thereafter):

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of greater than or equal to 10% within any 12 month period. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Approval period: 12 months

Exclusion Criteria:
Combination use of pirfenidone and nintedanib will not be funded.

NINTEDANIB ESILATE

Notes:
Patients who have experienced intolerance or failure to pirfenidone or nintedanib will be considered for the alternate agent provided that the patient continues to meet the above coverage criteria."

All requests for nintedanib must be completed using the Nintedanib/Pirfenidone Special Authorization Request Form (ABC 60051).

100 MG (BASE) ORAL CAPSULE				
00002443066	OFEV	BOE	$	28.3216
150 MG (BASE) ORAL CAPSULE				
00002443074	OFEV	BOE	$	56.6431

NITISINONE

"For the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine, when prescribed by a physician with experience in the diagnosis and management of HT-1."

Special authorization may be granted for 12 months.

The following product(s) are eligible for auto-renewal.

2 MG ORAL TABLET				
00002458616	NITISINONE	CYC	$	12.9500
5 MG ORAL TABLET				
00002458624	NITISINONE	CYC	$	25.0600
10 MG ORAL TABLET				
00002458632	NITISINONE	CYC	$	47.4000
2 MG ORAL CAPSULE				
☒ 00002457717	MDK-NITISINONE	MEN	$	12.9500
☒ 00002459698	ORFADIN	BVM	$	12.9500
5 MG ORAL CAPSULE				
☒ 00002457725	MDK-NITISINONE	MEN	$	25.0600
☒ 00002459701	ORFADIN	BVM	$	25.0600
10 MG ORAL CAPSULE				
☒ 00002457733	MDK-NITISINONE	MEN	$	47.4000
☒ 00002459728	ORFADIN	BVM	$	47.4000
20 MG ORAL CAPSULE				
☒ 00002470055	MDK-NITISINONE	MEN	$	128.1000
☒ 00002459736	ORFADIN	BVM	$	128.1000

NUSINERSEN SODIUM

"For patients diagnosed with 5q Spinal Muscular Atrophy (SMA) under the care of a specialist with experience in the diagnosis and management of SMA, if the following clinical criteria are met:

1) Genetic documentation of 5q SMA homozygous gene deletion, homozygous mutation, or compound heterozygote, AND
2) Patients who:
- are pre-symptomatic with two or three copies of SMN2, OR
- have had disease duration of less than six months, two copies of SMN2, and symptom onset after the first week after birth and on or before seven months of age, OR
- are under the age of 18 with symptom onset after six months of age, regardless of the ability to walk independently.
AND
3) Patient is not currently requiring permanent invasive ventilation*, AND
4) A baseline assessment using an age-appropriate scale (the Hammersmith Infant Neurological Examination [HINE] Section 2, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders [CHOP INTEND], or Hammersmith Functional Motor Scale-Expanded [HFMSE]) must be completed prior to initiation of nusinersen treatment.

Other patients who do not meet the expanded funding criteria may be considered in exceptional cases.

Initial coverage may be approved for three 12 mg doses at Day 0, Day 14 and Day 28, followed by one 12 mg dose at Day 63.

Patients will be limited to receiving one dose of nusinersen per prescription at their pharmacy.

For continued coverage, the patient must meet the following criteria:
1) There is demonstrated achievement or maintenance of motor milestone function (as assessed using age-appropriate scales: the [HINE] Section 2), CHOP INTEND, or HFMSE) since treatment initiation in patients who were pre-symptomatic at the time of treatment initiation;
OR
There is demonstrated maintenance of motor milestone function (as assessed using age-appropriate scales: the HINE Section 2, CHOP INTEND, or HFMSE) since treatment initiation in patients who were symptomatic at the time of treatment initiation;
AND
2) Patient does not require permanent invasive ventilation*.

Continued coverage may be considered for one 12 mg maintenance dose at a time, to be administered at 4-month intervals.
Each maintenance dose cannot be considered prior to 4 months elapsing from the date of the previous dose.
Treatment should be discontinued if, prior to the fifth dose or every subsequent dose of nusinersen, the above renewal criteria are not met.

*Permanent invasive ventilation is defined as the use of tracheostomy and a ventilator due to progression of SMA that is not due to an identifiable and reversible cause.

SMA drug therapy and adeno-associated virus (AAV) vector-based gene therapy may not be used concomitantly. Additionally, use of a SMA drug therapy after administration of an AAV vector-based gene therapy will not be permitted, and coverage will not be approved when any SMA drug therapies are to be used in combination.

Patients currently receiving SMA drug therapy may be eligible to switch to an alternate SMA drug therapy; however, patients will not be permitted to switch back to a previously trialed SMA drug."

All requests (including renewal requests) for nusinersen must be completed using the Nusinersen/Risdiplam Special Authorization Request Form (ABC 60064).

NUSINERSEN SODIUM

2.4 MG / ML (BASE)	INJECTION		
00002465663	SPINRAZA	BIO	$ 23600.0000

OBETICHOLIC ACID

"For the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA, where the following criteria are met:

I. A confirmed diagnosis of PBC, defined as:
- Positive antimitochondrial antibodies (AMA); or
- Liver biopsy results consistent with PBC.

AND

II.a. The patient has received ursodeoxycholic acid (UDCA) for a minimum of 12 months and has experienced an inadequate response to UDCA and can benefit from the addition of obeticholic acid. An inadequate response is defined as:
- alkaline phosphatase (ALP) greater than or equal to 1.67 x upper limit of normal (ULN) and/or
- bilirubin > ULN and < 2 x ULN.

OR

II.b. The patient has experienced documented and unmanageable intolerance to UDCA and can benefit from switching therapy to obeticholic acid.

AND

III. Initiated by a gastroenterologist or hepatologist (or an internal medicine specialist with an interest in gastroenterology / hepatology on a case-by-case basis, in geographic areas where access to these specialities is not available).

Initial coverage may be approved for a period of 12 months.

Ongoing coverage may be considered only if the patient continues to benefit from treatment with obeticholic acid as evidenced by:

- A reduction in the ALP level to less than 1.67 x ULN; or
- A 15% reduction in the ALP level compared with values before beginning treatment with obeticholic acid.

Continued coverage may be approved for up to 12 months."

All requests (including renewal requests) for obeticholic acid must be completed using the Obeticholic Acid Special Authorization Request Form (ABC 60065).

5 MG ORAL TABLET			
00002463121	OCALIVA	ICP	$ 105.9435
10 MG ORAL TABLET			
00002463148	OCALIVA	ICP	$ 105.9435

OCRELIZUMAB

Relapsing Remitting Multiple Sclerosis (RRMS)

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory adult patients (18 years of age or older) with relapsing remitting multiple sclerosis.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.
To register to become an MS Neurologist, please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

1) The registered MS Neurologist must confirm a diagnosis of RRMS;

2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).
Initial coverage may be approved for an initial dose of ocrelizumab 300 mg given by intravenous (IV) infusion, followed 2 weeks later by a second 300 mg dose. A maintenance dose of ocrelizumab 600 mg at 6 months will also be provided in the initial coverage period. Patients will be limited to receiving one dose of ocrelizumab per prescription at their pharmacy.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

1) The patient must be assessed by a registered MS Neurologist;

2) The registered MS Neurologist must confirm a diagnosis of RRMS;

3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more.

Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.
Continued coverage may be approved for one dose of ocrelizumab 600 mg every 6 months for up to 12 months. Patients may receive one dose of ocrelizumab 600 mg per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the

OCRELIZUMAB

patient must meet the following criteria:

1) At least one relapse* per 12 month period; or
2) At least two relapses* during the previous 24 month period."

All requests (including renewal requests) for ocrelizumab for RRMS must be completed using the Dimethyl Fumarate/Glatiramer Acetate/Interferon Beta-1b/Ocrelizumab/Peginterferon Beta-1a/Teriflunomide for RRMS/Interferon Beta-1a for SPMS or RRMS Special Authorization Request Form (ABC 60001).

Primary Progressive Multiple Sclerosis (PPMS):

"Special authorization coverage may be provided for the management of adult patients with early primary progressive multiple sclerosis (PPMS), as defined by disease duration and level of disability in conjunction with imaging features characteristic of inflammatory activity.

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.

To register to become an MS Neurologist, please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

1) The registered MS Neurologist must confirm a diagnosis of PPMS (based on McDonald criteria 2017);

2) The patient must have an Expanded Disability Status Scale (EDSS) score between 3.0 and 6.5;

3) The patient must have a score of at least 2.0 on the Functional Systems scale for the pyramidal system due to lower extremity findings;

4) There are documented imaging features characteristic of inflammatory activity;

5) Disease duration must be less than 15 years for those with an EDSS greater than 5.0, or less than 10 years for those with an EDSS of 5.0 or less.

Initial coverage may be approved for an initial dose of ocrelizumab 300 mg given by intravenous (IV) infusion, followed 2 weeks later by a second 300 mg dose. A maintenance dose of ocrelizumab 600 mg at 6 months will also be provided in the initial coverage period. Patients will be limited to receiving one dose of ocrelizumab per prescription at their pharmacy.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must be assessed between 6 months and 12 months, and every 12 months thereafter, and the request must meet the following criteria:

1) The registered MS Neurologist must confirm a diagnosis of PPMS;

2) A current updated EDSS score must be provided and the patient must not have an EDSS score of 7.0 or above.

Continued coverage may be approved for one dose of ocrelizumab 600 mg every 6 months for up to 12 months. Patients may receive one dose of ocrelizumab 600 mg per prescription at their pharmacy."

All requests (including renewal requests) for ocrelizumab for PPMS must be completed using the Ocrelizumab for PPMS Special Authorization Request Form (ABC 60067).

OCRELIZUMAB

30 MG / ML INJECTION				
00002467224	OCREVUS	HLR	$	815.0000

OCTREOTIDE ACETATE

"For control of symptoms in patients with metastatic carcinoid and vasoactive intestinal peptide-secreting tumors (VIPomas) when prescribed by or in consultation with a Specialist in Internal Medicine, Palliative Care or General Surgery."

"For the treatment of acromegaly when prescribed by or in consultation with a Specialist in Internal Medicine."

"For the treatment of intractable diarrhea which has not responded to less costly therapy [e.g. associated with (secondary to) AIDS, intra-abdominal fistulas, short bowel syndrome]. Treatment for these indications must be prescribed by or in consultation with a Specialist in, Internal Medicine, Palliative Care, or General Surgery."

"Special authorization may be granted for 12 months."

In order to comply with the third criterion, information is required regarding previous medications utilized and the patient's response to therapy.

The following product(s) are eligible for auto-renewal.

50 MCG / ML (BASE) INJECTION				
00002248639	**OCTREOTIDE ACETATE OMEGA**	**OMG**	$	**4.0080**
00000839191	SANDOSTATIN	NOV	$	5.1460
100 MCG / ML (BASE) INJECTION				
00002248640	**OCTREOTIDE ACETATE OMEGA**	**OMG**	$	**7.5660**
00000839205	SANDOSTATIN	NOV	$	9.7135
200 MCG / ML (BASE) INJECTION				
00002248642	OCTREOTIDE ACETATE OMEGA	OMG	$	14.5540
500 MCG / ML (BASE) INJECTION				
00002248641	OCTREOTIDE ACETATE OMEGA	OMG	$	40.3019
10 MG / VIAL INJECTION				
00002503751	**OCTREOTIDE**	**TEV**	$	**990.6975**
00002239323	SANDOSTATIN LAR	NOV	$	1315.7400
20 MG / VIAL INJECTION				
00002503778	**OCTREOTIDE**	**TEV**	$	**1279.9350**
00002239324	SANDOSTATIN LAR	NOV	$	1699.8900
30 MG / VIAL INJECTION				
00002503786	**OCTREOTIDE**	**TEV**	$	**1642.1400**
00002239325	SANDOSTATIN LAR	NOV	$	2180.9400

OFATUMUMAB

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory adult patients (18 years of age or older) with relapsing remitting multiple sclerosis.

Coverage
For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.

To register to become an MS Neurologist, please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage
1) The registered MS Neurologist must confirm a diagnosis of RRMS;
2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).

Coverage may be approved for an initial dose of ofatumumab 20 mg given by subcutaneous (SC) injection at weeks 0, 1, 2, and 4, followed by monthly injections. Patients will be limited to receiving a one month's supply of ofatumumab per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage
For continued coverage beyond the initial coverage period, the patient must meet the following criteria:
1) The patient must be assessed by a registered MS Neurologist;
2) The registered MS Neurologist must confirm a diagnosis of RRMS;
3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more.

Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of ofatumumab per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months
In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the patient must meet the following criteria:
1) At least one relapse* per 12 month period; or
2) At least two relapses* during the previous 24 month period."

All requests (including renewal requests) for ofatumumab must be completed using the Dimethyl Fumarate/Glatiramer Acetate/Interferon Beta-1b/Ocrelizumab/Ofatumumab/Peginterferon Beta-1a/Teriflunomide for RRMS/Interferon Beta-1a for SPMS or RRMS Special Authorization Request Form (ABC 60001).

OFATUMUMAB

20 MG / SYR INJECTION SYRINGE

00002511355	KESIMPTA (PEN)	NOV	$ 2208.3300

OMALIZUMAB

ASTHMA

"Special authorization coverage may be provided for adults and adolescents (12 years of age and above) with severe persistent asthma who are identified as having severe disease despite optimized standard therapy. Optimized standard therapy defined by a full trial of, and documented compliance with:

- high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent) for at least twelve (12) months; AND,
- long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms daily or 24 micrograms of formoterol fumarate daily) for at least twelve (12) months; AND,
- Therapeutic trial with systemic corticosteroids (at least 10mg per day prednisolone (or equivalent)) for at least 4 weeks in the previous twelve (12) months, unless contraindicated or not tolerated.

For coverage, the drug must be initiated and monitored by a respirologist or clinical immunologist or allergist and meet the following clinical criteria (Initial Coverage or Continued Coverage, as appropriate). Patients will be limited to receiving a one (1) month supply of omalizumab per prescription at their pharmacy.

INITIAL COVERAGE:
Special authorization requests must meet all of the following criteria for initial approval:

1) Confirmation of severe persistent asthma through recent clinical and physiologic review with exclusion of other obstructive airways processes contributing to symptoms of severe asthma (i.e. psychogenic dyspnea; cardiac dyspnea);

2) Must be a non-smoker;

3) Confirmation of IgE mediated allergy to a perennial allergen by clinical history and allergy skin testing;

4) Baseline IgE level greater than/equal to 30 IU/mL and less than/equal to 700 IU/mL;

5) A weight between 20kg and 150kg;

6) An Asthma Control Questionnaire (ACQ-5) of at least 1.25, on at least two occasions over the past 6 months in a stable state;

7) Must provide documentation:
- Spirometry measurement of FEV1;
- Asthma Quality of Life Questionnaire (AQLQ - Juniper) score;
- Number of exacerbations of asthma within the previous twelve (12) month period that resulted in:
- an emergency room visit or hospitalization;
- physician visits resulting in oral corticosteroids or an increased dose of oral corticosteroids;
- chronic use (greater than 50% of the year) of oral corticosteroids;

8) One (1) or more severe exacerbations of asthma requiring a hospital admission or Emergency Room visit within the previous year while on systemic corticosteroids; OR
- One (1) or more severe exacerbations of asthma requiring a hospital admission or Emergency Room visit requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least three (3) days, or parenteral corticosteroids); OR
- Three (3) or more severe exacerbations of asthma within the previous year which required a physician visit and resulted in courses (or chronic use greater than 50% of the year), or increased dose of systemic corticosteroids.

Initial coverage may be approved for twenty-eight (28) weeks of up to 375 mg administered every 2 weeks based on the recommended dose and dosage adjustment outlined in the Health

OMALIZUMAB

Canada approved Product Monograph.

CONTINUED MAINTENANCE TREATMENT:
A patient must be assessed for response to initial coverage of omalizumab with a minimum of twenty-four (24) weeks of therapy with omalizumab, and this assessment must be submitted to Alberta Blue Cross no later than four (4) weeks from the date of assessment.

The assessment must be done by a respirologist or clinical immunologist or allergist or such other clinicians as the Minister may designate. If the following criteria are met, special authorization may be granted for a further twelve (12) month period. Continued coverage may be considered if the following criteria are met at the end of each additional twelve (12) month period:

1) Demonstrated that the patient has an Improvement in FEV1 greater than 12% (and for adults a minimum greater than 200 mL) from initiation of therapy; OR
Unchanged FEV1 with a clinically meaningful Improvement in Asthma Quality of Life Questionnaire score from baseline (greater than/equal to 0.5 mean from baseline); AND
- a decrease in the ACQ-5 of at least 0.5; OR
- a ACQ-5 score of less than/equal to 1.

2) Patients must demonstrate at least a 25% reduction in the number of exacerbations, which required oral corticosteroids from the twelve (12) months prior to initiation of omalizumab that required systemic corticosteroids; OR
For patients that were on chronic (greater than 50% of the year) courses of oral corticosteroids in the twelve (12) months prior to initiation of omalizumab, tapering of oral corticosteroid use by at least 25% from baseline.

3) A reduction in the number of exacerbations that have led to a hospital admission or emergency room visits, compared to the twelve (12) months prior to the commencement of omalizumab."

All requests (including renewal requests) for omalizumab for Asthma must be completed using the Omalizumab for Asthma Special Authorization Request Form (ABC 60020).

CHRONIC IDIOPATHIC URTICARIA

"For the treatment of adults and adolescents (12 years of age and above) with moderate to severe chronic idiopathic urticaria (CIU), defined as having a baseline Urticaria Activity Score over 7 days (UAS7) of greater than or equal to 16, who remain symptomatic (presence of hives and/or associated itching) despite optimum management with available oral therapies. Oral therapies should include a therapeutic trial with H1 antihistamines, unless contraindicated or not tolerated.

For coverage, the drug must be initiated and monitored by a Specialist in Dermatology, Clinical Immunology or Allergy.

Coverage may be approved for a period of 24 weeks at a maximum dose of 300 mg every 4 weeks.
Patients will be limited to receiving a one-month supply of omalizumab per prescription at their pharmacy.
Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

Continued coverage of a further 24-week treatment period may be considered if the patient has experienced:
- complete symptom control (i.e., UAS7 of 0) for less than 12 consecutive weeks; OR
- partial symptom control, with a reduction in baseline UAS7 of greater than or equal to 9.5 points.

OMALIZUMAB

Treatment cessation should be considered for patients who experience complete symptom control for at least 12 consecutive weeks at the end of a 24-week treatment period.

In patients where treatment is discontinued due to temporary symptom control, treatment re-initiation should be considered should CIU symptoms reappear."

All requests (including renewal requests) for omalizumab for Chronic Idiopathic Urticaria must be completed using the Omalizumab for Chronic Idiopathic Urticaria Special Authorization Request Form (ABC 60056).

150 MG / VIAL	**INJECTION**			
00002260565	XOLAIR	NOV	$	646.4400

PALIPERIDONE PALMITATE

"For the management of the manifestations of schizophrenia in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success and who possess clinical evidence of previous successful treatment with risperidone or paliperidone therapy;

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR

- Is refractory to trials of at least two other antipsychotic therapies.

Special Authorization may be granted for six months."

All requests (including renewal requests) for paliperidone prolonged release injection must be
completed using the Aripiprazole/Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 60024).

The following product(s) are eligible for auto-renewal.

50 MG / SYR (BASE)	**INJECTION SYRINGE**			
00002354217	INVEGA SUSTENNA (0.5 ML SYR)	JAI	$	327.0000

"For the management of the manifestations of schizophrenia in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success and who possess clinical evidence of previous successful treatment with risperidone or paliperidone therapy;

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR

- Is refractory to trials of at least two other antipsychotic therapies.

Special Authorization may be granted for six months."

All requests (including renewal requests) for paliperidone prolonged release injection must be
completed using the Aripiprazole/Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 60024).

The following product(s) are eligible for auto-renewal.

75 MG / SYR (BASE)	**INJECTION SYRINGE**			
00002354225	INVEGA SUSTENNA (0.75 ML SYR)	JAI	$	490.5000

PALIPERIDONE PALMITATE

"For the management of the manifestations of schizophrenia in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success and who possess clinical evidence of previous successful treatment with risperidone or paliperidone therapy;

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR

- Is refractory to trials of at least two other antipsychotic therapies.

Special Authorization may be granted for six months."

All requests (including renewal requests) for paliperidone prolonged release injection must be
completed using the Aripiprazole/Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 60024).

The following product(s) are eligible for auto-renewal.

100 MG / SYR (BASE)	INJECTION SYRINGE			
00002354233	INVEGA SUSTENNA (1 ML SYR)	JAI	$	490.5000

"For the management of the manifestations of schizophrenia in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success and who possess clinical evidence of previous successful treatment with risperidone or paliperidone therapy;

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR

- Is refractory to trials of at least two other antipsychotic therapies.

Special Authorization may be granted for six months."

All requests (including renewal requests) for paliperidone prolonged release injection must be
completed using the Aripiprazole/Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 60024).

The following product(s) are eligible for auto-renewal.

150 MG / SYR (BASE)	INJECTION SYRINGE			
00002354241	INVEGA SUSTENNA (1.5 ML SYR)	JAI	$	654.0300

PALIPERIDONE PALMITATE

"For the management of the manifestations of schizophrenia in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success and who possess clinical evidence of previous successful treatment with risperidone or paliperidone therapy;

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR

- Is refractory to trials of at least two other antipsychotic therapies.

To be considered for coverage of Invega Trinza, patients must have been maintained on Invega Sustenna for at least four months. The last two doses of Invega Sustenna should be the same dosage strength and dosing interval, before initiating Invega Trinza.

Special Authorization may be granted for six months."

All requests (including renewal requests) for paliperidone prolonged release injection must be completed using the Aripiprazole/Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 60024).

The following product(s) are eligible for auto-renewal.

175 MG / SYR (BASE)	INJECTION	SYRINGE		
00002455943	INVEGA TRINZA (0.875 ML SYR)	JAI	$	934.2900

"For the management of the manifestations of schizophrenia in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success and who possess clinical evidence of previous successful treatment with risperidone or paliperidone therapy;

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR

- Is refractory to trials of at least two other antipsychotic therapies.

To be considered for coverage of Invega Trinza, patients must have been maintained on Invega Sustenna for at least four months. The last two doses of Invega Sustenna should be the same dosage strength and dosing interval, before initiating Invega Trinza.

Special Authorization may be granted for six months."

All requests (including renewal requests) for paliperidone prolonged release injection must be completed using the Aripiprazole/Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 60024).

The following product(s) are eligible for auto-renewal.

263 MG / SYR (BASE)	INJECTION	SYRINGE		
00002455986	INVEGA TRINZA (1.315 ML SYR)	JAI	$	1401.5400

PALIPERIDONE PALMITATE

"For the management of the manifestations of schizophrenia in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success and who possess clinical evidence of previous successful treatment with risperidone or paliperidone therapy;

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR

- Is refractory to trials of at least two other antipsychotic therapies.

To be considered for coverage of Invega Trinza, patients must have been maintained on Invega Sustenna for at least four months. The last two doses of Invega Sustenna should be the same dosage strength and dosing interval, before initiating Invega Trinza.

Special Authorization may be granted for six months."

All requests (including renewal requests) for paliperidone prolonged release injection must be completed using the Aripiprazole/Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 60024).

The following product(s) are eligible for auto-renewal.

350 MG / SYR (BASE)	INJECTION SYRINGE			
00002455994	INVEGA TRINZA (1.75 ML SYR)	JAI	$	1401.5400

"For the management of the manifestations of schizophrenia in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success and who possess clinical evidence of previous successful treatment with risperidone or paliperidone therapy;

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR

- Is refractory to trials of at least two other antipsychotic therapies.

To be considered for coverage of Invega Trinza, patients must have been maintained on Invega Sustenna for at least four months. The last two doses of Invega Sustenna should be the same dosage strength and dosing interval, before initiating Invega Trinza.

Special Authorization may be granted for six months."

All requests (including renewal requests) for paliperidone prolonged release injection must be completed using the Aripiprazole/Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 60024).

The following product(s) are eligible for auto-renewal.

525 MG / SYR (BASE)	INJECTION SYRINGE			
00002456001	INVEGA TRINZA (2.625 ML SYR)	JAI	$	1868.6700

PATISIRAN SODIUM

"For the treatment of polyneuropathy in adult patients with a confirmed genetic diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in patients who meet the following criteria:

-Patients are symptomatic with early-stage neuropathy, defined as polyneuropathy disability [PND] stage I to less than or equal to IIIB or familial amyloidotic polyneuropathy [FAP] stage I or II
And
- do not exhibit severe heart failure symptoms (defined as New York Heart Association [NYHA] class III or IV)
And
-have not previously undergone a liver transplant.

For coverage, this drug must be prescribed by a specialist with experience in the diagnosis and management of hATTR.

Initial coverage may be approved 30 mg administered intravenously once every three weeks for a period of nine months.

Patients will be limited to receiving one dose of patisiran per prescription at their pharmacy.

For renewal of coverage, patients must show continued benefit from treatment with patisiran and must NOT be:
- permanently bedridden and dependent on assistance for basic activities of daily living, NOR
- receiving end-of-life care.

Continued coverage may be approved for 30 mg every three weeks for a period of six months.

Coverage cannot be provided for use in combination with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat hATTR."

All requests (including renewal requests) for patisiran must be completed using the Inotersen/Patisiran for HATTR-PN Special Authorization Request Form (ABC 60084).

2 MG / ML (BASE)	INJECTION		
00002489252	ONPATTRO	ANT	$ 2100.4813

PEGFILGRASTIM

"In patients with non-myeloid malignancies, receiving myelosuppressive anti-neoplastic drugs with curative intent, to decrease the incidence of infection, as manifested by febrile neutropenia."

All requests for pegfilgrastim must be completed using the Filgrastim/Pegfilgrastim/Plerixafor Special Authorization Request Form (ABC 60013).

Please note: Coverage cannot be considered for palliative patients.

6 MG / SYR	INJECTION	SYRINGE		
☒ 00002484153	FULPHILA (0.6 ML SYRINGE)	BGP	$	1375.0000
☒ 00002474565	LAPELGA (0.6 ML SYRINGE)	APX	$	1375.0000
☒ 00002506238	NYVEPRIA (0.6 ML SYRINGE)	PFI	$	1375.0000
☒ 00002497395	ZIEXTENZO (0.6 ML SYRINGE)	SDZ	$	1375.0000

PEGINTERFERON BETA-1A

Relapsing Remitting Multiple Sclerosis (RRMS)

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.
To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

1) The registered MS Neurologist must confirm a diagnosis of RRMS;

2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).
Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of peg-interferon beta-1a per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

1) The patient must be assessed by a registered MS Neurologist;

2) The registered MS Neurologist must confirm a diagnosis of RRMS;

3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more.

Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of peg-interferon beta-1a per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the patient must meet the following criteria:

PEGINTERFERON BETA-1A

1) At least one relapse* per 12 month period; or

2) At least two relapses* during the previous 24 month period."

All requests (including renewal requests) for interferon beta-1b must be completed using the Dimethyl Fumarate/Glatiramer Acetate/Interferon Beta-1a/Ocrelizumab/Peginterferon Beta-1a/Teriflunomide for RRMS/Interferon Beta-1b for SPMS or RRMS Special Authorization Request Form (ABC 60001).

125 MCG / SYR INJECTION SYRINGE				
00002444399	PLEGRIDY	BIO	$	926.0452

PEGINTERFERON BETA-1A/ PEGINTERFERON BETA-1A

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.

To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

1) The registered MS Neurologist must confirm a diagnosis of RRMS;

2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).
Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of peg-interferon beta-1a per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

1) The patient must be assessed by a registered MS Neurologist;

2) The registered MS Neurologist must confirm a diagnosis of RRMS;

3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more.

Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of peg-interferon beta-1a per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the patient must meet the following criteria:

1) At least one relapse* per 12 month period; or

PEGINTERFERON BETA-1A/ PEGINTERFERON BETA-1A

2) At least two relapses* during the previous 24 month period."

All requests (including renewal requests) for interferon beta-1b must be completed using the Dimethyl Fumarate/Glatiramer Acetate/Interferon Beta-1a/Ocrelizumab/Peginterferon Beta-1a/Teriflunomide for RRMS/Interferon Beta-1b for SPMS or RRMS Special Authorization Request Form (ABC 60001).

63 MCG / SYR * 94 MCG / SYR INJECTION SYRINGE				
00002444402	PLEGRIDY	BIO	$	926.0452

PERAMPANEL

"For adjunctive therapy in patients with refractory partial-onset seizures or primary generalized tonic-clonic (PGTC) seizures who meet all of the following criteria:

- Are currently receiving two or more antiepileptic medications, AND
- Have failed or demonstrated intolerance to three other antiepileptic medications, AND
- Therapy must be initiated by a Neurologist.

For the purpose of administering these criteria failure is defined as inability to achieve satisfactory seizure control.

Special authorization may be granted for six months.

Coverage cannot be provided for brivaracetam, eslicarbazepine, lacosamide or perampanel when these medications are intended for use in combination.

Each of these products are eligible for auto-renewal"

2 MG ORAL TABLET				
00002404516	FYCOMPA	EIS	$	10.2697
4 MG ORAL TABLET				
00002404524	FYCOMPA	EIS	$	10.2697
6 MG ORAL TABLET				
00002404532	FYCOMPA	EIS	$	10.2697
8 MG ORAL TABLET				
00002404540	FYCOMPA	EIS	$	10.2697
10 MG ORAL TABLET				
00002404559	FYCOMPA	EIS	$	10.2697
12 MG ORAL TABLET				
00002404567	FYCOMPA	EIS	$	10.2697

PIBRENTASVIR/ GLECAPREVIR

"For treatment-naive or treatment-experienced (1) adult patients with chronic hepatitis C infection who meet all of the following criteria:
I) Prescribed by or in consultation with a hepatologist, gastroenterologist or infectious disease specialist (except on a case-by-case basis, in geographic areas where access to these specialties is not available);
AND
II) Laboratory confirmed hepatitis C genotype (2) 1, 2, 3, 4, 5, 6;
AND
III) Laboratory confirmed quantitative HCV RNA value within the last 6 months:
AND
IV) Fibrosis (3) stage of F0 or greater (Metavir scale or equivalent).

Duration of therapy reimbursed:
- Treatment-naive, without cirrhosis: 8 weeks
- Treatment-naive, with compensated cirrhosis (4): 8 weeks
- Treatment-experienced (1) genotype 1, 2, 4, 5, or 6, without cirrhosis: 8 weeks
- Treatment-experienced (1) genotype 1, 2, 4, 5, or 6, with compensated cirrhosis (4): 12 weeks
- NS3/4A protease inhibitor treatment-experienced (5) genotype 1, without cirrhosis or with compensated cirrhosis (4): 12 weeks
- NS5A inhibitor treatment-experienced (6) genotype 1, without cirrhosis or with compensated cirrhosis (4): 16 weeks
- Treatment-experienced (1) genotype 3, without cirrhosis or with compensated cirrhosis (4): 16 weeks

Exclusion criteria:
- Patients currently being treated with another HCV antiviral agent

Notes:
1. Treatment experienced is defined as those who have previously been treated with a regimen containing interferon, peginterferon (P), ribavirin (R), and/or sofosbuvir (e.g. PR, SOF + PR, SOF + R), but have no prior treatment experience with an NS3/4A protease inhibitor or NS5A inhibitor.
2. HCV genotype testing is optional for treatment naive patients.
3. Fibrosis score test is optional. Acceptable methods include liver biopsy, transient elastography (FibroScan), fibrotest and serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.
4. Compensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh A (i.e. score 5 to 6).
5. NS3/4A protease inhibitor treatment-experienced is defined as those who have previously been treated with a regimen containing a non-structural protein 3/4A (NS3/4A) protease inhibitor, but without an NS5A inhibitor.
6. NS5A inhibitor treatment-experienced is defined as those who have previously been treated with a regimen containing an NS5A inhibitor, but without an NS3/4A protease inhibitor, such as daclatasavir + sofosbuvir, ledipasvir/sofosbuvir, or sofosbuvir/velpatasvir.
7. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations."

All requests for pibrentasvir/glecaprevir must be completed using the Glecaprevir/Pibrentasvir for Chronic Hepatitis C Special Authorization Request Form (ABC 60102).

40 MG * 100 MG ORAL TABLET				
00002467550	MAVIRET	ABV	$	238.0952

PIOGLITAZONE HCL

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): METFORMIN

"For the treatment of Type 2 diabetes in patients who have an inadequate response to a sufficient trial (i.e. a minimum of 6 months) of metformin or who are intolerant to metformin (e.g. dermatologic reactions) or for whom the product is contraindicated."

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

15 MG (BASE) ORAL TABLET				
00002391600	**ACH-PIOGLITAZONE**	**AHI**	$	**0.6225**
00002302861	**ACT PIOGLITAZONE**	**TEV**	$	**0.6225**
00002302942	**APO-PIOGLITAZONE**	**APX**	$	**0.6225**
00002397307	**JAMP-PIOGLITAZONE**	**JPC**	$	**0.6225**
00002326477	**MINT-PIOGLITAZONE**	**MPI**	$	**0.6225**
30 MG (BASE) ORAL TABLET				
00002339587	**ACH-PIOGLITAZONE**	**AHI**	$	**0.8721**
00002302888	**ACT PIOGLITAZONE**	**TEV**	$	**0.8721**
00002302950	**APO-PIOGLITAZONE**	**APX**	$	**0.8721**
00002365529	**JAMP-PIOGLITAZONE**	**JPC**	$	**0.8721**
00002326485	**MINT-PIOGLITAZONE**	**MPI**	$	**0.8721**
45 MG (BASE) ORAL TABLET				
00002339595	**ACH-PIOGLITAZONE**	**AHI**	$	**1.3113**
00002302896	**ACT PIOGLITAZONE**	**TEV**	$	**1.3113**
00002302977	**APO-PIOGLITAZONE**	**APX**	$	**1.3113**
00002365537	**JAMP-PIOGLITAZONE**	**JPC**	$	**1.3113**
00002326493	**MINT-PIOGLITAZONE**	**MPI**	$	**1.3113**

PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or Hematology, or a designated prescriber.)

"For the treatment of:

1) Second-line therapy of intra-abdominal sepsis where there are serious adverse events due to first-line therapy or documented failure of first-line therapy (e.g. ampicillin + gentamicin + metronidazole), as defined by clinical deterioration after 72 h of antibiotic therapy or lack of improvement after completion of antibiotic therapy or

2) Second-line therapy of severe polymicrobial skin and skin structure infections (e.g. limb threatening diabetic foot) or

3) Therapy of severe ventilator-associated pneumonia where Pseudomonas and Staphylococcus aureus coverage is needed, or

4) Therapy for infections involving multi-resistant Pseudomonas aeruginosa from pulmonary secretions in cystic fibrosis patients, lung transplant patients or patients with bronchiectasis , where there is documented susceptibility to piperacillin/tazobactam sodium, or

5) For use in other Health Canada approved indications, in consultation with a specialist in Infectious Diseases."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or Hematology, or a designated prescriber.

In order to comply with all of the above criteria, information is required regarding the type of infection and organisms involved. Also, where the criteria restrict coverage of the requested drug to non-first line therapy, information is required regarding previous first-line antibiotic therapy that has been utilized, the patient's response to therapy, and the first line agents the organism is resistant to or why other first-line therapies cannot be used in this patient. Also, where applicable, the specialist in Infectious Diseases that recommended this drug is required.

2 G / VIAL (BASE) * 250 MG / VIAL (BASE) INJECTION				
00002308444	**PIPERACILLIN AND TAZOBACTAM**	**APX**	$	**4.1727**
00002362619	**PIPERACILLIN AND TAZOBACTAM**	**STM**	$	**4.1727**
00002401312	**PIPERACILLIN AND TAZOBACTAM**	**TGT**	$	**4.1727**
00002299623	**PIPERACILLIN SODIUM/TAZOBACTAM SODIUM**	**SDZ**	$	**4.1727**
3 G / VIAL (BASE) * 375 MG / VIAL (BASE) INJECTION				
00002362627	**PIPERACILLIN AND TAZOBACTAM**	**STM**	$	**6.2591**
00002401320	**PIPERACILLIN AND TAZOBACTAM**	**TGT**	$	**6.2591**
00002299631	**PIPERACILLIN SODIUM/TAZOBACTAM SODIUM**	**SDZ**	$	**6.2591**
00002370166	**PIPERACILLIN/TAZOBACTAM**	**TEV**	$	**6.2591**
4 G / VIAL (BASE) * 500 MG / VIAL (BASE) INJECTION				
00002308460	**PIPERACILLIN AND TAZOBACTAM**	**APX**	$	**8.3458**
00002362635	**PIPERACILLIN AND TAZOBACTAM**	**STM**	$	**8.3458**
00002401339	**PIPERACILLIN AND TAZOBACTAM**	**TGT**	$	**8.3458**
00002299658	**PIPERACILLIN SODIUM/TAZOBACTAM SODIUM**	**SDZ**	$	**8.3458**
00002370174	**PIPERACILLIN/TAZOBACTAM**	**TEV**	$	**8.3458**

PIRFENIDONE

"Initial approval criteria:

Adult patients with a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF):
- Diagnosis confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.
-All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded.
- Mild to moderate IPF is defined as forced vital capacity (FVC) greater than or equal to 50% of predicted.
- Patient is under the care of a physician with experience in IPF.

Initial approval period: 7 months (allow 4 weeks for repeat pulmonary function tests)

Initial renewal criteria (at 6 months):

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of greater than or equal to 10% from initiation of therapy until renewal (initial 6 month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Approval period: 6 months

Second and subsequent renewals (at 12 months and thereafter):

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of greater than or equal to 10% within any 12 month period. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Approval period: 12 months

Exclusion Criteria:

Combination use of pirfenidone and nintedanib will not be funded.

Notes:

Patients who have experienced intolerance or failure to pirfenidone or nintedanib will be considered for the alternate agent provided that the patient continues to meet the above coverage criteria."

All requests for pirfenidone must be completed using the Nintedanib/Pirfenidone Special Authorization Request Form (ABC 60051).

267 MG ORAL TABLET				
00002514702	**JAMP PIRFENIDONE**	**JPC**	$	**6.7120**
00002488507	**SANDOZ PIRFENIDONE**	**SDZ**	$	**6.7120**
00002464489	ESBRIET	HLR	$	13.4240
801 MG ORAL TABLET				
00002514710	**JAMP PIRFENIDONE**	**JPC**	$	**20.1360**
00002488515	**SANDOZ PIRFENIDONE**	**SDZ**	$	**20.1360**
00002464500	ESBRIET	HLR	$	40.2720
267 MG ORAL CAPSULE				
00002509938	**JAMP PIRFENIDONE**	**JPC**	$	**6.7120**
00002488833	**SANDOZ PIRFENIDONE**	**SDZ**	$	**6.7120**
00002393751	ESBRIET	HLR	$	13.6251

PLERIXAFOR

"For the treatment of patients with Non-Hodgkin's lymphoma (NHL) or multiple myeloma (MM) undergoing Peripheral Blood Progenitor Cell (PBPC) collection and therapy, in combination with filgrastim, when prescribed by a designated prescriber."

Coverage may be approved for a maximum of 4 doses (0.24mg/kg given daily) for a single mobilization attempt.

All requests for Plerixafor must be completed using the Filgrastim/Pegfilgrastim/Plerixafor Special Authorization Request Form (ABC 60013).

Special authorization may be granted for 12 months.

20 MG / VIAL	**INJECTION**			
00002377225	MOZOBIL	SAV	$	7555.0000

PROPRANOLOL HCL

"For the treatment of proliferating infantile hemangioma requiring systemic therapy and at least one of the following:

- Life- or function-threatening hemangioma, OR
- Ulcerated hemangioma with pain and/or lack of response to simple wound care measures, OR
- Hemangioma with a risk of permanent scarring or disfigurement.

Special authorization may be granted for 12 months.

Continued coverage may be approved for a period of 12 months for patients who are responding to therapy or experience relapse of symptoms after treatment discontinuation."

3.75 MG / ML	**ORAL**	**SOLUTION**		
00002457857	HEMANGIOL	PIE	$	2.2808

RALOXIFENE HCL

Osteoporosis:

"For the treatment of osteoporosis in patients with a 20% or greater 10-year fracture risk who have documented intolerance to alendronate 70 mg or risedronate 35 mg. Special authorization may be granted for 6 months."

"Requests for other osteoporosis medications covered via special authorization will not be considered until 6 months after the last dose of denosumab 60 mg/syr injection syringe."

"Requests for other osteoporosis medications covered via special authorization will not be considered until 12 months after the last dose of zoledronic acid 0.05 mg/ml injection."

Note: The fracture risk can be determined by the World Health Organization's fracture risk assessment tool, FRAX, or the most recent (2010) version of the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) table.

All requests for raloxifene hydrochloride for Osteoporosis must be completed using the Alendronate/Raloxifene/Risedronate for Osteoporosis Special Authorization Request Form (ABC 60043).

The following product(s) are eligible for auto-renewal for the treatment of osteoporosis.

60 MG ORAL TABLET

00002358840	**ACT RALOXIFENE**	**APH**	$	**1.0268**
00002279215	**APO-RALOXIFENE**	**APX**	$	**1.0268**
00002239028	EVISTA	LIL	$	1.9593

RIBAVIRIN

200 MG ORAL TABLET

00002439212	IBAVYR	PPH	$	12.2399

For use within an Alberta Drug Benefit List (ADBL) funded combination therapy regimen for the treatment of chronic hepatitis C according to specific eligibility criteria corresponding to the regimen in which it is being administered. Use of ribavirin outside of an ADBL hepatitis C funded regimen will not be reimbursed.

(Refer to Section 3 of the Alberta Drug Benefit List for specific eligibility criteria corresponding to the regimen in which ribavirin is being administered for the treatment of Chronic Hepatitis C.)

RIFABUTIN

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For susceptible infections when prescribed in consultation with a Specialist in Infectious Diseases.

Special authorization may be granted for 6 months."*

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

The following product(s) are eligible for auto-renewal.

150 MG ORAL CAPSULE

00002063786	MYCOBUTIN	PFI	$	6.2161

RIFAXIMIN

"For reducing the risk of recurrent Hepatic Encephalopathy (HE) (i.e. 2 or more episodes), in patients with a diagnosis of cirrhosis of the liver or presence of portal hypertension.
Patients must have tried lactulose and been unable to achieve adequate control of HE recurrence with lactulose alone.
Rifaximin must be used in combination with a maximal tolerated dose of lactulose.

Special authorization may be granted for 6 months."

This product is eligible for auto-renewal.

550 MG ORAL TABLET

00002410702	ZAXINE	SLX	$	8.3030

RILUZOLE

"For use in patients who have probable or definite diagnosis of amyotrophic lateral sclerosis (ALS) as defined by World Federation of Neurology (WFN) criteria who have a vital capacity of >60% predicted and do not have a tracheostomy for invasive ventilation. This drug must be prescribed by a Specialist in Neurology."

"Patients who previously received Rilutek and were not eligible for the Phase IV study can also be considered for coverage if they meet the special authorization criteria."

"Coverage cannot be renewed once the patient has a tracheostomy for the purpose of invasive ventilation."

50 MG ORAL TABLET

00002352583	**APO-RILUZOLE**	**APX**	$	**3.4361**
00002390299	**MYLAN-RILUZOLE**	**MYP**	$	**3.4361**
00002242763	RILUTEK	SAV	$	10.3960

RISANKIZUMAB

Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:

- Have a total PASI of 10 or more and a DLQI of more than 10, OR

- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND

- Who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR

- Cyclosporine (6 weeks treatment); AND

- Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology (''Dermatology Specialist'').

Initial coverage may be approved for three doses of 150 mg of risankizumab at weeks 0, 4 and 16.

- Patients will be limited to receiving one 150 mg dose of risankizumab per prescription at their pharmacy.

- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of the initial coverage period.

- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.

- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet all of the following criteria:

1) The patient must be assessed by a Dermatology Specialist after the initial three doses to determine response.

2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:

- Greater than or equal to 75% reduction in PASI score, OR

- Greater than or equal to 50% reduction in PASI score AND improvement of greater than or

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equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for one 150 mg dose of risankizumab every 12 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above.

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for risankizumab for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Tildrakizumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:

- Have a total PASI of 10 or more and a DLQI of more than 10, OR

- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND

- Who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR

- Cyclosporine (6 weeks treatment); AND

- Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

Initial coverage may be approved for three doses of 150 mg of risankizumab at weeks 0, 4 and 16.

- Patients will be limited to receiving one 150 mg dose of risankizumab per prescription at their pharmacy.

- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of the initial coverage period.

- Patients will not be permitted to switch back to a previously trialed biologic agent if they

RISANKIZUMAB

were deemed unresponsive to therapy.

- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet all of the following criteria:

1) The patient must be assessed by a Dermatology Specialist after the initial three doses to determine response.

2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:

- Greater than or equal to 75% reduction in PASI score, OR

- Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for one 150 mg dose of risankizumab every 12 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above.

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for risankizumab for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Tildrakizumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

75 MG / SYR INJECTION SYRINGE				
00002487454	SKYRIZI	ABV	$	2467.5000
150 MG / SYR INJECTION SYRINGE				
☒ 00002519283	SKYRIZI	ABV	$	4935.0000
☒ 00002519291	SKYRIZI (PEN)	ABV	$	4935.0000

RISDIPLAM

"For patients diagnosed with 5q Spinal Muscular Atrophy (SMA) under the care of a specialist with experience in the diagnosis and management of SMA, if the following clinical criteria are met:

1) Genetic documentation of 5q SMA homozygous gene deletion or compound heterozygote, AND
2) Patients who:
- are symptomatic with two or three copies of SMN2, AND
- are between 2 months and 7 months (inclusive), OR
- are aged 8 months and up to 25 years inclusive, and are non-ambulatory.
AND
3) Patient is not currently requiring permanent invasive ventilation, AND
4) A baseline assessment using an age-appropriate scale (the Hammersmith Infant Neurological Examination [HINE] Section 2, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders [CHOP INTEND] or Hammersmith Functional Motor Scale-Expanded [HFMSE]) must be completed prior to initiation of risdiplam treatment.

Patients will be limited to receiving one month of risdiplam per prescription at their pharmacy. Coverage for risdiplam may be approved for 12 months as follows:
- 0.2 mg/kg/day for patients from 2 months to <2 years of age, or 0.25 mg/kg/day for patients >/=2 years of age and weighing less than 20 kg, or 5 mg/day for patients >/=2 years of age and weighing >/= 20 kg.

For continued coverage, the patient must meet the following criteria:
1) There is demonstrated maintenance of motor milestone function (as assessed using age-appropriate scales: the HINE Section 2, CHOP INTEND, or HFMSE) since treatment initiation; AND
2) Patient does not require permanent invasive ventilation*.

*Permanent invasive ventilation is defined as the use of tracheostomy and a ventilator due to progression of SMA that is not due to an identifiable and reversible cause.

SMA drug therapy and adeno-associated virus (AAV) vector-based gene therapy may not be used concomitantly. Additionally, use of a SMA drug therapy after administration of an AAV vector-based gene therapy will not be permitted, and coverage will not be approved when any SMA drug therapies are to be used in combination.

Patients currently receiving SMA drug therapy may be eligible to switch to an alternate SMA drug therapy; however, patients will not be permitted to switch back to a previously trialed SMA drug."

All requests (including renewal requests) for risdiplam must be completed using the Nusinersen/Risdiplam Special Authorization Request Form (ABC 60064).

0.75 MG / ML	**ORAL**	**SOLUTION**			
00002514931		EVRYSDI	HLR	$	145.4794

RISEDRONATE SODIUM

Osteoporosis:

"For the treatment of osteoporosis in patients with a 20% or greater 10-year fracture risk who have documented intolerance to alendronate 70 mg or risedronate 35 mg. Special authorization may be granted for 6 months."

"Requests for other osteoporosis medications covered via special authorization will not be considered until 6 months after the last dose of denosumab 60 mg/syr injection syringe."

"Requests for other osteoporosis medications covered via special authorization will not be considered until 12 months after the last dose of zoledronic acid 0.05 mg/ml injection."

Note: The fracture risk can be determined by the World Health Organization's fracture risk assessment tool, FRAX, or the most recent (2010) version of the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) table.

All requests for risedronate for Osteoporosis must be completed using the Alendronate/Raloxifene/Risedronate for Osteoporosis Special Authorization Request Form (ABC 60043).

The following product(s) are eligible for auto-renewal for the treatment of osteoporosis.

Paget's Disease:

"For the treatment of Paget's disease. Special Authorization for this criteria may be granted to a maximum of 2 months. Renewal requests may be considered following an observation period of at least 2 months."

"Coverage cannot be provided for two or more medications used in the treatment of Paget's disease when these medications are intended for use in combination or when therapy with two or more medications overlap."

5 MG ORAL TABLET				
00002298376	TEVA-RISEDRONATE	TEV	$	1.7565
30 MG ORAL TABLET				
00002298384	TEVA-RISEDRONATE	TEV	$	11.3807

RISPERIDONE

"For the management of the manifestations of schizophrenia and related psychotic disorders in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success and who possess clinical evidence of previous successful treatment with risperidone or paliperidone therapy;

AND who meet at least one of the following criteria:

- Experiences extra-pyramidal symptoms with either an oral or depot first generation antipsychotic agent that precludes the use of a first generation antipsychotic depot product; OR
- Is refractory to trials of at least two other antipsychotic therapies.

Special Authorization may be granted for six months."

All requests (including renewal requests) for risperidone prolonged release injection must be completed using the Aripiprazole/Paliperidone/Risperidone Prolonged Release Injection Special Authorization Request Form (ABC 60024).

The following product(s) are eligible for auto-renewal.

25 MG / VIAL INJECTION				
00002255707	RISPERDAL CONSTA	JAI	$	180.1000
37.5 MG / VIAL INJECTION				
00002255723	RISPERDAL CONSTA	JAI	$	270.1400
50 MG / VIAL INJECTION				
00002255758	RISPERDAL CONSTA	JAI	$	360.1800

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10 MG / ML INJECTION

☒ 00002498316 RIXIMYO SDZ $ 29.7000

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily); AND
- One anti-tumor necrosis factor (anti-TNF) therapy (minimum 12 week trial).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for a dose of 1000 mg of rituximab administered at 0 and 2 weeks (total of 2 - 1000 mg doses).
- Patients will be limited to receiving one dose of rituximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For coverage for an additional two-dose course of therapy, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after each course of therapy, between 16 and 24 weeks after receiving the initial dose of each course of therapy, to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- An improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place] following the initial course of rituximab; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places] following the initial course of rituximab.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above, AND
3) The patient must have residual disease or disease activity returning to a level above a DAS28 score of 2.6.

Subsequent courses of therapy cannot be considered prior to 24 weeks elapsing from the initial dose of the previous course of therapy."

All requests (including renewal requests) for rituximab for Rheumatoid Arthritis must be completed using the Rituximab for Rheumatoid Arthritis Special Authorization Request Form (ABC 60046).

Granulomatosis with polyangiitis (GPA) or Microscopic Polyangiitis (MPA)

"For use in combination with glucocorticoids for the induction of remission of severely active granulomatosis with polyangiitis (GPA, also known as Wegener's granulomatosis) or microscopic polyangiitis (MPA) in adult patients who have:
- Severe active disease that is life- or organ-threatening. The organ(s) and how the organ(s) is (are) threatened must be specified;
AND

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- A positive serum assay for either proteinase 3-ANCA (anti-neutrophil cytoplasmic antibody) or myeloperoxidase-ANCA. A copy of the lab report must be provided; AND
- Cyclophosphamide cannot be used for ONE of the following reasons:
a) The patient has failed a minimum of six intravenous pulses of cyclophosphamide; OR
b) The patient has failed three months of oral cyclophosphamide therapy; OR
c) The patient has a severe intolerance or an allergy to cyclophosphamide; OR
d) Cyclophosphamide is contraindicated; OR
e) The patient has received a cumulative lifetime dose of at least 25 grams of cyclophosphamide.

- Coverage may be approved for a maximum of 375 mg per square metre of body surface area weekly for 4 weeks.
- Patients will be limited to receiving two doses of rituximab per prescription at their pharmacy.
- For relapse following a remission, coverage may be provided for patients who experience a flare of severe active disease that is life- or organ-threatening; or, who experience worsening symptoms in 2 or more organs even if not life-threatening. Note: For relapse following a rituximab-induced remission, additional coverage may be approved no sooner than 6 months after previous rituximab treatment."

All requests (including renewal requests) for rituximab for Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA) must be completed using the Rituximab for Granulomatosis with Polyangiitis/Microscopic Polyangiitis Special Authorization Request Form (ABC 60018).

☒ 00002495724 RUXIENCE PFI $ 29.7000

Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA)

"For use in combination with glucocorticoids for the induction of remission of severely active granulomatosis with polyangiitis (GPA, also known as Wegener's granulomatosis) or microscopic polyangiitis (MPA) in adult patients who have:
- Severe active disease that is life- or organ-threatening. The organ(s) and how the organ(s) is (are) threatened must be specified;
AND
- A positive serum assay for either proteinase 3-ANCA (anti-neutrophil cytoplasmic antibody) or myeloperoxidase-ANCA. A copy of the lab report must be provided; AND
- Cyclophosphamide cannot be used for ONE of the following reasons:
a) The patient has failed a minimum of six intravenous pulses of cyclophosphamide; OR
b) The patient has failed three months of oral cyclophosphamide therapy; OR
c) The patient has a severe intolerance or an allergy to cyclophosphamide; OR
d) Cyclophosphamide is contraindicated; OR
e) The patient has received a cumulative lifetime dose of at least 25 grams of cyclophosphamide.

- Coverage may be approved for a maximum of 375 mg per square metre of body surface area weekly for 4 weeks.
- Patients will be limited to receiving two doses of rituximab per prescription at their pharmacy.
- For relapse following a remission, coverage may be provided for patients who experience a flare of severe active disease that is life- or organ-threatening; or, who experience worsening symptoms in 2 or more organs even if not life-threatening. Note: For relapse following a rituximab-induced remission, additional coverage may be approved no sooner than 6 months after previous rituximab treatment."

All requests (including renewal requests) for rituximab for Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA) must be completed using the Rituximab for Granulomatosis with Polyangiitis/Microscopic Polyangiitis Special Authorization Request Form (ABC 60018).

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily); AND
- One anti-tumor necrosis factor (anti-TNF) therapy (minimum 12 week trial).

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'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for a dose of 1000 mg of rituximab administered at 0 and 2 weeks (total of 2 - 1000 mg doses).
- Patients will be limited to receiving one dose of rituximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For coverage for an additional two-dose course of therapy, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after each course of therapy, between 16 and 24 weeks after receiving the initial dose of each course of therapy, to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- An improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place] following the initial course of rituximab; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places] following the initial course of rituximab.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above, AND
3) The patient must have residual disease or disease activity returning to a level above a DAS28 score of 2.6.

Subsequent courses of therapy cannot be considered prior to 24 weeks elapsing from the initial dose of the previous course of therapy."

All requests (including renewal requests) for rituximab for Rheumatoid Arthritis must be completed using the Rituximab for Rheumatoid Arthritis Special Authorization Request Form (ABC 60046).

☒ 00002478382 TRUXIMA (10 ML) CTC $ 29.7000

Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA)

"For use in combination with glucocorticoids for the induction of remission of severely active granulomatosis with polyangiitis (GPA, also known as Wegener's granulomatosis) or microscopic polyangiitis (MPA) in adult patients who have:
- Severe active disease that is life- or organ-threatening. The organ(s) and how the organ(s) is (are) threatened must be specified;
AND
- A positive serum assay for either proteinase 3-ANCA (anti-neutrophil cytoplasmic antibody) or myeloperoxidase-ANCA. A copy of the lab report must be provided; AND
- Cyclophosphamide cannot be used for ONE of the following reasons:
a) The patient has failed a minimum of six intravenous pulses of cyclophosphamide; OR
b) The patient has failed three months of oral cyclophosphamide therapy; OR
c) The patient has a severe intolerance or an allergy to cyclophosphamide; OR
d) Cyclophosphamide is contraindicated; OR
e) The patient has received a cumulative lifetime dose of at least 25 grams of cyclophosphamide.

- Coverage may be approved for a maximum of 375 mg per square metre of body surface area weekly for 4 weeks.
- Patients will be limited to receiving two doses of rituximab per prescription at their pharmacy.
- For relapse following a remission, coverage may be provided for patients who experience a flare of severe active disease that is life- or organ-threatening; or, who experience worsening symptoms in 2 or more organs even if not life-threatening. Note: For relapse following a rituximab-induced

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remission, additional coverage may be approved no sooner than 6 months after previous rituximab treatment."

All requests (including renewal requests) for rituximab for Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA) must be completed using the Rituximab for Granulomatosis with Polyangiitis/Microscopic Polyangiitis Special Authorization Request Form (ABC 60018).

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily); AND
- One anti-tumor necrosis factor (anti-TNF) therapy (minimum 12 week trial).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for a dose of 1000 mg of rituximab administered at 0 and 2 weeks (total of 2 - 1000 mg doses).
- Patients will be limited to receiving one dose of rituximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For coverage for an additional two-dose course of therapy, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after each course of therapy, between 16 and 24 weeks after receiving the initial dose of each course of therapy, to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- An improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place] following the initial course of rituximab; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places] following the initial course of rituximab.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above, AND
3) The patient must have residual disease or disease activity returning to a level above a DAS28 score of 2.6.

Subsequent courses of therapy cannot be considered prior to 24 weeks elapsing from the initial dose of the previous course of therapy."

All requests (including renewal requests) for rituximab for Rheumatoid Arthritis must be completed using the Rituximab for Rheumatoid Arthritis Special Authorization Request Form (ABC 60046).

☒	00002478390	TRUXIMA (50 ML)	CTC	$	29.7000

Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA)

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"For use in combination with glucocorticoids for the induction of remission of severely active granulomatosis with polyangiitis (GPA, also known as Wegener's granulomatosis) or microscopic polyangiitis (MPA) in adult patients who have:
- Severe active disease that is life- or organ-threatening. The organ(s) and how the organ(s) is (are) threatened must be specified;
AND
- A positive serum assay for either proteinase 3-ANCA (anti-neutrophil cytoplasmic antibody) or myeloperoxidase-ANCA. A copy of the lab report must be provided; AND
- Cyclophosphamide cannot be used for ONE of the following reasons:
a) The patient has failed a minimum of six intravenous pulses of cyclophosphamide; OR
b) The patient has failed three months of oral cyclophosphamide therapy; OR
c) The patient has a severe intolerance or an allergy to cyclophosphamide; OR
d) Cyclophosphamide is contraindicated; OR
e) The patient has received a cumulative lifetime dose of at least 25 grams of cyclophosphamide.

- Coverage may be approved for a maximum of 375 mg per square metre of body surface area weekly for 4 weeks.
- Patients will be limited to receiving two doses of rituximab per prescription at their pharmacy.
- For relapse following a remission, coverage may be provided for patients who experience a flare of severe active disease that is life- or organ-threatening; or, who experience worsening symptoms in 2 or more organs even if not life-threatening. Note: For relapse following a rituximab-induced remission, additional coverage may be approved no sooner than 6 months after previous rituximab treatment."

All requests (including renewal requests) for rituximab for Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA) must be completed using the Rituximab for Granulomatosis with Polyangiitis/Microscopic Polyangiitis Special Authorization Request Form (ABC 60018).

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily); AND
- One anti-tumor necrosis factor (anti-TNF) therapy (minimum 12 week trial).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for a dose of 1000 mg of rituximab administered at 0 and 2 weeks (total of 2 - 1000 mg doses).
- Patients will be limited to receiving one dose of rituximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For coverage for an additional two-dose course of therapy, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after each course of therapy, between 16 and

RITUXIMAB

24 weeks after receiving the initial dose of each course of therapy, to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- An improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place] following the initial course of rituximab; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places] following the initial course of rituximab.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above, AND
3) The patient must have residual disease or disease activity returning to a level above a DAS28 score of 2.6.

Subsequent courses of therapy cannot be considered prior to 24 weeks elapsing from the initial dose of the previous course of therapy."

All requests (including renewal requests) for rituximab for Rheumatoid Arthritis must be completed using the Rituximab for Rheumatoid Arthritis Special Authorization Request Form (ABC 60046).

RIVAROXABAN

For use in combination with acetylsalicylic acid (ASA; 75 mg to 100 mg) for the prevention of stroke, myocardial infarction, and cardiovascular death, and for the prevention of acute limb ischemia and mortality in patients with concomitant coronary artery disease (CAD) and peripheral artery disease (PAD) as defined below.

Patients with CAD are defined as having one or more of the following:
1) myocardial infarction within the last 20 years
2) multi-vessel coronary disease (i.e., stenosis of greater than or equal to 50 per cent in two or more coronary arteries, or in one coronary territory if at least one other territory has been revascularized) with symptoms or history of stable or unstable angina
3) multi-vessel percutaneous coronary intervention
4) multi-vessel coronary artery bypass graft surgery.

For coverage, patients with CAD as defined above must also meet one of the following criteria:
- aged 65 years or older, or
- aged younger than 65 years with documented atherosclerosis or revascularization involving at least two vascular beds (coronary and other vascular) or at least two additional risk factors (current smoker, diabetes mellitus, estimated glomerular filtration rate less than 60 mL/min, heart failure, non-lacunar ischemic stroke 1 month or more ago).

Patients with PAD are defined as having one or more of the following:
1) previous aorto-femoral bypass surgery, limb bypass surgery, or percutaneous transluminal angioplasty revascularization of the iliac or infrainguinal arteries
2) previous limb or foot amputation for arterial vascular disease
3) history of intermittent claudication and one or more of the following:
- an anklebrachial index less than 0.90
- significant peripheral stenosis (greater than or equal to 50%) documented by angiography or by duplex ultrasound
4) previous carotid revascularization or asymptomatic carotid artery stenosis greater than or equal to 50%, as diagnosed by duplex ultrasound or angiography.

Exclusions from coverage:
- Patients who have CAD or PAD alone, OR;
- Patients with any one of the following characteristics:
1) at high risk of bleeding
2) a history of stroke within one month of treatment initiation or any history of hemorrhagic or lacunar stroke
3) severe heart failure with a known ejection fraction less than 30% or New York Heart Association (NYHA) class III or IV symptoms
4) an estimated glomerular filtration rate less than 15 mL/min
5) require dual antiplatelet therapy, other non-ASA antiplatelet therapy, or oral anticoagulant therapy.

Special authorization may be granted for six months. This product is eligible for auto-renewal.

All requests for rivaroxaban 2.5 mg must be completed using the Rivaroxaban 2.5 mg Special Authorization Request Form (ABC 60081).

2.5 MG ORAL TABLET

00002480808	XARELTO	BAI	$	1.4200

RIVAROXABAN
NON-VALVULAR ATRIAL FIBRILLATION

SPECIAL AUTHORIZATION (step therapy approval process)

FIRST-LINE DRUG PRODUCT(S): WARFARIN

Coverage

Members of Alberta Government Sponsored Drug Plans who are at-risk with non-valvular atrial fibrillation (AF) who require the Drug Products for the prevention of stroke and systemic embolism AND in whom one of the following is also present:

- Inadequate Anticoagulation following a Reasonable Trial on Warfarin; OR
- Anticoagulation with warfarin is contraindicated or not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

At-risk patients with atrial fibrillation are defined as those with a CHADS2 score of greater than or equal to 1. Although the ROCKET-AF trial included patients with higher CHADS2 scores (greater than or equal to 2), other landmark studies with the other newer oral anticoagulants demonstrated a therapeutic benefit in patients with a CHADS2 score of 1. Coverage may be considered for an antiplatelet regimen or oral anticoagulation for patients with a CHADS2 score of 1.

Exclusion from Coverage:
- Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate <30 mL/min) OR
- Greater than or equal to 75 years of age and without Documented Stable Renal Function; OR
- hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis; OR
- prosthetic heart valves.

Definitions:
- Documented Stable Renal Function is defined as creatinine clearance or estimated glomerular filtration rate that is maintained for at least 3 months (i.e. 30-49 mL/min for 15 mg once daily dosing or greater than or equal to 50 mL/Min for 20 mg once daily dosing).
- Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period (i.e. adequate anticoagulation is defined as INR test results that are within the desired INR range for at least 65% of the tests during the monitoring period).
- Reasonable Trial on Warfarin is defined as at least 2 months of therapy.

OTHER CRITERIA:
- Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see Drug Product monograph).
- Patients starting the Drug Product should have ready access to appropriate medical services to manage a major bleeding event.
- There is currently no data to support that the Drug Product provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so Drug Product is not recommended in these populations.

Special Authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

RIVAROXABAN

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

VENOUS THROMBOEMBOLIC EVENTS

SPECIAL AUTHORIZATION

COVERAGE:

"For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE).

OTHER CRITERIA:

The recommended dose of rivaroxaban for patients initiating DVT or PE treatment is 15 mg twice daily for 3 weeks, followed by 20 mg once daily.

Drug plan coverage for rivaroxaban is an alternative to heparin/warfarin for up to 6 months. When used for greater than 6 months, rivaroxaban is more costly than heparin/warfarin. As such, patients with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin.

Special authorization may be granted for up to 6 months."

All requests for rivaroxaban must be completed using the Apixaban/Dabigatran/Edoxaban/Rivaroxaban Special Authorization Request Form (ABC 60019).

15 MG ORAL TABLET

00002378604	XARELTO	BAI	$	2.8700

RIVAROXABAN
NON-VALVULAR ATRIAL FIBRILLATION

SPECIAL AUTHORIZATION (step therapy approval process)

FIRST-LINE DRUG PRODUCT(S): WARFARIN

Coverage

Members of Alberta Government Sponsored Drug Plans who are at-risk with non-valvular atrial fibrillation (AF) who require the Drug Products for the prevention of stroke and systemic embolism AND in whom one of the following is also present:

- Inadequate Anticoagulation following a Reasonable Trial on Warfarin; OR
- Anticoagulation with warfarin is contraindicated or not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

At-risk patients with atrial fibrillation are defined as those with a CHADS2 score of greater than or equal to 1. Although the ROCKET-AF trial included patients with higher CHADS2 scores (greater than or equal to 2), other landmark studies with the other newer oral anticoagulants demonstrated a therapeutic benefit in patients with a CHADS2 score of 1. Coverage may be considered for an antiplatelet regimen or oral anticoagulation for patients with a CHADS2 score of 1.

Exclusion from Coverage:
- Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate <30 mL/min) OR
- Greater than or equal to 75 years of age and without Documented Stable Renal Function; OR
- hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis; OR
- prosthetic heart valves.

Definitions:
- Documented Stable Renal Function is defined as creatinine clearance or estimated glomerular filtration rate that is maintained for at least 3 months (i.e. 30-49 mL/min for 15 mg once daily dosing or greater than or equal to 50 mL/Min for 20 mg once daily dosing).
- Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period (i.e. adequate anticoagulation is defined as INR test results that are within the desired INR range for at least 65% of the tests during the monitoring period).
- Reasonable Trial on Warfarin is defined as at least 2 months of therapy.

OTHER CRITERIA:
- Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see Drug Product monograph).
- Patients starting the Drug Product should have ready access to appropriate medical services to manage a major bleeding event.
- There is currently no data to support that the Drug Product provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so Drug Product is not recommended in these populations.

Special Authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

RIVAROXABAN

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

VENOUS THROMBOEMBOLIC EVENTS

SPECIAL AUTHORIZATION

COVERAGE:

"For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE).

OTHER CRITERIA:

The recommended dose of rivaroxaban for patients initiating DVT or PE treatment is 15 mg twice daily for 3 weeks, followed by 20 mg once daily.

Drug plan coverage for rivaroxaban is an alternative to heparin/warfarin for up to 6 months. When used for greater than 6 months, rivaroxaban is more costly than heparin/warfarin. As such, patients with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin.

Special authorization may be granted for up to 6 months."

All requests for rivaroxaban must be completed using the Apixaban/Dabigatran/Edoxaban/Rivaroxaban Special Authorization Request Form (ABC 60019).

20 MG ORAL TABLET

00002378612	XARELTO	BAI	$	2.8700

RIVASTIGMINE HYDROGEN TARTRATE

"For the treatment of Alzheimers disease in patients who meet the following criteria:
- a Mini Mental State Exam (MMSE) score between 10-26, or
- a St. Louis University Mental Status Examination (SLUMS) score between 6-26, or
- a Rowland Universal Dementia Assessment Scale (RUDAS) score between 9-22, or
- an InterRAI-Cognitive Performance Scale score between 1-4

Coverage cannot be provided for two or more medications used in the treatment of Alzheimer's disease (donepezil, galantamine, rivastigmine) when these medications are intended for use in combination.

Special Authorization coverage may be granted for a maximum of 24 months per request.

For each request, an updated score (MMSE, SLUMS, RUDAS or InterRAI-Cognitive Performance Scale) and the date on which the exam was administered must be provided.

Renewal requests may be considered for patients where an updated score while on this drug meets the following criteria:
- MMSE score is 10 or higher, or
- SLUMS score is 6 or higher, or
- RUDAS score is 9 or higher, or
- InterRAI-Cognitive Performance Scale is 4 or lower."

All requests (including renewal requests) for rivastigmine hydrogen tartrate must be completed using the Donepezil/Galantamine/Rivastigmine Special Authorization Request From (ABC 60034).

1.5 MG (BASE) ORAL CAPSULE				
00002336715	**APO-RIVASTIGMINE**	**APX**	$	**0.6514**
00002485362	**JAMP RIVASTIGMINE**	**JPC**	$	**0.6514**
00002401614	**MED-RIVASTIGMINE**	**GMP**	$	**0.6514**
00002324563	**SANDOZ RIVASTIGMINE**	**SDZ**	$	**0.6514**
00002242115	EXELON	KTI	$	2.9111
3 MG (BASE) ORAL CAPSULE				
00002336723	**APO-RIVASTIGMINE**	**APX**	$	**0.6514**
00002485370	**JAMP RIVASTIGMINE**	**JPC**	$	**0.6514**
00002401622	**MED-RIVASTIGMINE**	**GMP**	$	**0.6514**
00002324571	**SANDOZ RIVASTIGMINE**	**SDZ**	$	**0.6514**
00002242116	EXELON	KTI	$	2.9111
4.5 MG (BASE) ORAL CAPSULE				
00002336731	**APO-RIVASTIGMINE**	**APX**	$	**0.6514**
00002485389	**JAMP RIVASTIGMINE**	**JPC**	$	**0.6514**
00002401630	**MED-RIVASTIGMINE**	**GMP**	$	**0.6514**
00002324598	**SANDOZ RIVASTIGMINE**	**SDZ**	$	**0.6514**
00002242117	EXELON	KTI	$	2.9111
6 MG (BASE) ORAL CAPSULE				
00002336758	**APO-RIVASTIGMINE**	**APX**	$	**0.6514**
00002485397	**JAMP RIVASTIGMINE**	**JPC**	$	**0.6514**
00002401649	**MED-RIVASTIGMINE**	**GMP**	$	**0.6514**
00002324601	**SANDOZ RIVASTIGMINE**	**SDZ**	$	**0.6514**
00002242118	EXELON	KTI	$	2.9111
2 MG / ML (BASE) ORAL SOLUTION				
00002245240	EXELON	KTI	$	1.5304

RIZATRIPTAN BENZOATE

(Refer to 28:32.28 of the Alberta Drug Benefit List for coverage of patients 18 to 64 years of age inclusive.)

"For the treatment of acute migraine attacks in patients 65 years of age and older where other standard therapy has failed."

"For the treatment of acute migraine attacks in patients 65 years of age and older who have been using rizatriptan benzoate prior to turning 65."

"Special authorization for both criteria may be granted for 24 months."

In order to comply with the first criteria, information is required regarding previous medications utilized and the patient's response to therapy.

The following product(s) are eligible for auto-renewal.

5 MG (BASE) ORAL TABLET				
00002393468	APO-RIZATRIPTAN	APX	$	7.4100
10 MG (BASE) ORAL TABLET				
00002381702	**ACT RIZATRIPTAN**	**TEV**	$	**3.7050**
00002393476	**APO-RIZATRIPTAN**	**APX**	$	**3.7050**
00002441144	**AURO-RIZATRIPTAN**	**AUR**	$	**3.7050**
00002380463	**JAMP-RIZATRIPTAN**	**JPC**	$	**3.7050**
00002429241	**JAMP-RIZATRIPTAN IR**	**JPC**	$	**3.7050**
00002379678	**MAR-RIZATRIPTAN**	**MAR**	$	**3.7050**
00002516756	**RIZATRIPTAN**	**SNS**	$	**3.7050**
00002240521	MAXALT	ORC	$	17.3420
5 MG (BASE) ORAL DISINTEGRATING TABLET				
00002483270	**ACCEL-RIZATRIPTAN ODT**	**ACP**	$	**2.8150**
00002458764	CCP-RIZATRIPTAN ODT	CEL	$	2.9633
00002465086	JAMP-RIZATRIPTAN ODT	JPC	$	3.7050
00002462788	MAR-RIZATRIPTAN ODT	MAR	$	3.7050
00002379198	MYLAN-RIZATRIPTAN ODT	MYP	$	3.7050
00002436604	NAT-RIZATRIPTAN ODT	NTP	$	3.7050
00002393360	PMS-RIZATRIPTAN RDT	PMS	$	3.7050
00002442906	RIZATRIPTAN ODT	SNS	$	3.7050
00002446111	RIZATRIPTAN ODT	SIV	$	3.7050
00002351870	SANDOZ RIZATRIPTAN ODT	SDZ	$	3.7050
00002396661	TEVA-RIZATRIPTAN ODT	TEV	$	3.7050
00002240518	MAXALT RPD	ORC	$	17.3420
10 MG (BASE) ORAL DISINTEGRATING TABLET				
00002483289	**ACCEL-RIZATRIPTAN ODT**	**ACP**	$	**2.8150**
00002458772	CCP-RIZATRIPTAN ODT	CEL	$	2.9633
00002492490	AG-RIZATRIPTAN ODT	AGP	$	3.7050
00002465094	JAMP-RIZATRIPTAN ODT	JPC	$	3.7050
00002462796	MAR-RIZATRIPTAN ODT	MAR	$	3.7050
00002379201	MYLAN-RIZATRIPTAN ODT	MYP	$	3.7050
00002436612	NAT-RIZATRIPTAN ODT	NTP	$	3.7050
00002393379	PMS-RIZATRIPTAN RDT	PMS	$	3.7050
00002442914	RIZATRIPTAN ODT	SNS	$	3.7050
00002446138	RIZATRIPTAN ODT	SIV	$	3.7050
00002351889	SANDOZ RIZATRIPTAN ODT	SDZ	$	3.7050
00002396688	TEVA-RIZATRIPTAN ODT	TEV	$	3.7050
00002240519	MAXALT RPD	ORC	$	17.3420

ROSIGLITAZONE MALEATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): METFORMIN

"For the treatment of Type 2 diabetes in patients who have an inadequate response to a sufficient trial (i.e. a minimum of 6 months) of metformin or who are intolerant to metformin (e.g. dermatologic reactions) or for whom the product is contraindicated."

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

2 MG (BASE) ORAL TABLET				
00002403366	ROSIGLITAZONE	AAP	$	1.0316
4 MG (BASE) ORAL TABLET				
00002403374	ROSIGLITAZONE	AAP	$	1.6188
8 MG (BASE) ORAL TABLET				
00002403382	ROSIGLITAZONE	AAP	$	2.3150

ROTIGOTINE

"For adjunctive therapy to levodopa for the treatment of patients with advanced stage Parkinson's disease (APD).

Special authorization may be granted for six months."

This product is eligible for auto-renewal.

2 MG/24HR TRANSDERMAL PATCH				
00002403900	NEUPRO	UCB	$	3.5400
4 MG/24HR TRANSDERMAL PATCH				
00002403927	NEUPRO	UCB	$	6.5000
6 MG/24HR TRANSDERMAL PATCH				
00002403935	NEUPRO	UCB	$	7.2700
8 MG/24HR TRANSDERMAL PATCH				
00002403943	NEUPRO	UCB	$	7.2700

RUFINAMIDE

"For the treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients who meet the following criteria:
- are currently taking two or more anti-epileptic drugs (AEDs) without optimal seizure control; AND
- have failed or demonstrated intolerance to adequate trials of both lamotrigine AND topiramate; AND
- therapy must be initiated by a Neurologist.

Special authorization may be granted for six months."

This product is eligible for auto-renewal.

100 MG ORAL TABLET				
00002369613	BANZEL	EIS	$	0.7805
200 MG ORAL TABLET				
00002369621	BANZEL	EIS	$	1.5610
400 MG ORAL TABLET				
00002369648	BANZEL	EIS	$	3.4013

SACUBITRIL/ VALSARTAN

"For the treatment of heart failure (HF) in patients with the following criteria:

1) reduced left ventricular ejection fraction (LVEF) (< 40%)
And
2) New York Heart Association (NYHA) class II or III HF symptoms despite at least FOUR weeks of treatment with:
- a stable dose of an angiotensin-converting enzyme inhibitor (ACEI) or an angiotensin II receptor antagonist (ARB)
- in combination with a beta-blocker and other recommended therapies, including an aldosterone antagonist (if tolerable)
And
3) who have Plasma B-type natriuretic peptide (BNP) >= 150 pg/mL or N-terminal prohormone B-type natriuretic peptide (NT-proBNP) >= 600 pg/mL; or
- if the patient has been hospitalized for HF within the past 12 months and has plasma BNP >= 100 pg/mL or NT-proBNP >= 400 pg/mL levels

For coverage, this drug must be initiated by a Specialist in Cardiology or Internal Medicine, and the initial request must be completed by the Specialist.

Special authorization may be granted for six months."

This product is eligible for auto-renewal.

All requests (including renewal requests) for sacubitril+valsartan must be completed using the Eplerenone/Ivabradine/Sacubitril+Valsartan Special Authorization Request Form (ABC 60050).

24.3 MG * 25.7 MG ORAL TABLET				
00002446928	ENTRESTO	NOV	$	3.7060
48.6 MG * 51.4 MG ORAL TABLET				
00002446936	ENTRESTO	NOV	$	3.7060
97.2 MG * 102.8 MG ORAL TABLET				
00002446944	ENTRESTO	NOV	$	3.7060

SALMETEROL XINAFOATE/ FLUTICASONE PROPIONATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

ASTHMA

FIRST-LINE DRUG PRODUCT(S): INHALED CORTICOSTEROID (ICS)

"For the treatment of asthma in patients uncontrolled on inhaled steroid therapy."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for salmeterol xinafoate + fluticasone propionate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

25 MCG / DOSE (BASE)	* 125 MCG / DOSE	INHALATION	METERED DOSE AEROSOL		
00002245126	ADVAIR 125		GSK	$	0.9099

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

ASTHMA

FIRST-LINE DRUG PRODUCT(S): INHALED CORTICOSTEROID (ICS)

"For the treatment of asthma in patients uncontrolled on inhaled steroid therapy."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for salmeterol xinafoate + fluticasone propionate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

25 MCG / DOSE (BASE)	* 250 MCG / DOSE	INHALATION	METERED DOSE AEROSOL		
00002245127	ADVAIR 250		GSK	$	1.2917

SALMETEROL XINAFOATE/ FLUTICASONE PROPIONATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

ASTHMA

FIRST-LINE DRUG PRODUCT(S): INHALED CORTICOSTEROID (ICS)

"For the treatment of asthma in patients uncontrolled on inhaled steroid therapy."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for salmeterol xinafoate + fluticasone propionate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

50 MCG / DOSE (BASE)	* 100 MCG / DOSE	INHALATION	METERED INHALATION POWDER		
00002494507	**PMS-FLUTICASONE/SALMETEROL DPI**	**PMS**	$	**0.7068**
00002495597	**WIXELA INHUB**	**MYP**	$	**0.7068**
00002240835	ADVAIR 100 DISKUS	GSK	$	1.5202

SALMETEROL XINAFOATE/ FLUTICASONE PROPIONATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

ASTHMA

FIRST-LINE DRUG PRODUCT(S): INHALED CORTICOSTEROID (ICS)

"For the treatment of asthma in patients uncontrolled on inhaled steroid therapy."

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S): LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])

"For the long-term maintenance treatment of airflow obstruction in patients with moderate to severe (i.e., FEV1 < 80% predicted) chronic obstructive pulmonary disease (COPD), who have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA])."

"For the long-term maintenance treatment of airflow obstruction in patients with severe (i.e., FEV1 < 50% predicted) chronic obstructive pulmonary disease (COPD)."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for salmeterol xinafoate + fluticasone propionate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

50 MCG / DOSE (BASE) * 250 MCG / DOSE INHALATION METERED INHALATION POWDER				
00002494515	**PMS-FLUTICASONE/SALMETEROL DPI**	**PMS**	$	**0.8460**
00002495600	**WIXELA INHUB**	**MYP**	$	**0.8460**
00002240836	ADVAIR 250 DISKUS	GSK	$	1.8198

SALMETEROL XINAFOATE/ FLUTICASONE PROPIONATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

ASTHMA

FIRST-LINE DRUG PRODUCT(S): INHALED CORTICOSTEROID (ICS)

"For the treatment of asthma in patients uncontrolled on inhaled steroid therapy."

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S): LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])

"For the long-term maintenance treatment of airflow obstruction in patients with moderate to severe (i.e., FEV1 < 80% predicted) chronic obstructive pulmonary disease (COPD), who have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA])."

"For the long-term maintenance treatment of airflow obstruction in patients with severe (i.e., FEV1 < 50% predicted) chronic obstructive pulmonary disease (COPD)."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for salmeterol xinafoate + fluticasone propionate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

50 MCG / DOSE (BASE) * 500 MCG / DOSE INHALATION METERED INHALATION POWDER

00002494523	**PMS-FLUTICASONE/SALMETEROL DPI**	**PMS**	$	**1.2010**
00002495619	**WIXELA INHUB**	**MYP**	$	**1.2010**
00002240837	ADVAIR 500 DISKUS	GSK	$	2.5834

SARILUMAB

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial) [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

Initial coverage may be approved for up to 200 mg of sarilumab given subcutaneously every 2 weeks for 12 weeks.
- Patients will be limited to receiving a one-month supply of sarilumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 12 weeks to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for one subcutaneous dose of up to 200 mg every 2 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- confirmation of maintenance of ACR20, OR
- maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal

SARILUMAB

requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for sarilumab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

150 MG / SYR INJECTION				
00002472961	KEVZARA (PREFILLED PEN)	SAV	$	745.6900
200 MG / SYR INJECTION				
00002472988	KEVZARA (PREFILLED PEN)	SAV	$	745.6900
200 MG / SYR INJECTION SYRINGE				
00002460548	KEVZARA	SAV	$	745.6900

SAXAGLIPTIN HCL

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): METFORMIN
SECOND-LINE DRUG PRODUCT(S): SULFONYLUREAS
AND WHERE INSULIN IS NOT AN OPTION

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:
- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated
CA - Prior adverse reaction
CB - Previous treatment failure
CJ - Product is not effective

All requests for saxagliptin must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

2.5 MG ORAL TABLET				
00002507471	**APO-SAXAGLIPTIN**	**APX**	$	**1.2650**
00002468603	**SANDOZ SAXAGLIPTIN**	**SDZ**	$	**1.2650**
00002375842	ONGLYZA	AZC	$	2.6153
5 MG (BASE) ORAL TABLET				
00002507498	**APO-SAXAGLIPTIN**	**APX**	$	**1.5195**
00002468611	**SANDOZ SAXAGLIPTIN**	**SDZ**	$	**1.5195**
00002333554	ONGLYZA	AZC	$	3.1015

SAXAGLIPTIN HCL/ METFORMIN HCL

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): METFORMIN
SECOND-LINE DRUG PRODUCT(S): SULFONYLUREAS
AND WHERE INSULIN IS NOT AN OPTION

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:
- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated
CA - Prior adverse reaction
CB - Previous treatment failure
CJ - Product is not effective

All requests for saxagliptin+metformin must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

2.5 MG (BASE) * 500 MG ORAL TABLET				
00002389169	KOMBOGLYZE	AZC	$	1.3335
2.5 MG (BASE) * 850 MG ORAL TABLET				
00002389177	KOMBOGLYZE	AZC	$	1.3335
2.5 MG (BASE) * 1,000 MG ORAL TABLET				
00002389185	KOMBOGLYZE	AZC	$	1.3335

SEBELIPASE ALFA

1. ELIGIBILITY CRITERIA FOR SEBELIPASE ALFA COVERAGE

In order to maintain the integrity of the ADBL, and having regard to the financial and social implications of covering sebelipase alfa for the treatment of lysosomal acid lipase (LAL) deficiency, the following special authorization criteria must be satisfied.

In order to be eligible for sebelipase alfa coverage for the treatment of LAL deficiency, a patient must have submitted a completed Application and have satisfied all of the following requirements:

The patient must:
1) Be diagnosed with LAL deficiency in accordance with the requirements specified in the Clinical Criteria for sebelipase alfa;
2) Have Alberta government-sponsored drug coverage;
3) Meet the Registration Requirements; AND
4) Satisfy the Clinical Criteria for sebelipase alfa (initial or continued coverage, as appropriate).

There is no guarantee that any application, whether for initial or continued coverage, will be approved. Depending on the circumstances of each case, the Minister or the Minister's delegate may:
- approve an Application;
- approve an Application with conditions;
- deny an Application;
- discontinue an approved Application; OR
- defer an Application pending the provision of further supporting information.

The process for review and approval is explained in further detail below.

2. REGISTRATION REQUIREMENTS

If the patient is a citizen or permanent resident of Canada, the patient must be continuously registered in the Alberta Health Care Insurance Plan for a minimum of one (1) year prior to an application for coverage unless:
- the patient is less than one (1) year of age at the date of the application, then the patient's parent/guardian/legal representative must be registered continuously in the Alberta Health Care Insurance Plan for a minimum of one (1) year; OR
- the patient has moved to Alberta from another province or territory in Canada (the "province of origin"), and immediately prior to moving to Alberta, was covered for sebelipase alfa in the province of origin by a provincial or territorial government sponsored drug plan, (or the province of origin provided equivalent coverage for sebelipase alfa as does Alberta) and the patient has been registered in the Alberta Health Care Insurance Plan (the patient must provide supporting documentation from the province of origin to prove prior coverage).

If the patient is not a citizen or permanent resident of Canada, the patient must be continuously registered in the Alberta Health Care Insurance Plan for a minimum of five (5) years prior to an application for coverage unless:
- the patient is less than five years of age at the date of the application, then the patient's parent/guardian/legal representative must be registered continuously in the Alberta Health Care Insurance Plan for a minimum of five years; OR
- the patient has moved to Alberta from another province or territory in Canada (the "province of origin"), and immediately prior to moving to Alberta, was covered for sebelipase alfa in the province of origin by a provincial or territorial government sponsored drug plan, (or the province of origin provided equivalent coverage for sebelipase alfa as does Alberta) and the patient has been registered in the Alberta Health Care Insurance Plan (the patient must provide supporting documentation from the province of origin to prove prior coverage).

The Minister reserves the right to modify or waive the Registration Requirements applicable to a given patient if the patient or the patient's parent/guardian/legal representative can establish to the satisfaction of the Minister that the patient has not moved to Alberta for the sole/primary purpose of obtaining coverage of sebelipase alfa.

SEBELIPASE ALFA

3. CLINICAL CRITERIA

"For the treatment of lysosomal acid lipase (LAL) deficiency in patients who have:
- documented biochemical evidence of deficient LAL activity (a copy of the lab report must be provided),
- two documented pathogenic mutations in the LIPA gene (a copy of the lab report must be provided),
- onset of clinical manifestations of LAL deficiency before six months of age.

For coverage, this drug must be prescribed by a specialist with experience in the diagnosis and management of LAL deficiency.

Coverage may be approved for up to 3 mg/kg once weekly as an intravenous infusion. Patients will be limited to receiving a 4-week supply of sebelipase alfa per prescription at their pharmacy.

Special authorization may be granted 12 months.

Renewal of coverage for sebelipase alfa may be continued for patients who do not experience any of the following adverse events from sebelipase alfa: hypersensitivity reactions (including anaphylaxis, hypotension, or fever), which cannot be managed with standard treatment, and/or have a significant impact on the patient's quality of life, or are life-threatening."

All requests (including renewal requests) for sebelipase alfa must be completed using the Sebelipase Alfa Special Authorization Request Form (ABC 60089).

4. PROCESS FOR SEBELIPASE ALFA COVERAGE

For both initial and continued coverage the following documents (the Application) must be completed and submitted:

- A Sebelipase Alfa Special Authorization Request Form completed by the patient's Specialist; AND
- Any other documentation that may be required by the Minister or the Minister's delegate.

The Application is forwarded to the Minister or the Minister's delegate to confirm that the patient meets the Registration Requirement or grant a waiver of the Registration Requirement, and thereafter render a decision regarding coverage.

After the Minister or Minister's delegate has rendered a decision, the patient's Specialist and the patient or patient's parent/guardian/legal representative will be notified by letter of the Minister's decision.

5. APPROVAL OF COVERAGE

The Minister or the Minister's delegate's decision in respect of an Application will specify the effective date of sebelipase alfa, if coverage is approved.

Initial or continued coverage may be approved for a period of up to twelve (12) months for up to 3 mg/kg once weekly as an intravenous infusion.

If a patient is approved for coverage, prescriptions for sebelipase alfa must be written by a specialist with experience in the diagnosis and management of LAL deficiency. To avoid wastage, prescription quantities are limited to a four-week supply. Extended quantity and vacation supplies are not permitted. The Government is not responsible and will not pay for costs associated with wastage or improper storage of sebelipase alfa.

Approval of coverage is granted for a specific period, to a maximum of twelve (12) months. If continued treatment is necessary, it is the responsibility of the patient or patient's parent/guardian/legal representative and the Specialist to submit a new Application to re-apply

SEBELIPASE ALFA

for sebelipase alfa coverage, and receive a decision thereon, prior to the expiry date of the authorization period.

6. WITHDRAWAL

Therapy may be withdrawn at the request of the patient or the patient's parent/guardian/legal representative at any time. Notification of withdrawal from therapy must be made by the Specialist or patient in writing.

Applications, withdrawal requests, and any other information to be provided must be sent to Clinical Drug Services, Alberta Blue Cross.

20 MG / VIAL INJECTION

00002469596	KANUMA	APG	$ 8546.0000

SECUKINUMAB

Plaque Psoriasis

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:
- Have a total PASI of 10 or more and a DLQI of more than 10, OR
- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
- Cyclosporine (6 weeks treatment); AND
- Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

Initial coverage may be approved for 12 weeks as follows:
- Four weekly doses of 300 mg of secukinumab at weeks 0, 1, 2 and 3, followed by monthly dosing at weeks 4, 8 and 12.
- Patients will be limited to receiving two doses of secukinumab per prescription at their pharmacy during the initial 3 weeks, then one dose per prescription thereafter. Each 300 mg dose is provided as two subcutaneous injections of 150 mg.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of the initial coverage period.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond seven doses, the patient must meet all of the following criteria:
1) The patient must be assessed by a Dermatology Specialist after the initial seven doses to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Greater than or equal to 75% reduction in PASI score, OR
- Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for one 300 mg dose of secukinumab every month for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

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All requests (including renewal requests) for secukinumab for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Tildrakizumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

Psoriatic Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).
Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

Initial coverage may be approved for 16 weeks as follows:
- Four weekly doses of 150 mg of secukinumab at weeks 0, 1, 2 and 3, followed by monthly dosing at weeks 4, 8, 12 and 16. A dose of 300 mg (given as 2 subcutaneous injections of 150 mg each) may be considered for anti-TNF alpha inadequate responders.
- Patients will be limited to receiving two doses of secukinumab per prescription at their pharmacy during the initial 3 weeks, then one dose per prescription thereafter.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond eight doses, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial eight doses to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be considered for one 150 mg (or 300 mg for anti-TNF alpha inadequate responders) dose of secukinumab every month for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;

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2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for secukinumab for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

Ankylosing Spondylitis

"Special authorization coverage may be provided for the reduction in the signs and symptoms of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

Initial coverage may be approved for 16 weeks as follows:
- Four weekly doses of 150 mg of secukinumab at weeks 0, 1, 2 and 3, followed by monthly dosing at weeks 4, 8, 12 and 16.
- Patients will be limited to receiving two doses of secukinumab per prescription at their pharmacy during the initial 3 weeks, then one dose per prescription thereafter.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond eight doses, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial eight doses to determine response.
2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
- Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be considered for one 150 mg dose of

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secukinumab every month for a period of 12 months. [Note: For patients who continue to have active Ankylosing Spondylitis, a monthly maintenance dosage of 300 mg may be considered.] Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for secukinumab for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

150 MG / ML INJECTION SYRINGE				
00002438070	COSENTYX	NOV	$	872.5900

SEMAGLUTIDE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): METFORMIN
SECOND-LINE DRUG PRODUCT(S): SULFONYLUREAS
AND WHERE INSULIN IS NOT AN OPTION

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:
- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated
CA - Prior adverse reaction
CB - Previous treatment failure
CJ - Product is not effective

All requests for semaglutide must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

1.34 MG / ML INJECTION				
00002471469	OZEMPIC (1 MG DOSE)	NNA	$	69.5433
1.34 MG / ML INJECTION				
00002471477	OZEMPIC (0.25 MG OR 0.5 MG DOSE)	NNA	$	139.0866

SILTUXIMAB

"For the treatment of multicentric Castleman's disease (MCD) in patients who are human immunodeficiency virus (HIV) negative and human herpes virus-8 (HHV-8) negative and who have an ECOG performance status of less than or equal to 2.

Initial coverage may be approved for a period of 6 months.

Continued coverage may be approved for a period of 12 months for patients who continue to meet initial coverage criteria.

Coverage for siltuximab will be provided for one intravenous dose of 11 mg/kg every 3 weeks. Patients will be limited to receiving one dose of siltuximab per prescription at their pharmacy."

100 MG / VIAL INJECTION				
00002435128	SYLVANT	RRD	$	697.7000
400 MG / VIAL INJECTION				
00002435136	SYLVANT	RRD	$	2790.8000

SIPONIMOD

"Special authorization coverage may be provided for the treatment of adult patients with secondary progressive multiple sclerosis (SPMS) with active disease to delay the progression of physical disability.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.
To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

1) The registered MS Neurologist must confirm a history of relapsing-remitting multiple sclerosis (RRMS) and current active SPMS.

2) The patient must have an Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5 at treatment initiation.

3) The patient must have documented EDSS progression during the two years prior to initiating treatment with siponimod (increase by 1 point or more if EDSS is less than 6.0; increase by 0.5 points or more if EDSS 6.0 or more at screening).

4) A baseline timed 25-foot walk (T25W) score is required at treatment initiation.

Coverage will not be approved when any MS disease-modifying therapy (DMT) or other immunosuppressive therapy is to be used in combination with siponimod.

Initial coverage may be approved for a 5-day dose titration followed by maintenance dosing of up to 2 mg daily for a period of 6 months. Patients will be limited to receiving a one-month supply of siponimod per prescription at their pharmacy for the first 6 months of coverage.

Continued Coverage

For continued coverage beyond the initial coverage period, the following criteria must be met:
1) The patient must be assessed for response to siponimod by a registered MS Neurologist.
2) The registered MS Neurologist must confirm a diagnosis of active SPMS.
3) The registered MS Neurologist must provide a current updated EDSS score and T25W.
a) Siponimod may be renewed for patients who do not exhibit evidence of disease progression since the previous assessment. Disease progression is defined as:
-an increase in the EDSS score of greater than or equal to 1 point if the EDSS score was 3.0 to 5.0 at siponimod initiation, OR
-an increase of greater than or equal to 0.5 points if the EDSS score was 5.5. to 6.5 at siponimod initiation.
b) Coverage will not be renewed for patients who exhibit:
-progression to an EDSS score of 7.0 or above at any time during siponimod treatment OR
-confirmed worsening of at least 20% on the T25W since initiating siponimod treatment.

Continued coverage may be approved for up to 2 mg daily for a period of 12 months. Patients may receive up to 100 days' supply of siponimod per prescription at their pharmacy."

All requests (including renewal requests) for siponimod must be completed using the Siponimod for SPMS Special Authorization Request Form (ABC 60092).

0.25 MG ORAL TABLET				
00002496429	MAYZENT	NOV	$	22.3285
2 MG ORAL TABLET				
00002496437	MAYZENT	NOV	$	89.3150

SITAGLIPTIN

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): METFORMIN
SECOND-LINE DRUG PRODUCT(S): SULFONYLUREAS
AND WHERE INSULIN IS NOT AN OPTION

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:
- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated
CA - Prior adverse reaction
CB - Previous treatment failure
CJ - Product is not effective

All requests for sitagliptin must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

25 MG ORAL TABLET				
00002508656	**APO-SITAGLIPTIN MALATE (SITAGLIPTIN MALATE)**	**APX**	$	**0.8197**
00002504049	**SANDOZ SITAGLIPTIN**	**SDZ**	$	**0.8197**
00002388839	JANUVIA (SITAGLIPTIN PHOSPHATE MONOHYDRATE)	MFC	$	3.2229
50 MG ORAL TABLET				
00002508664	**APO-SITAGLIPTIN MALATE (SITAGLIPTIN MALATE)**	**APX**	$	**0.8197**
00002504057	**SANDOZ SITAGLIPTIN**	**SDZ**	$	**0.8197**
00002388847	JANUVIA (SITAGLIPTIN PHOSPHATE MONOHYDRATE)	MFC	$	3.2229
100 MG ORAL TABLET				
00002508672	**APO-SITAGLIPTIN MALATE (SITAGLIPTIN MALATE)**	**APX**	$	**0.8197**
00002504065	**SANDOZ SITAGLIPTIN**	**SDZ**	$	**0.8197**
00002303922	JANUVIA (SITAGLIPTIN PHOSPHATE MONOHYDRATE)	MFC	$	3.2229

SITAGLIPTIN/ METFORMIN HCL

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): METFORMIN
SECOND-LINE DRUG PRODUCT(S): SULFONYLUREAS
AND WHERE INSULIN IS NOT AN OPTION

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:
- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated
CA - Prior adverse reaction
CB - Previous treatment failure
CJ - Product is not effective

All requests for sitagliptin+metformin must be completed using the DPP-4/SGLT2 Inhibitors/GLP-1 Receptor Agonist Special Authorization Request Form (ABC 60012).

50 MG (BASE) * 500 MG ORAL TABLET				
00002333856	JANUMET (SITAGLIPTIN PHOSPHATE MONOHYDRATE)	MFC	$	1.7465
50 MG (BASE) * 850 MG ORAL TABLET				
00002333864	JANUMET (SITAGLIPTIN PHOSPHATE MONOHYDRATE)	MFC	$	1.7465
50 MG (BASE) * 1,000 MG ORAL TABLET				
00002333872	JANUMET (SITAGLIPTIN PHOSPHATE MONOHYDRATE)	MFC	$	1.7465
50 MG (BASE) * 500 MG ORAL EXTENDED-RELEASE TABLET				
00002416786	JANUMET XR (SITAGLIPTIN PHOSPHATE MONOHYDRATE)	MFC	$	1.7345
50 MG (BASE) * 1,000 MG ORAL EXTENDED-RELEASE TABLET				
00002416794	JANUMET XR (SITAGLIPTIN PHOSPHATE MONOHYDRATE)	MFC	$	1.7345
100 MG (BASE) * 1,000 MG ORAL EXTENDED-RELEASE TABLET				
00002416808	JANUMET XR (SITAGLIPTIN PHOSPHATE MONOHYDRATE)	MFC	$	3.4691

SODIUM PHENYLBUTYRATE

"For chronic management of patients with urea cycle disorders (UCDs) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone.

For coverage, this drug must be prescribed by or in consultation with a metabolic or genetic physician. The diagnosis must be confirmed by blood, enzymatic, biochemical, or genetic testing.

Special authorization may be granted for 12 months."

The following product(s) are eligible for auto-renewal.

483 MG / G ORAL GRANULE					
00002436663	PHEBURANE	MDK	$	9.2690	

SOFOSBUVIR

"For use as combination therapy with ribavirin for treatment-naive or treatment-experienced (1) adult patients with chronic hepatitis C (CHC) infection who meet all of the following criteria:

I) Prescribed by or in consultation with a hepatologist, gastroenterologist or infectious disease specialist (except on a case-by-case basis, in geographic areas where access to these specialties is not available);
AND
II) Laboratory confirmed hepatitis C genotype 2 or genotype 3;
AND
III) Laboratory confirmed quantitative HCV RNA value within the last 6 months;
AND
IV) Fibrosis (2) stage of F0 or greater (Metavir scale or equivalent).

Duration of therapy reimbursed:
- Treatment-naive or treatment experienced genotype 2, without cirrhosis or with compensated cirrhosis (3): 12 weeks in combination with ribavirin
- Treatment-naive or treatment-experienced genotype 3, without cirrhosis or with compensated cirrhosis (3), or with decompensated cirrhosis (4), or post-liver transplant: 24 weeks in combination with ribavirin

Exclusion criteria:
- Patients currently being treated with another HCV antiviral agent
- Retreatment for failure or re-infection in patients who have received an adequate prior course of an HCV direct-acting antiviral drug regimen may be considered on an exceptional case-by-case basis
- Combination therapy with elbasvir/grazoprevir will not be considered

Notes:
1. Treatment-experienced are those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor.
2. Fibrosis score test is optional. Acceptable methods include liver biopsy, transient elastography (FibroScan), fibrotest and serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.
3. Compensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh A (i.e. score 5 to 6).
4. Decompensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh B or C (i.e. score 7 or above).
5. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations."

All requests for sofosbuvir must be completed using the Sofosbuvir for Chronic Hepatitis C Special Authorization Request Form (ABC 60103).

400 MG ORAL TABLET

00002418355	SOVALDI	GIL	$	654.7619

SOFOSBUVIR/ LEDIPASVIR

"For treatment-naive or treatment-experienced (1) adult patients with chronic hepatitis C (CHC) infection who meet all of the following criteria:
I) Prescribed by or in consultation with a hepatologist, gastroenterologist or infectious disease specialist (except on a case-by-case basis, in geographic areas where access to these specialties is not available);
AND
II) Laboratory confirmed hepatitis C genotype 1;
AND
III) Laboratory confirmed quantitative HCV RNA value within the last 6 months;
AND
IV) Fibrosis (2) stage of F0 or greater (Metavir scale or equivalent).

Duration of therapy reimbursed:
- Treatment-naive, without cirrhosis, recent quantitative hepatitis C viral load less than 6 M IU/mL: 8 weeks or 12 weeks (3)
- Treatment-naive, without cirrhosis, viral load greater than or equal to 6 M IU/mL: 12 weeks
- Treatment-naive, with compensated cirrhosis (4): 12 weeks
- Treatment-experienced, without cirrhosis: 12 weeks
- Treatment-naive or treatment-experienced with decompensated cirrhosis (5): 12 weeks in combination with ribavirin
- Treatment-naive or treatment-experienced liver transplant recipients, without cirrhosis or with compensated cirrhosis (4): 12 weeks in combination with ribavirin
- Treatment-experienced, with compensated cirrhosis (4): 24 weeks

Exclusion criteria:
- Patients currently being treated with another HCV antiviral agent
- Retreatment for failure or re-infection in patients who have received an adequate prior course of an HCV direct-acting antiviral drug regimen may be considered on an exceptional case-by-case basis

Notes:
1. Treatment-experienced are those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor.
2. Fibrosis score test is optional. Acceptable methods include liver biopsy, transient elastography (FibroScan), fibrotest and serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.
3. For this population cohort, evidence has shown that the SVR rates with 8-week and 12-week treatment regimens are similar. Treatment regimens of up to 12 weeks are recognized by Health Canada as an approved treatment option. 12-week treatment regimens may be considered for patients with advanced liver fibrosis.
4. Compensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh A (i.e. score 5 to 6).
5. Decompensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh B or C (i.e. score 7 or above).
6. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations."

All requests for sofosbuvir/ledipasvir must be completed using the Sofosbuvir/Ledipasvir for Chronic Hepatitis C Special Authorization Request Form (ABC 60101).

400 MG * 90 MG ORAL TABLET				
00002432226	HARVONI	GIL	$	797.6190

SOFOSBUVIR/ VELPATASVIR

"For treatment-naive or treatment-experienced (1) adult patients with chronic hepatitis C (CHC) infection who meet all of the following criteria:
I) Prescribed by or in consultation with a hepatologist, gastroenterologist or infectious disease specialist (except on a case-by-case basis, in geographic areas where access to these specialties is not available);
AND
II) Laboratory confirmed hepatitis C genotype (2) 1, 2, 3, 4, 5, 6 or mixed genotypes;
AND
III) Laboratory confirmed quantitative HCV RNA value within the last 6 months;
AND
IV) Fibrosis (3) stage of F0 or greater (Metavir scale or equivalent).

Duration of therapy reimbursed:
- Treatment-naive or treatment-experienced, without cirrhosis or with compensated cirrhosis (4): 12 weeks
- Treatment-naive or treatment-experienced, with decompensated cirrhosis (5): 12 weeks in combination with ribavirin

Exclusion criteria:
- Patients currently being treated with another HCV antiviral agent
- Retreatment for failure or re-infection in patients who have received an adequate prior course of an HCV direct-acting antiviral drug regimen may be considered on an exceptional case-by-case basis

Notes:
1. Treatment-experienced is defined as those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor.
2. HCV genotype testing is optional.
3. Fibrosis score test is optional. Acceptable methods include liver biopsy, transient elastography (FibroScan), fibrotest and serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.
4. Compensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh A (i.e. score 5 to 6).
5. Decompensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh B or C (i.e. score 7 or above).
6. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations."

All requests for sofosbuvir/velpatasvir must be completed using the Sofosbuvir/Velpatasvir for Chronic Hepatitis C Special Authorization Request Form (ABC 60100).

400 MG * 100 MG ORAL TABLET				
00002456370	EPCLUSA	GIL	$	714.2857

SOFOSBUVIR/ VELPATASVIR/ VOXILAPREVIR

"For treatment-experienced (1) adult patients with chronic hepatitis C (CHC) infection who meet all of the following criteria:
I) Prescribed by or in consultation with a hepatologist, gastroenterologist or infectious disease specialist (except on a case-by-case basis, in geographic areas where access to these specialties is not available);
AND
II) Laboratory confirmed hepatitis C genotype (2) 1, 2, 3, 4, 5, 6 or mixed genotypes and have previously been treated with a CHC antiviral drug regimen containing a non-structural protein 5A (NS5A) inhibitor;
OR
Laboratory confirmed hepatitis C genotype 1, 2, 3, 4 and have previously been treated with a CHC antiviral drug regimen containing sofosbuvir without an NS5A inhibitor;
AND
III) Laboratory confirmed quantitative HCV RNA value within the last 6 months;
AND
IV) Fibrosis (3) stage of F0 or greater (Metavir scale or equivalent).

Duration of therapy reimbursed:
- Treatment-experienced, without cirrhosis or with compensated cirrhosis (4): 12 weeks

Exclusion criteria:
- Patients currently being treated with another HCV antiviral agent

Notes:
1. Treatment-experienced is defined as those who have previously been treated with a CHC antiviral drug regimen.
2. HCV genotype testing is optional for patients previously treated with a CHC antiviral drug regimen containing a non-structural protein 5A (NS5A) inhibitor.
3. Fibrosis score test is optional. Acceptable methods include liver biopsy, transient elastography (FibroScan), fibrotest and serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.
4. Compensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh A (i.e. score 5 to 6).
5. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations."

All requests for sofosbuvir/velpatasvir/voxilaprevir must be completed using the Sofosbuvir/Velpatasvir/Voxilaprevir for Chronic Hepatitis C Special Authorization Request Form (ABC 60104).

400 MG * 100 MG * 100 MG ORAL TABLET				
00002467542	VOSEVI	GIL	$	714.2857

SOMATROPIN

"For replacement of endogenous growth hormone in adults with severe growth hormone deficiency. Information is required regarding the results of either a diagnostic insulin tolerance test or a glucagon stimulation test. Growth hormone values less than 3 mcg/litre are indicative of severe growth hormone deficiency.

Special authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

0.6 MG / SYR INJECTION				
00002401762	GENOTROPIN MINIQUICK	PFI	$	17.5000
0.8 MG / SYR INJECTION				
00002401770	GENOTROPIN MINIQUICK	PFI	$	23.3329
1 MG / SYR INJECTION				
00002401789	GENOTROPIN MINIQUICK	PFI	$	29.1657

SOMATROPIN

1.2 MG / SYR INJECTION				
00002401797	GENOTROPIN MINIQUICK	PFI	$	35.0000
1.4 MG / SYR INJECTION				
00002401800	GENOTROPIN MINIQUICK	PFI	$	40.8314
1.6 MG / SYR INJECTION				
00002401819	GENOTROPIN MINIQUICK	PFI	$	46.6657
1.8 MG / SYR INJECTION				
00002401827	GENOTROPIN MINIQUICK	PFI	$	52.4986
2 MG / SYR INJECTION				
00002401835	GENOTROPIN MINIQUICK	PFI	$	58.3314
5.3 MG / SYR INJECTION				
00002401703	GENOTROPIN GOQUICK	PFI	$	154.5840
12 MG / SYR INJECTION				
00002401711	GENOTROPIN GOQUICK	PFI	$	349.9880

SOMATROPIN

"For replacement of endogenous growth hormone in adults with severe growth hormone deficiency. Information is required regarding the results of either a diagnostic insulin tolerance test or a glucagon stimulation test. Growth hormone values less than 3 mcg/litre are indicative of severe growth hormone deficiency.

Special authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

6 MG / VIAL INJECTION				
00002243077	HUMATROPE	LIL	$	294.0200
12 MG / VIAL INJECTION				
00002243078	HUMATROPE	LIL	$	588.0400

SOMATROPIN R-DNA ORIGIN

"For replacement of endogenous growth hormone in adults with severe growth hormone deficiency. Information is required regarding the results of either a diagnostic insulin tolerance test or a glucagon stimulation test. Growth hormone values less than 3 mcg/litre are indicative of severe growth hormone deficiency.

Special authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

3.3 MG / ML INJECTION				
00002325063	OMNITROPE	SDZ	$	103.8667
5 MG / VIAL INJECTION				
00002237971	SAIZEN	SRO	$	220.7828
5.83 MG / ML INJECTION				
00002350122	SAIZEN	SRO	$	264.9150
6.7 MG / ML INJECTION				
00002325071	OMNITROPE	SDZ	$	207.7333
8 MG / ML INJECTION				
☒ 00002350130	SAIZEN (1.5 ML)	SRO	$	353.2200
☒ 00002350149	SAIZEN (2.5 ML)	SRO	$	353.2200

STIRIPENTOL

"For use in combination with clobazam and valproate as adjunctive therapy of refractory generalized tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy (Dravet Syndrome), whose seizures are not adequately controlled with clobazam and valproate alone.

This medication must be prescribed in consultation with a Neurologist.

Special authorization may be granted for 6 months."

Each of these products is eligible for auto-renewal.

250 MG ORAL CAPSULE				
00002398958	DIACOMIT	BCF	$	5.8984
500 MG ORAL CAPSULE				
00002398966	DIACOMIT	BCF	$	11.7783
250 MG ORAL POWDER PACKET				
00002398974	DIACOMIT	BCF	$	5.8984

SUMATRIPTAN HEMISULFATE

(Refer to 28:32.28 of the Alberta Drug Benefit List for coverage of patients 18 to 64 years of age inclusive.)

"For the treatment of acute migraine attacks in patients 65 years of age and older where other standard therapy has failed."

"For the treatment of acute migraine attacks in patients 65 years of age and older who have been using sumatriptan prior to turning 65."

"Special authorization for both criteria may be granted for 24 months."

In order to comply with the first criteria, information is required regarding previous medications utilized and the patient's response to therapy.

The following product(s) are eligible for auto-renewal.

5 MG / DOSE (BASE) NASAL UNIT DOSE SPRAY				
00002230418	IMITREX	GSK	$	16.7423
20 MG / DOSE (BASE) NASAL UNIT DOSE SPRAY				
00002230420	IMITREX	GSK	$	17.2253

SUMATRIPTAN SUCCINATE

(Refer to 28:32.28 of the Alberta Drug Benefit List for coverage of patients 18 to 64 years of age inclusive.)

"For the treatment of acute migraine attacks in patients 65 years of age and older where other standard therapy has failed."

"For the treatment of acute migraine attacks in patients 65 years of age and older who have been using sumatriptan prior to turning 65."

"Special authorization for both criteria may be granted for 24 months."

In order to comply with the first criteria, information is required regarding previous medications utilized and the patient's response to therapy.

The following product(s) are eligible for auto-renewal.

50 MG (BASE) ORAL TABLET				
00002268388	**APO-SUMATRIPTAN**	**APX**	$	**2.7732**
00002268914	**MYLAN-SUMATRIPTAN**	**MYP**	$	**2.7732**
00002256436	**PMS-SUMATRIPTAN**	**PMS**	$	**2.7732**
00002286521	**SUMATRIPTAN**	**SNS**	$	**2.7732**
00002385570	**SUMATRIPTAN DF**	**SIV**	$	**2.7732**
00002286823	**TEVA-SUMATRIPTAN DF**	**TEV**	$	**2.7732**
00002212153	IMITREX DF	GSK	$	16.9860
100 MG (BASE) ORAL TABLET				
00002268396	**APO-SUMATRIPTAN**	**APX**	$	**3.0549**
00002268922	**MYLAN-SUMATRIPTAN**	**MYP**	$	**3.0549**
00002256444	**PMS-SUMATRIPTAN**	**PMS**	$	**3.0549**
00002286548	**SUMATRIPTAN**	**SNS**	$	**3.0549**
00002385589	**SUMATRIPTAN DF**	**SIV**	$	**3.0549**
00002239367	**TEVA-SUMATRIPTAN**	**TEV**	$	**3.0549**
00002286831	**TEVA-SUMATRIPTAN DF**	**TEV**	$	**3.0549**
00002212161	IMITREX DF	GSK	$	18.7119
12 MG / SYR (BASE) INJECTION SYRINGE				
00002361698	**TARO-SUMATRIPTAN (0.5 ML)**	**TAR**	$	**39.9209**
00002212188	IMITREX (0.5 ML)	GSK	$	50.5500

TACROLIMUS

"For use in patients 2 to 15 years of age inclusive with atopic dermatitis who are unable to tolerate or have failed topical steroid therapy."

"For use in patients 2 to 15 years of age inclusive with atopic dermatitis who require ongoing use of potent (Class 3 or higher) topical steroids."

"For use in patients 16 years of age and older with atopic dermatitis affecting face and flexures who are unable to tolerate or have failed topical steroid therapy."

"For use in patients 16 years of age and older with atopic dermatitis who require ongoing use of potent (Class 3 or higher) topical steroids over greater than 30 % of body surface area."

"Special authorization for all criteria may be granted for 6 months."

Information is required regarding the patient's diagnosis, previous medications utilized (including specific topical steroids) and the patient's response to therapy. In order to comply with the third criterion, information is also required regarding the area(s) affected. In order to comply with the fourth criterion, information is also required regarding the percentage body surface area affected.

The following product(s) are eligible for auto-renewal.

All requests for tacrolimus topical ointment must be completed using the Tacrolimus Topical Ointment Special Authorization Request Form (ABC 60047).

0.03 % TOPICAL OINTMENT

00002244149	PROTOPIC	LEO	$	2.3731

"For use in patients 16 years of age and older with atopic dermatitis affecting face and flexures who are unable to tolerate or have failed topical steroid therapy."

"For use in patients 16 years of age and older with atopic dermatitis who require ongoing use of potent (Class 3 or higher) topical steroids over greater than 30 % of body surface area."

"Special authorization for all criteria may be granted for 6 months."

Information is required regarding the patient's diagnosis, previous medications utilized (including specific topical steroids) and the patient's response to therapy. In order to comply with the first criterion, information is also required regarding the area(s) affected. In order to comply with the second criterion, information is also required regarding the percentage body surface area affected.

The following product(s) are eligible for auto-renewal.

All requests for tacrolimus topical ointment must be completed using the Tacrolimus Topical Ointment Special Authorization Request Form (ABC 60047).

0.1 % TOPICAL OINTMENT

00002244148	PROTOPIC	LEO	$	2.5195

TAFAMIDIS

"For the treatment of cardiomyopathy due to transthyretin-mediated amyloidosis (ATTR-CM), wild-type or hereditary, to reduce cardiovascular mortality and cardiovascular-related hospitalization in adult patients who meet the following criteria:
- Documented wild-type ATTR-CM* OR documented hereditary ATTR-CM**
And
- New York Heart Association (NYHA) class I to III
And
- a history of heart failure, defined as at least one prior hospitalization for heart failure or clinical evidence of heart failure that required treatment with a diuretic
And
- have not received a heart or liver transplant
And
- do not have an implanted cardiac mechanical assist device (CMAD)

* Documented wild-type ATTR-CM consists of all of the following:
-absence of a variant TTR genotype; and,
-evidence of cardiac involvement by echocardiography with end diastolic interventricular septal wall thickness of greater than 12 mm; and,
-presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connective tissue sheath, or cardiac) OR Tc-99m-pyrophosphate nuclear scintigraphy (PYP scan) indicating TTR-related cardiac amyloidosis; and
-TTR precursor protein identification by immunohistochemistry, scintigraphy, or mass spectrometry.

** Documented hereditary ATTR-CM consists of all of the following:
-presence of a variant TTR genotype associated with cardiomyopathy and presenting with a cardiomyopathy phenotype; and,
-evidence of cardiac involvement by echocardiography with end diastolic interventricular septal wall thickness of greater than 12 mm; and,
-presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connective tissue sheath, or cardiac) OR PYP scan indicating TTR-related cardiac amyloidosis.

For coverage, this drug must be prescribed by a Specialist in Cardiology, Internal Medicine or Oncology.
Initial coverage may be approved up to 80 mg of tafamidis meglumine or 61 mg of tafamidis once daily for 6 months.

Patients will be limited to receiving a one-month supply of tafamidis meglumine or tafamidis per prescription at their pharmacy.

For renewal of coverage, patients must NOT have:
- progressed to NYHA class IV, NOR
- received a heart or liver transplant, NOR
- received an implanted CMAD

Continued coverage may be approved for up to 80 mg of tafamidis meglumine or 61 mg of tafamidis once daily for a period of 6 months.

Coverage cannot be provided for use in combination with other disease modifying treatments for ATTR including interfering ribonucleic acid drugs or transthyretin stabilizers."

All requests for tafamidis or tafamidis meglumine must be completed using the Tafamidis for ATTR-CM Special Authorization Request Form (ABC 60086).

61 MG ORAL CAPSULE

00002517841	VYNDAMAX	PFI	$	534.2800

TAFAMIDIS MEGLUMINE

"For the treatment of cardiomyopathy due to transthyretin-mediated amyloidosis (ATTR-CM), wild-type or hereditary, to reduce cardiovascular mortality and cardiovascular-related hospitalization in adult patients who meet the following criteria:
- Documented wild-type ATTR-CM* OR documented hereditary ATTR-CM**
And
- New York Heart Association (NYHA) class I to III
And
- a history of heart failure, defined as at least one prior hospitalization for heart failure or clinical evidence of heart failure that required treatment with a diuretic
And
- have not received a heart or liver transplant
And
- do not have an implanted cardiac mechanical assist device (CMAD)

* Documented wild-type ATTR-CM consists of all of the following:
-absence of a variant TTR genotype; and,
-evidence of cardiac involvement by echocardiography with end diastolic interventricular septal wall thickness of greater than 12 mm; and,
-presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connective tissue sheath, or cardiac) OR Tc-99m-pyrophosphate nuclear scintigraphy (PYP scan) indicating TTR-related cardiac amyloidosis; and
-TTR precursor protein identification by immunohistochemistry, scintigraphy, or mass spectrometry.

** Documented hereditary ATTR-CM consists of all of the following:
-presence of a variant TTR genotype associated with cardiomyopathy and presenting with a cardiomyopathy phenotype; and,
-evidence of cardiac involvement by echocardiography with end diastolic interventricular septal wall thickness of greater than 12 mm; and,
-presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connective tissue sheath, or cardiac) OR PYP scan indicating TTR-related cardiac amyloidosis.

For coverage, this drug must be prescribed by a Specialist in Cardiology, Internal Medicine or Oncology.
Initial coverage may be approved up to 80 mg of tafamidis meglumine or 61 mg of tafamidis once daily for 6 months.

Patients will be limited to receiving a one-month supply of tafamidis meglumine or tafamidis per prescription at their pharmacy.

For renewal of coverage, patients must NOT have:
- progressed to NYHA class IV, NOR
- received a heart or liver transplant, NOR
- received an implanted CMAD

Continued coverage may be approved for up to 80 mg of tafamidis meglumine or 61 mg of tafamidis once daily for a period of 6 months.

Coverage cannot be provided for use in combination with other disease modifying treatments for ATTR including interfering ribonucleic acid drugs or transthyretin stabilizers."

All requests for tafamidis or tafamidis meglumine must be completed using the Tafamidis for ATTR-CM Special Authorization Request Form (ABC 60086).

20 MG ORAL CAPSULE

00002495732	VYNDAQEL	PFI	$	133.5700

TALIGLUCERASE ALFA

For long-term enzyme replacement therapy (ERT) for pediatric and adult patients with type 1 Gaucher disease (GD) when the following criteria are met:

1. The diagnosis of GD must have been established by the demonstration of specific deficiency of glucocerebrosidase (GCase) in tissue or cultured skin fibroblasts, or by demonstration of the presence, in tissue or peripheral blood leukocytes, of mutations in the GCase gene known to result in severe enzyme deficiency.

2. Other potentially confounding diagnoses, such as Hodgkin disease or other storage disorders, must have been ruled out. The symptoms experienced by the patient should be shown to be attributable to GD and not some other condition that might mimic it. A trial of therapy would normally be considered in situations of uncertainty only if the symptoms were accompanied by objective evidence (hematological or imaging changes consistent with complaints).

3. The patient should not have any GD-related or other medical condition that might reasonably be expected to compromise their response to treatment. In some patients with GD, secondary pathologic changes, such as avascular necrosis of bone, may already have occurred that would not be expected to respond to enzyme replacement. In such patients, reversal of the pathology is unlikely. Treatment of patients with significant secondary pathology would be directed at preventing further progression of the disease. In these cases, the extent to which symptoms, such as bone pain, are due to active progression of the disease, rather than the secondary pathology, may only be established by a trial of therapy.

4. Treatment should be provided under the care of a specialist with experience in the diagnosis and management of GD.

5. None of the following exclusion criteria apply:
a. The presence of any GD-related condition that might reasonably be expected to compromise a response to therapy
b. The presence of another medical condition that might reasonably be expected to compromise a response to therapy
c. Asymptomatic GD
d. The presence of primary neurological disease due to GD

6. Patients must have the following baseline parameters assessed prior to initiating therapy on taliglucerase alfa:
- Hemoglobin level and platelet count
- Presence of splenic infarction, bone crises, radiographic or MRI evidence of incipient destruction of any major joint, spontaneous fractures, chronic bone pain, major joint replacement, liver synthetic dysfunction, symptomatic hepatosplenomegaly, progressive pulmonary disease due to GD, or growth failure in children.

7. The patient is unable to receive ERT with velaglucerase alfa, including:
a. Rare cases of severe allergic reactions or hypersensitivity to velaglucerase alfa.
b. Patients who are sub-optimally responsive despite maximum doses of velaglucerase alfa for at least 12 months.
c. Patients unable to receive velaglucerase alfa for medical reasons.

Notes:
- Pregnancy is not considered a contraindication to ERT.
- Patients to be considered for reimbursement of drug costs for ERT must be willing to participate in the long term evaluation of the efficacy of treatment by periodic medical assessment. Failure to comply with recommended medical assessment and investigations may result in withdrawal of financial support of drug therapy.

Initial coverage may be approved at a dosage of up to 60 units/kg every 2 weeks for a period of 6 months.

Ongoing coverage may be considered for up to 60 units/kg every 2 weeks for a period of 6 months at a time during the first 2 years of treatment, and thereafter for 12-month periods, only if

TALIGLUCERASE ALFA

the following criteria are met:

- The patient demonstrates all of the following expected treatment outcomes, where applicable:
1. For patients with baseline hemoglobin <85% of lower limit of age- and sex-appropriate normal: Increase hemoglobin levels to >110 g/L for women and children and >120 g/L for men
2. For patients with a baseline platelet count <50 x 10^9/L on two separate occasions at least one month apart:
a. Increase platelet count to level sufficient to prevent spontaneous bleeding
b. Normalization of platelet count in splenectomized patients
c. In patients with intact spleen, an increase of at least 1.5X in baseline platelet count
3. For patients with a prior splenic infarct at baseline:
a. Reduction of spleen volume by at least 50%
b. Prevention of further splenic infarcts
4. Prevention of bone crises
5. For patients with radiographic or MRI evidence of incipient destruction of any major joint at baseline: Improvement in imaging parameters (either MRI, QCSI2, or BMD)
6. Prevention of spontaneous fractures
7. Reduced bone pain in patients with chronic bone pain at baseline
8. No major joint replacement surgery
9. Improvement in liver function in patients with liver synthetic dysfunction at baseline
10. For patients with symptomatic hepatosplenomegaly at baseline:
a. Reduction of spleen volume by at least 50%
b. Reduction in liver volume by at least 30%
11. For patients with progressive pulmonary disease due to GD at baseline:
c. Improvement in pulmonary hypertension
d. Improvement in oxygenation
e. Reversal of hepatopulmonary syndrome
12. For children with growth failure at baseline: Return to normal range on height percentiles

- Treatment should be discontinued if the above treatment outcomes have not been demonstrated, as evidenced by readings consistent over the previous 12-month period at the maximum dosage of 60 units/kg every 2 weeks.

Patients will be limited to receiving a one-month supply of taliglucerase alfa per prescription at their pharmacy.
Coverage cannot be provided for taliglucerase alfa when this medication is intended for use in combination with other ERT.
Patients will not be permitted to switch back to a previously trialed ERT if they were deemed sub-optimally responsive despite maximum doses.

The dosage of taliglucerase alfa prescribed would depend on the severity of the disease and would be at the discretion of the specialist. The efficacy of treatment should be re-evaluated every 6 months and dosage adjustments made as appropriate. If there has been insufficient response to treatment after 6 months on a lower dose, the dosage may be increased to a maximum of 60 units/kg every 2 weeks. In the event of severe drug reaction, treatment may have to be discontinued. ERT has been shown to be well tolerated with minimal toxicity reported.

All requests for Taliglucerase Alfa must be completed using the Velaglucerase Alfa/Taliglucerase Alfa for Gaucher Disease Special Authorization Request Form (ABC 60070).

200 UNIT / VIAL	**INJECTION**			
00002425637	ELELYSO	PFI	$	648.3600

TEDUGLUTIDE

Adult Short Bowel Syndrome

"Special authorization coverage may be provided for the treatment of adult patients (18 years of age or older) with short bowel syndrome (SBS) if all of the following criteria are met:

- SBS is a result of major intestinal resection (e.g., due to injury, volvulus, vascular disease, cancer, Crohn's Disease), and

- Resection has resulted in dependency on parenteral nutrition (PN) for at least 12 months, and

- PN is required at least three times weekly to meet caloric, fluid or electrolyte needs due to ongoing malabsorption, and

- PN frequency and volume have been stable for at least one month.

For coverage, the drug must be initiated and monitored by a specialist in gastroenterology or an internal medicine specialist with an interest in gastroenterology on a case-by-case basis, in geographic areas where access to this specialty is not available ('Specialist').

Initial coverage may be approved for up to 24 weeks of 0.05 mg/kg/day administered subcutaneously once daily.

- Patients will be limited to receiving a four week supply of teduglutide per prescription at their pharmacy.

For continued coverage beyond 24 weeks, the patient must meet the following criteria:

1) The patient must be assessed by the Specialist between weeks 20 and 24, after initiation of therapy to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' as demonstrated by:
- at least a 20% reduction in weekly PN volume from baseline.

Following this assessment, continued coverage may be provided for 0.05 mg/kg/day administered subcutaneously once daily for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

1) The patient has been assessed by the Specialist to determine response;

2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:

- confirmation of maintenance of at least a 20% reduction in weekly PN volume from baseline."

Pediatric Short Bowel Syndrome

"Special authorization coverage may be provided for the treatment of pediatric patients (between 1 and 17 years of age) with short bowel syndrome (SBS) if all of the following criteria are met:

- Cumulative lifetime duration of parenteral support therapy must be at least 12 months, and
- Parenteral support must provide more than 30% of caloric and/or fluid/electrolyte needs, and
- Parenteral support requirements must be stable or there must have been no improvement in enteral feeding for at least the preceding three months.
For coverage, the drug must be initiated and monitored by a physician currently working within a specialized multi-disciplinary intestinal rehabilitation program ('Specialist').
Initial coverage may be approved for up to 24 weeks of 0.05 mg/kg/day administered subcutaneously once daily.
- Patients will be limited to receiving a four week supply of teduglutide per prescription at their pharmacy.
For continued coverage beyond 24 weeks, the patient must meet the following criteria:
1) The patient must be assessed by the Specialist between weeks 20 and 24, after initiation of

TEDUGLUTIDE

therapy to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' as demonstrated by:
- at least a 20% reduction in parenteral support volume compared to the baseline volume.

Following this assessment, continued coverage may be provided for 0.05 mg/kg/day administered subcutaneously once daily for a period of 6 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 6-month period:

1) The patient has been assessed by the Specialist to determine a continued response to treatment.

Note: Discontinuation of treatment should be based on the prescribing physician's assessment of the patient's response and tolerance to treatment with teduglutide."

5 MG / VIAL	**INJECTION**				
00002445727	REVESTIVE		TAK	$	925.0000

TERIFLUNOMIDE

Relapsing Remitting Multiple Sclerosis (RRMS):

"Special authorization coverage may be provided for the reduction of the frequency and severity of clinical relapses and reduction of the number and volume of active brain lesions, identified on MRI scans, in ambulatory patients with relapsing remitting multiple sclerosis.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.

To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

1) The registered MS Neurologist must confirm a diagnosis of RRMS;

2) The patient must have active disease which is defined as at least two relapses* of MS during the previous two years or in the two years prior to starting an MS disease modifying therapy (DMT).

*A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one new T2 lesion or definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).

Coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of teriflunomide per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

1) The patient must be assessed by a registered MS Neurologist;

2) The registered MS Neurologist must confirm a diagnosis of RRMS;

3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more.

Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.

Continued coverage may be approved for up to 12 months. Patients may receive up to 100 days' supply of teriflunomide per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption in therapy greater than 12 months, the

TERIFLUNOMIDE

patient must meet the following criteria:

1) At least one relapse* per 12 month period; or
2) At least two relapses* during the previous 24 month period."

All requests (including renewal requests) for teriflunomide must be completed using the Dimethyl Fumarate/Glatiramer Acetate/Interferon Beta-1a/Ocrelizumab/Peginterferon Beta-1a/Teriflunomide for RRMS/Interferon Beta-1b for SPMS or RRMS Special Authorization Request Form (ABC 60001).

14 MG ORAL TABLET

00002502933	**ACH-TERIFLUNOMIDE**	**AHI**	$	**14.9300**
00002500639	**APO-TERIFLUNOMIDE**	**APX**	$	**14.9300**
00002504170	**JAMP TERIFLUNOMIDE**	**JPC**	$	**14.9300**
00002523833	**M-TERIFLUNOMIDE**	**MTR**	$	**14.9300**
00002500469	**MAR-TERIFLUNOMIDE**	**MAR**	$	**14.9300**
00002500310	**NAT-TERIFLUNOMIDE**	**NTP**	$	**14.9300**
00002500434	**PMS-TERIFLUNOMIDE**	**PMS**	$	**14.9300**
00002505843	**SANDOZ TERIFLUNOMIDE**	**SDZ**	$	**14.9300**
00002501090	**TEVA-TERIFLUNOMIDE**	**TEV**	$	**14.9300**
00002416328	AUBAGIO	GZM	$	59.7200

TESTOSTERONE

"For use in males for the treatment of congenital and acquired primary and secondary hypogonadism."

"Coverage cannot be considered when used for the treatment of androgen decline in the aging male (ADAM)."

"Special authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

12.2 MG TRANSDERMAL PATCH

00002239653	ANDRODERM (2.5 MG/DAY)	ALL	$	2.2217

24.3 MG TRANSDERMAL PATCH

00002245972	ANDRODERM (5 MG/DAY)	ALL	$	4.4433

TESTOSTERONE UNDECANOATE

"For use in males for the treatment of congenital and acquired primary and secondary hypogonadism."

"Coverage cannot be considered when used for the treatment of androgen decline in the aging male (ADAM)."

"Special authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

40 MG ORAL CAPSULE

00002322498	**PMS-TESTOSTERONE**	**PMS**	$	**0.4700**
00002421186	**TARO-TESTOSTERONE**	**TAR**	$	**0.4700**

TETRABENAZINE

"For the treatment of hyperkinetic movement disorders when prescribed by specialists in Neurology, Psychiatry, or Geriatric Medicine.

Special authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

25 MG ORAL TABLET

00002407590	**APO-TETRABENAZINE**	**APX**	$	**3.3746**
00002402424	**PMS-TETRABENAZINE**	**PMS**	$	**3.3746**
00002199270	NITOMAN	VCL	$	7.8745

TICAGRELOR

(Refer to 20:12.18 of the Alberta Drug Benefit List for coverage of ticagrelor when prescribed by a specialist in Cardiology, Cardiac Surgery, Cardiovascular & Thoracic Surgery, Internal Medicine or General Surgery.)

For the treatment of Acute Coronary Syndrome, defined as unstable angina or myocardial infarction, when initiated in hospital in consultation with a Specialist in Cardiology, Cardiac Surgery, Cardiovascular & Thoracic Surgery, Internal Medicine or General Surgery. Treatment must be in combination with low dose ASA. Special authorization may be granted for 6 months.*

*Special Authorization is only required when the initiating prescriber is not a Specialist in Cardiology, Cardiac Surgery, Cardiovascular & Thoracic Surgery, Internal Medicine or General Surgery.

The following product(s) are eligible for auto-renewal.

90 MG ORAL TABLET

00002482630	**APO-TICAGRELOR**	**APX**	$	**0.3960**
00002529769	**M-TICAGRELOR**	**MTR**	$	**0.3960**
00002492598	**TARO-TICAGRELOR**	**TAR**	$	**0.3960**
00002368544	BRILINTA	AZC	$	1.6401

TILDRAKIZUMAB

Plaque Psoriasis

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:
- Have a total PASI of 10 or more and a DLQI of more than 10, OR
- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
- Cyclosporine (6 weeks treatment); AND
- Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

- Initial coverage may be approved for three doses of 100 mg of tildrakizumab at weeks 0, 4 and 16.
- Patients will be limited to receiving one 100 mg dose of tildrakizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of the initial coverage period.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet all of the following criteria:
1) The patient must be assessed by a Dermatology Specialist after the initial three doses to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Greater than or equal to 75% reduction in PASI score, OR
- Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for one 100 mg dose of tildrakizumab every 12 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for tildrakizumab for Plaque Psoriasis must be completed using the

TILDRAKIZUMAB

Adalimumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Tildrakizumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

100 MG / SYR	INJECTION	SYRINGE			
00002516098	ILUMYA		SPF	$	4935.0000

TIOTROPIUM BROMIDE MONOHYDRATE/ OLODATEROL HYDROCHLORIDE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S): LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])

"For the long-term maintenance treatment of airflow obstruction in patients with moderate to severe (i.e., FEV1 < 80% predicted) chronic obstructive pulmonary disease (COPD), who have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA])."

"For the long-term maintenance treatment of airflow obstruction in patients with severe (i.e., FEV1 < 50% predicted) chronic obstructive pulmonary disease (COPD)."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for tiotropium bromide monohydrate + olodaterol hydrochloride must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

2.5 MCG / DOSE * 2.5 MCG / DOSE	INHALATION	SOLUTION			
00002441888	INSPIOLTO RESPIMAT		BOE	$	1.0692

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80 MG / VIAL INJECTION

00002350092	ACTEMRA (4 ML)	HLR	$	182.8000

Rheumatoid Arthritis:

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 16 weeks as follows:
- Tocilizumab intravenous infusion: one dose of 4 mg/kg or 8 mg/kg (up to a maximum of 800 mg per dose) of tocilizumab administered at 0, 4, 8, 12 and 16 weeks (total of 5 doses). Patients will be limited to receiving one dose of intravenous tocilizumab per prescription at their pharmacy.
-Tocilizumab subcutaneous injection: for patients weighing less than 100 kg, initial coverage may be approved for one 162 mg dose of tocilizumab administered every other week, up to weekly based on clinical response. For patients weighing 100 kg or more, initial coverage may be approved for one 162 mg dose of tocilizumab administered every week. Patients will be limited to receiving a one-month supply of subcutaneous tocilizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial 16 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 16 weeks, but no longer than 20 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for tocilizumab will be provided for one intravenous dose of 4 mg/kg to 8 mg/kg (up to a maximum of 800 mg per dose) every 4 weeks, or one 162 mg subcutaneous dose administered every one to two weeks (based on weight and clinical response). Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, OR
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal

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place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for tocilizumab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Polyarticular Juvenile Idiopathic Arthritis

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older who:
- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDs) conventionally used in children (minimum three month trial).

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects (e.g., leukopenia, hepatitis) or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric Rheumatology Specialist).

- Initial coverage may be approved for 12 weeks as follows:
- Tocilizumab intravenous infusion: 10 mg/kg/dose for patients less than 30 kg, or 8 mg/kg/dose for patients 30 kg or greater every 4 weeks.
- Tocilizumab subcutaneous injection: one 162 mg dose of tocilizumab administered every 3 weeks for patients less than 30 kg, or administered every other week for patients 30 kg or greater.
- Patients will be limited to receiving up to a one-month supply of tocilizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
- 30% improvement from baseline in at least three of the following six response variables, with worsening of 30% or more in no more than one of the six variables. The variables include:
i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,
ii. global assessment of overall well-being by the patient or parent,
iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
iv. number of joints with limitation of motion,
v. functional ability based on CHAQ scores,
vi. ESR or CRP
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for tocilizumab will be provided for one intravenous dose of 8 mg/kg to 10 mg/kg every 4 weeks, or one 162 mg subcutaneous dose administered every two to three weeks (based on weight). After twelve months, in order to be considered for continued coverage, the patient must be

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re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:
1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Once a child with pJIA has had two disease-free years, it is common clinical practice for drug treatment to be stopped."

All requests (including renewal requests) for tocilizumab for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Adalimumab/Etanercept/Tocilizumab for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60011).

Systemic Juvenile Idiopathic Arthritis

"Special authorization coverage may be provided for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older when all of the following conditions are met:
- the patient has a diagnosis of systemic JIA with fever (greater than 38 degrees Celsius) for at least two weeks and at least one of the following: rash of systemic JIA; serositis; lymphadenopathy; hepatomegaly; splenomegaly; AND
- the physician has ruled out other potential etiologies; AND
- the patient is refractory to one or more non-steroidal anti-inflammatory drugs (NSAIDs) and one or more systemic corticosteroids.

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric RA Specialist).

- Initial coverage may be approved for 12 weeks as follows:
- Tocilizumab intravenous infusion: 12 mg/kg/dose for patients weighing less than 30 kg, or 8 mg/kg/dose for patients weighing greater than or equal to 30 kg (up to a maximum of 800 mg per dose), administered every two weeks, OR
- Tocilizumab subcutaneous injection: one 162 mg dose of tocilizumab administered once every 2 weeks for patients less than 30 kg, or administered once every week for patients 30 kg or greater.
- Patients will be limited to receiving one month of tocilizumab per prescription at their pharmacy.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric RA Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
2) The Pediatric RA Specialist must confirm in writing that the patient is a responder as demonstrated by JIA ACR30 response and/or absence of fever and/or reduction in inflammatory markers [e.g., C-reactive protein (CRP) concentration of less than 15 mg/L or reduction in erythrocyte sedimentation rate (ESR)].
Following this assessment, continued coverage may be approved for a period of 12 months.
Coverage for tocilizumab will be provided for:
- One intravenous dose of 12 mg/kg for patients weighing less than 30 kg or 8 mg/kg for patients weighing greater than or equal to 30 kg (up to a maximum of 800 mg per dose), administered every two weeks, OR
- One 162 mg subcutaneous dose administered every one to two weeks (based on weight).
After twelve months, in order to be considered for continued coverage, the patient must meet the following criteria:
1) The patient has been re-assessed every 12 months by a Pediatric RA Specialist to determine response, AND
2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy."

All requests (including renewal requests) for tocilizumab for Systemic Juvenile Idiopathic Arthritis must be completed using the Tocilizumab for Systemic Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60048).

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200 MG / VIAL INJECTION

00002350106 ACTEMRA (10 ML) HLR $ 457.0000

Rheumatoid Arthritis:

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 16 weeks as follows:
- Tocilizumab intravenous infusion: one dose of 4 mg/kg or 8 mg/kg (up to a maximum of 800 mg per dose) of tocilizumab administered at 0, 4, 8, 12 and 16 weeks (total of 5 doses). Patients will be limited to receiving one dose of intravenous tocilizumab per prescription at their pharmacy.
-Tocilizumab subcutaneous injection: for patients weighing less than 100 kg, initial coverage may be approved for one 162 mg dose of tocilizumab administered every other week, up to weekly based on clinical response. For patients weighing 100 kg or more, initial coverage may be approved for one 162 mg dose of tocilizumab administered every week. Patients will be limited to receiving a one-month supply of subcutaneous tocilizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial 16 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 16 weeks, but no longer than 20 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for tocilizumab will be provided for one intravenous dose of 4 mg/kg to 8 mg/kg (up to a maximum of 800 mg per dose) every 4 weeks, or one 162 mg subcutaneous dose administered every one to two weeks (based on weight and clinical response). Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, OR
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal

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place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for tocilizumab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Polyarticular Juvenile Idiopathic Arthritis

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older who:
- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDs) conventionally used in children (minimum three month trial).

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects (e.g., leukopenia, hepatitis) or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric Rheumatology Specialist).

- Initial coverage may be approved for 12 weeks as follows:
- Tocilizumab intravenous infusion: 10 mg/kg/dose for patients less than 30 kg, or 8 mg/kg/dose for patients 30 kg or greater every 4 weeks.
- Tocilizumab subcutaneous injection: one 162 mg dose of tocilizumab administered every 3 weeks for patients less than 30 kg, or administered every other week for patients 30 kg or greater.
- Patients will be limited to receiving up to a one-month supply of tocilizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
- 30% improvement from baseline in at least three of the following six response variables, with worsening of 30% or more in no more than one of the six variables. The variables include:
i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,
ii. global assessment of overall well-being by the patient or parent,
iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
iv. number of joints with limitation of motion,
v. functional ability based on CHAQ scores,
vi. ESR or CRP
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for tocilizumab will be provided for one intravenous dose of 8 mg/kg to 10 mg/kg every 4 weeks, or one 162 mg subcutaneous dose administered every two to three weeks (based on weight). After twelve months, in order to be considered for continued coverage, the patient must be

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re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:
1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Once a child with pJIA has had two disease-free years, it is common clinical practice for drug treatment to be stopped."

All requests (including renewal requests) for tocilizumab for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Adalimumab/Etanercept/Tocilizumab for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60011).

Systemic Juvenile Idiopathic Arthritis

"Special authorization coverage may be provided for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older when all of the following conditions are met:
- the patient has a diagnosis of systemic JIA with fever (greater than 38 degrees Celsius) for at least two weeks and at least one of the following: rash of systemic JIA; serositis; lymphadenopathy; hepatomegaly; splenomegaly; AND
- the physician has ruled out other potential etiologies; AND
- the patient is refractory to one or more non-steroidal anti-inflammatory drugs (NSAIDs) and one or more systemic corticosteroids.

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric RA Specialist).

- Initial coverage may be approved for 12 weeks as follows:
- Tocilizumab intravenous infusion: 12 mg/kg/dose for patients weighing less than 30 kg, or 8 mg/kg/dose for patients weighing greater than or equal to 30 kg (up to a maximum of 800 mg per dose), administered every two weeks, OR
- Tocilizumab subcutaneous injection: one 162 mg dose of tocilizumab administered once every 2 weeks for patients less than 30 kg, or administered once every week for patients 30 kg or greater.
- Patients will be limited to receiving one month of tocilizumab per prescription at their pharmacy.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric RA Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
2) The Pediatric RA Specialist must confirm in writing that the patient is a responder as demonstrated by JIA ACR30 response and/or absence of fever and/or reduction in inflammatory markers [e.g., C-reactive protein (CRP) concentration of less than 15 mg/L or reduction in erythrocyte sedimentation rate (ESR)].
Following this assessment, continued coverage may be approved for a period of 12 months.
Coverage for tocilizumab will be provided for:
- One intravenous dose of 12 mg/kg for patients weighing less than 30 kg or 8 mg/kg for patients weighing greater than or equal to 30 kg (up to a maximum of 800 mg per dose), administered every two weeks, OR
- One 162 mg subcutaneous dose administered every one to two weeks (based on weight).
After twelve months, in order to be considered for continued coverage, the patient must meet the following criteria:
1) The patient has been re-assessed every 12 months by a Pediatric RA Specialist to determine response, AND
2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy."

All requests (including renewal requests) for tocilizumab for Systemic Juvenile Idiopathic Arthritis must be completed using the Tocilizumab for Systemic Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60048).

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400 MG / VIAL INJECTION

00002350114	ACTEMRA (20 ML)	HLR	$	914.0000

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 16 weeks as follows:
- Tocilizumab intravenous infusion: one dose of 4 mg/kg or 8 mg/kg (up to a maximum of 800 mg per dose) of tocilizumab administered at 0, 4, 8, 12 and 16 weeks (total of 5 doses). Patients will be limited to receiving one dose of intravenous tocilizumab per prescription at their pharmacy.
-Tocilizumab subcutaneous injection: for patients weighing less than 100 kg, initial coverage may be approved for one 162 mg dose of tocilizumab administered every other week, up to weekly based on clinical response. For patients weighing 100 kg or more, initial coverage may be approved for one 162 mg dose of tocilizumab administered every week. Patients will be limited to receiving a one-month supply of subcutaneous tocilizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial 16 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 16 weeks, but no longer than 20 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for tocilizumab will be provided for one intravenous dose of 4 mg/kg to 8 mg/kg (up to a maximum of 800 mg per dose) every 4 weeks, or one 162 mg subcutaneous dose administered every one to two weeks (based on weight and clinical response). Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, OR
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal

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place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for tocilizumab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Systemic Juvenile Idiopathic Arthritis

"Special authorization coverage may be provided for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older when all of the following conditions are met:
- the patient has a diagnosis of systemic JIA with fever (greater than 38 degrees Celsius) for at least two weeks and at least one of the following: rash of systemic JIA; serositis; lymphadenopathy; hepatomegaly; splenomegaly; AND
- the physician has ruled out other potential etiologies; AND
- the patient is refractory to one or more non-steroidal anti-inflammatory drugs (NSAIDs) and one or more systemic corticosteroids.

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric RA Specialist).

- Initial coverage may be approved for 12 weeks as follows:
- Tocilizumab intravenous infusion: 12 mg/kg/dose for patients weighing less than 30 kg, or 8 mg/kg/dose for patients weighing greater than or equal to 30 kg (up to a maximum of 800 mg per dose), administered every two weeks, OR
- Tocilizumab subcutaneous injection: one 162 mg dose of tocilizumab administered once every 2 weeks for patients less than 30 kg, or administered once every week for patients 30 kg or greater.
- Patients will be limited to receiving one month of tocilizumab per prescription at their pharmacy.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric RA Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
2) The Pediatric RA Specialist must confirm in writing that the patient is a responder as demonstrated by JIA ACR30 response and/or absence of fever and/or reduction in inflammatory markers [e.g., C-reactive protein (CRP) concentration of less than 15 mg/L or reduction in erythrocyte sedimentation rate (ESR)].
Following this assessment, continued coverage may be approved for a period of 12 months.
Coverage for tocilizumab will be provided for:
- One intravenous dose of 12 mg/kg for patients weighing less than 30 kg or 8 mg/kg for patients weighing greater than or equal to 30 kg (up to a maximum of 800 mg per dose), administered every two weeks, OR
- One 162 mg subcutaneous dose administered every one to two weeks (based on weight).
After twelve months, in order to be considered for continued coverage, the patient must meet the following criteria:
1) The patient has been re-assessed every 12 months by a Pediatric RA Specialist to determine response, AND
2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy."

All requests (including renewal requests) for tocilizumab for Systemic Juvenile Idiopathic Arthritis must be completed using the Tocilizumab for Systemic Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60048).

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162 MG / SYR INJECTION SYRINGE

☒ 00002483327 ACTEMRA (0.9 ML AUTO INJECTOR) HLR $ 355.0000

Giant Cell Arteritis

"Special authorization coverage may be provided for use in combination with glucocorticoids for the treatment of giant cell arteritis (GCA) in adult patients.

For coverage, this drug must be initiated in consultation with a Specialist in Internal Medicine, Rheumatology or Neurology.

Initial coverage may be approved for 12 weeks as follows:
-Coverage may be approved for one 162 mg subcutaneous dose of tocilizumab administered every week.
-As an interim measure, coverage will be provided for additional doses up to week 16, to allow time to determine whether the patient meets criteria for continued coverage below.
-Patients will be limited to receiving a one-month supply of subcutaneous tocilizumab per prescription at their pharmacy.
-Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed after 12 weeks, but no longer than 16 weeks after treatment to determine response; AND
2) The patient must be a `responder' that meets the following criteria:
-Patient has achieved remission which is defined as the absence of flare* AND normalization of C-reactive protein (CRP) to <1 mg/dL (<10 mg/L).
*Flare is defined as the recurrence of signs or symptoms of GCA and/or erythrocyte sedimentation rate (ESR) greater or equal to 30 mm/hr attributable to GCA.

Following this assessment, continued coverage may be approved for one 162 mg subcutaneous dose administered every week for a period of 36 weeks.

Duration of therapy with tocilizumab will be limited to 52 weeks per treatment course. Re-treatment may be considered for patients who experience a disease flare after treatment discontinuation."

All requests (including renewal requests) for tocilizumab for Giant Cell Arteritis must be completed using the Tocilizumab for Giant Cell Arteritis Special Authorization Request Form (ABC 60066).

Polyarticular Juvenile Idiopathic Arthritis

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older who:
- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDs) conventionally used in children (minimum three month trial).

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects (e.g., leukopenia, hepatitis) or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric Rheumatology Specialist).

- Initial coverage may be approved for 12 weeks as follows:
- Tocilizumab intravenous infusion: 10 mg/kg/dose for patients less than 30 kg, or 8 mg/kg/dose for patients 30 kg or greater every 4 weeks.
- Tocilizumab subcutaneous injection: one 162 mg dose of tocilizumab administered every 3 weeks for patients less than 30 kg, or administered every other week for patients 30 kg or greater.
- Patients will be limited to receiving up to a one-month supply of tocilizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.

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- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
- 30% improvement from baseline in at least three of the following six response variables, with worsening of 30% or more in no more than one of the six variables. The variables include:
i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,
ii. global assessment of overall well-being by the patient or parent,
iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
iv. number of joints with limitation of motion,
v. functional ability based on CHAQ scores,
vi. ESR or CRP
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for tocilizumab will be provided for one intravenous dose of 8 mg/kg to 10 mg/kg every 4 weeks, or one 162 mg subcutaneous dose administered every two to three weeks (based on weight). After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:
1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Once a child with pJIA has had two disease-free years, it is common clinical practice for drug treatment to be stopped."

All requests (including renewal requests) for tocilizumab for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Adalimumab/Etanercept/Tocilizumab for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60011).

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)
Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 16 weeks as follows:

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- Tocilizumab intravenous infusion: one dose of 4 mg/kg or 8 mg/kg (up to a maximum of 800 mg per dose) of tocilizumab administered at 0, 4, 8, 12 and 16 weeks (total of 5 doses). Patients will be limited to receiving one dose of intravenous tocilizumab per prescription at their pharmacy.
-Tocilizumab subcutaneous injection: for patients weighing less than 100 kg, initial coverage may be approved for one 162 mg dose of tocilizumab administered every other week, up to weekly based on clinical response. For patients weighing 100 kg or more, initial coverage may be approved for one 162 mg dose of tocilizumab administered every week. Patients will be limited to receiving a one-month supply of subcutaneous tocilizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial 16 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 16 weeks, but no longer than 20 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for tocilizumab will be provided for one intravenous dose of 4 mg/kg to 8 mg/kg (up to a maximum of 800 mg per dose) every 4 weeks, or one 162 mg subcutaneous dose administered every one to two weeks (based on weight and clinical response). Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, OR
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for tocilizumab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Systemic Juvenile Idiopathic Arthritis

"Special authorization coverage may be provided for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older when all of the following conditions are met:
- the patient has a diagnosis of systemic JIA with fever (greater than 38 degrees Celsius) for at least two weeks and at least one of the following: rash of systemic JIA; serositis; lymphadenopathy; hepatomegaly; splenomegaly; AND
- the physician has ruled out other potential etiologies; AND
- the patient is refractory to one or more non-steroidal anti-inflammatory drugs (NSAIDs) and one or more systemic corticosteroids.

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects or contraindications to treatments as defined in the product monographs.

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For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric RA Specialist).

- Initial coverage may be approved for 12 weeks as follows:
- Tocilizumab intravenous infusion: 12 mg/kg/dose for patients weighing less than 30 kg, or 8 mg/kg/dose for patients weighing greater than or equal to 30 kg (up to a maximum of 800 mg per dose), administered every two weeks, OR
- Tocilizumab subcutaneous injection: one 162 mg dose of tocilizumab administered once every 2 weeks for patients less than 30 kg, or administered once every week for patients 30 kg or greater.
- Patients will be limited to receiving one month of tocilizumab per prescription at their pharmacy.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric RA Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
2) The Pediatric RA Specialist must confirm in writing that the patient is a responder as demonstrated by JIA ACR30 response and/or absence of fever and/or reduction in inflammatory markers [e.g., C-reactive protein (CRP) concentration of less than 15 mg/L or reduction in erythrocyte sedimentation rate (ESR)].
Following this assessment, continued coverage may be approved for a period of 12 months.
Coverage for tocilizumab will be provided for:
- One intravenous dose of 12 mg/kg for patients weighing less than 30 kg or 8 mg/kg for patients weighing greater than or equal to 30 kg (up to a maximum of 800 mg per dose), administered every two weeks, OR
- One 162 mg subcutaneous dose administered every one to two weeks (based on weight).
After twelve months, in order to be considered for continued coverage, the patient must meet the following criteria:
1) The patient has been re-assessed every 12 months by a Pediatric RA Specialist to determine response, AND
2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy."

All requests (including renewal requests) for tocilizumab for Systemic Juvenile Idiopathic Arthritis must be completed using the Tocilizumab for Systemic Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60048).

☒	00002424770	ACTEMRA (0.9 ML SYRINGE)	HLR	$	358.9050

Giant Cell Arteritis

"Special authorization coverage may be provided for use in combination with glucocorticoids for the treatment of giant cell arteritis (GCA) in adult patients.

For coverage, this drug must be initiated in consultation with a Specialist in Internal Medicine, Rheumatology or Neurology.

Initial coverage may be approved for 12 weeks as follows:
-Coverage may be approved for one 162 mg subcutaneous dose of tocilizumab administered every week.
-As an interim measure, coverage will be provided for additional doses up to week 16, to allow time to determine whether the patient meets criteria for continued coverage below.
-Patients will be limited to receiving a one-month supply of subcutaneous tocilizumab per prescription at their pharmacy.
-Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed after 12 weeks, but no longer than 16 weeks after treatment to determine response; AND
2) The patient must be a `responder' that meets the following criteria:
-Patient has achieved remission which is defined as the absence of flare* AND normalization of C-reactive protein (CRP) to <1 mg/dL (<10 mg/L).
*Flare is defined as the recurrence of signs or symptoms of GCA and/or erythrocyte sedimentation rate (ESR) greater or equal to 30 mm/hr attributable to GCA.

Following this assessment, continued coverage may be approved for one 162 mg subcutaneous dose administered every week for a period of 36 weeks.

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Duration of therapy with tocilizumab will be limited to 52 weeks per treatment course. Re-treatment may be considered for patients who experience a disease flare after treatment discontinuation."

All requests (including renewal requests) for tocilizumab for Giant Cell Arteritis must be completed using the Tocilizumab for Giant Cell Arteritis Special Authorization Request Form (ABC 60066).

Polyarticular Juvenile Idiopathic Arthritis

"Special authorization coverage may be provided for the reduction in signs and symptoms of severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older who:
- Have 5 or more active joints (defined by either swelling or limitation of motion plus pain and/or tenderness), AND
- Are refractory to one or more disease modifying anti-rheumatic agents (DMARDs) conventionally used in children (minimum three month trial).

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects (e.g., leukopenia, hepatitis) or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric Rheumatology Specialist).

- Initial coverage may be approved for 12 weeks as follows:
- Tocilizumab intravenous infusion: 10 mg/kg/dose for patients less than 30 kg, or 8 mg/kg/dose for patients 30 kg or greater every 4 weeks.
- Tocilizumab subcutaneous injection: one 162 mg dose of tocilizumab administered every 3 weeks for patients less than 30 kg, or administered every other week for patients 30 kg or greater.
- Patients will be limited to receiving up to a one-month supply of tocilizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
- 30% improvement from baseline in at least three of the following six response variables, with worsening of 30% or more in no more than one of the six variables. The variables include:
i. global assessment of the severity of the disease by the Pediatric Rheumatology Specialist,
ii. global assessment of overall well-being by the patient or parent,
iii. number of active joints (joints with swelling not due to deformity or joints with limitation of motion with pain tenderness or both),
iv. number of joints with limitation of motion,
v. functional ability based on CHAQ scores,
vi. ESR or CRP
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for tocilizumab will be provided for one intravenous dose of 8 mg/kg to 10 mg/kg every 4 weeks, or one 162 mg subcutaneous dose administered every two to three weeks (based on weight). After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:
1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by maintenance of the ACR Pedi 30,

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3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

Once a child with pJIA has had two disease-free years, it is common clinical practice for drug treatment to be stopped."

All requests (including renewal requests) for tocilizumab for Polyarticular Juvenile Idiopathic Arthritis must be completed using the Adalimumab/Etanercept/Tocilizumab for Polyarticular Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60011).

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4-month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 16 weeks as follows:
- Tocilizumab intravenous infusion: one dose of 4 mg/kg or 8 mg/kg (up to a maximum of 800 mg per dose) of tocilizumab administered at 0, 4, 8, 12 and 16 weeks (total of 5 doses). Patients will be limited to receiving one dose of intravenous tocilizumab per prescription at their pharmacy.
-Tocilizumab subcutaneous injection: for patients weighing less than 100 kg, initial coverage may be approved for one 162 mg dose of tocilizumab administered every other week, up to weekly based on clinical response. For patients weighing 100 kg or more, initial coverage may be approved for one 162 mg dose of tocilizumab administered every week. Patients will be limited to receiving a one-month supply of subcutaneous tocilizumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial 16 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 16 weeks, but no longer than 20 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for tocilizumab will be provided for one intravenous dose of 4 mg/kg to 8 mg/kg (up to a

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maximum of 800 mg per dose) every 4 weeks, or one 162 mg subcutaneous dose administered every one to two weeks (based on weight and clinical response). Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, OR
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for tocilizumab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Systemic Juvenile Idiopathic Arthritis

"Special authorization coverage may be provided for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older when all of the following conditions are met:
- the patient has a diagnosis of systemic JIA with fever (greater than 38 degrees Celsius) for at least two weeks and at least one of the following: rash of systemic JIA; serositis; lymphadenopathy; hepatomegaly; splenomegaly; AND
- the physician has ruled out other potential etiologies; AND
- the patient is refractory to one or more non-steroidal anti-inflammatory drugs (NSAIDs) and one or more systemic corticosteroids.

"Refractory" is defined as one or more of the following: lack of effect, serious adverse effects or contraindications to treatments as defined in the product monographs.

For coverage, this drug must be prescribed by a prescriber affiliated with a Pediatric Rheumatology Clinic in Edmonton or Calgary (Pediatric RA Specialist).

- Initial coverage may be approved for 12 weeks as follows:
- Tocilizumab intravenous infusion: 12 mg/kg/dose for patients weighing less than 30 kg, or 8 mg/kg/dose for patients weighing greater than or equal to 30 kg (up to a maximum of 800 mg per dose), administered every two weeks, OR
- Tocilizumab subcutaneous injection: one 162 mg dose of tocilizumab administered once every 2 weeks for patients less than 30 kg, or administered once every week for patients 30 kg or greater.
- Patients will be limited to receiving one month of tocilizumab per prescription at their pharmacy.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric RA Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
2) The Pediatric RA Specialist must confirm in writing that the patient is a responder as demonstrated by JIA ACR30 response and/or absence of fever and/or reduction in inflammatory markers [e.g., C-reactive protein (CRP) concentration of less than 15 mg/L or reduction in erythrocyte sedimentation rate (ESR)].
Following this assessment, continued coverage may be approved for a period of 12 months. Coverage for tocilizumab will be provided for:
- One intravenous dose of 12 mg/kg for patients weighing less than 30 kg or 8 mg/kg for patients weighing greater than or equal to 30 kg (up to a maximum of 800 mg per dose), administered every two weeks, OR
- One 162 mg subcutaneous dose administered every one to two weeks (based on weight).
After twelve months, in order to be considered for continued coverage, the patient must meet the following criteria:
1) The patient has been re-assessed every 12 months by a Pediatric RA Specialist to determine response, AND
2) The Pediatric RA Specialist must confirm in writing that the patient has maintained a response to therapy."

All requests (including renewal requests) for tocilizumab for Systemic Juvenile Idiopathic Arthritis

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must be completed using the Tocilizumab for Systemic Juvenile Idiopathic Arthritis Special Authorization Request Form (ABC 60048).

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Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial) [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for three months as follows:
- Tofacitinib 5 mg tablet: one tablet twice daily.
- Tofacitinib 11 mg extended-release tablet: one tablet daily.
- Patients will be limited to receiving a one-month supply of tofacitinib per prescription at their pharmacy.
- Patients will not be permitted to switch back to tofacitinib if they were deemed unresponsive to therapy.

For continued coverage beyond three months, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial three months to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 5 mg twice daily or 11 mg once daily for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- confirmation of maintenance of ACR20, or
- maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be

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rounded to the correct number of decimal places as indicated above.

Coverage cannot be provided for tofacitinib when intended for use in combination with a biologic agent or other Janus kinase (JAK) inhibitors."

All requests (including renewal requests) for tofacitinib for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Ulcerative Colitis

"Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:
- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks; AND
- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:
i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

For coverage, this drug must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross ('Specialist').

Initial coverage may be approved for an initial dose of 10 mg twice daily for 8 weeks. As an interim measure, coverage will be provided for additional doses of 5 mg twice daily for 4 weeks, to allow time to determine whether the New Patient meets coverage criteria for Maintenance Dosing below.

- Patients will be limited to receiving a one-month supply of tofacitinib per prescription at their pharmacy.
- Patients will not be permitted to switch back to tofacitinib if they were deemed unresponsive to therapy.

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:
1) The patient must be assessed by a Specialist after 8 weeks but no longer than 12 weeks after treatment to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for a dose of 5 mg twice daily for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist in Gastroenterology to determine response;

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2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of tofacitinib therapy.

Coverage cannot be provided for tofacitinib when intended for use in combination with a biologic agent."

Note: For patients who showed a response to induction therapy then experienced secondary loss of response while on maintenance dosing with 5 mg, the maintenance dose may be adjusted from 5 mg to 10 mg by making an additional special authorization request to Alberta Blue Cross for the increased dose.

All requests (including renewal requests) for tofacitinib for Ulcerative Colitis must be completed using the Adalimumab/Golimumab/Infliximab/Tofacitinib/Vedolizumab for Ulcerative Colitis Special Authorization Request Form (ABC 60008).

5 MG (BASE) ORAL TABLET

00002530007	**AURO-TOFACITINIB**	**AUR**	$	**5.9897**
00002522799	**PMS-TOFACITINIB**	**PMS**	$	**5.9897**
00002511304	**TARO-TOFACITINIB**	**TAR**	$	**5.9897**
00002423898	XELJANZ	PFI	$	24.7733

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Ulcerative Colitis

"Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:

- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks; AND
- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:
i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

For coverage, this drug must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross ('Specialist').

Initial coverage may be approved for an initial dose of 10 mg twice daily for 8 weeks. As an interim measure, coverage will be provided for additional doses of 5 mg twice daily for 4 weeks, to allow time to determine whether the New Patient meets coverage criteria for Maintenance Dosing below.

- Patients will be limited to receiving a one-month supply of tofacitinib per prescription at their pharmacy.
- Patients will not be permitted to switch back to tofacitinib if they were deemed unresponsive to therapy.

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:
1) The patient must be assessed by a Specialist after 8 weeks but no longer than 12 weeks after treatment to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for a dose of 5 mg twice daily for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist in Gastroenterology to determine response;
2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of tofacitinib therapy.

Coverage cannot be provided for tofacitinib when intended for use in combination with a biologic agent."

Note: For patients who showed a response to induction therapy then experienced secondary loss of response while on maintenance dosing with 5 mg, the maintenance

TOFACITINIB CITRATE

dose may be adjusted from 5 mg to 10 mg by making an additional special authorization request to Alberta Blue Cross for the increased dose.

All requests (including renewal requests) for tofacitinib for Ulcerative Colitis must be completed using the Adalimumab/Golimumab/Infliximab/Tofacitinib/Vedolizumab for Ulcerative Colitis Special Authorization Request Form (ABC 60008).

10 MG (BASE)	ORAL	TABLET			
☒ 00002480786	XELJANZ		PFI	$	43.7833

TOFACITINIB CITRATE

Rheumatoid Arthritis

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:
- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial) [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for three months as follows:
- Tofacitinib 5 mg tablet: one tablet twice daily.
- Tofacitinib 11 mg extended-release tablet: one tablet daily.
- Patients will be limited to receiving a one-month supply of tofacitinib per prescription at their pharmacy.
- Patients will not be permitted to switch back to tofacitinib if they were deemed unresponsive to therapy.

For continued coverage beyond three months, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial three months to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 5 mg twice daily or 11 mg once daily for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- confirmation of maintenance of ACR20, or
- maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be

TOFACITINIB CITRATE

rounded to the correct number of decimal places as indicated above.

Coverage cannot be provided for tofacitinib when intended for use in combination with a biologic agent or other Janus kinase (JAK) inhibitors."

All requests (including renewal requests) for tofacitinib for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

11 MG (BASE) ORAL EXTENDED-RELEASE TABLET				
00002470608	XELJANZ XR	PFI	$	49.5467

TRETINOIN

"For the treatment of severe acne as defined by scarring acne.

Special authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

0.025 % TOPICAL GEL				
00001926470	VITAMIN A ACID	VCL	$	0.3600
0.05 % TOPICAL GEL				
00001926489	VITAMIN A ACID	VCL	$	0.3600
0.01 % TOPICAL CREAM				
00000657204	STIEVA-A	GSK	$	0.3211
0.025 % TOPICAL CREAM				
00000578576	STIEVA-A	GSK	$	0.3211
0.05 % TOPICAL CREAM				
00000518182	STIEVA-A	GSK	$	0.2143
0.01 % TOPICAL GEL				
00001926462	VITAMIN A ACID	VCL	$	0.3600

TRIENTINE HYDROCHLORIDE

"For the treatment of Wilson's disease in patients who have experienced intolerance or have a contraindication to d-penicillamine.

For coverage of adult patients 18 years of age or older, this drug product must be initiated by clinicians experienced in the management of Wilson's disease.

For coverage of patients less than 18 years of age, this drug product must be prescribed by clinicians experienced in the management of Wilson's disease.

Coverage may be approved for 6 months."

The product(s) are eligible for auto-renewal.

250 MG ORAL CAPSULE				
☒ 00002504855	MAR-TRIENTINE	MAR	$	20.0000
☒ 00002515067	WAYMADE-TRIENTINE	WYM	$	20.0000

TROSPIUM CHLORIDE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

FIRST-LINE DRUG PRODUCT(S): SOLIFENACIN OR TOLTERODINE LA

"For patients who have failed on or are intolerant to solifenacin or tolterodine LA."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective
UQ - First-line therapy not tolerated

All requests for trospium chloride must be completed using the darifenacin hydrobromide/Fesoterodine fumarate/Mirabegron/Trospium chloride Special Authorization Request Form (ABC 60088).

20 MG ORAL TABLET

00002488353	**MAR-TROSPIUM**	**MAR**	$	**0.6108**
00002275066	TROSEC	SUN	$	0.7820

UMECLIDINIUM BROMIDE/ VILANTEROL TRIFENATATE

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

FIRST-LINE DRUG PRODUCT(S): LONG-ACTING BRONCHODILATOR (I.E., LONG-ACTING BETA-2 AGONIST [LABA] OR LONG-ACTING MUSCARINIC ANTAGONIST [LAMA])

"For the long-term maintenance treatment of airflow obstruction in patients with moderate to severe (i.e., FEV1 < 80% predicted) chronic obstructive pulmonary disease (COPD), who have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA])."

"For the long-term maintenance treatment of airflow obstruction in patients with severe (i.e., FEV1 < 50% predicted) chronic obstructive pulmonary disease (COPD)."

"Special authorization may be granted for 24 months."

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

UP - First-line therapy ineffective

All requests for umeclidinium bromide + vilanterol trifenatate must be completed using the Long-Acting Fixed-Dose Combination Products for Asthma/COPD Special Authorization Request Form (ABC 60025).

62.5 MCG / DOSE (BASE) * 25 MCG / DOSE (BASE) INHALATION METERED INHALATION POWDER

00002418401	ANORO ELLIPTA	GSK	$	2.9437

UPADACITINIB

RHEUMATOID ARTHRITIS

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial) [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 15 mg once daily for three months.
- Patients will be limited to receiving a one-month supply of upadacitinib per prescription at their pharmacy.
- Patients will not be permitted to switch back to upadacitinib if they were deemed unresponsive to therapy.

For continued coverage beyond three months, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial three months to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for upadacitinib 15 mg once daily for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- confirmation of maintenance of ACR20, or
- maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Coverage cannot be provided for upadacitinib when intended for use in combination with a biologic agent or other Janus kinase (JAK) inhibitors."

All requests (including renewal requests) for upadacitinib for Rheumatoid Arthritis must be

UPADACITINIB

completed using the Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab/Sarilumab/Tocilizumab/Tofacitinib/Upadacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

PSORIATIC ARTHRITIS

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for 15 mg once daily for three months.
- Patients will be limited to receiving a one-month supply of upadacitinib per prescription at their pharmacy.
- Patients will not be permitted to switch back to upadacitinib if they were deemed unresponsive to therapy.

For continued coverage beyond three months, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial 3 months to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 15 mg once daily, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests. It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

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Coverage cannot be provided for upadacitinib when intended for use in combination with a biologic agent or other Janus kinase (JAK) inhibitors."

All requests (including renewal requests) for upadacitinib for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab/Upadacitinib for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

15 MG ORAL EXTENDED-RELEASE TABLET

00002495155	RINVOQ	ABV	$	50.8935

USTEKINUMAB

PLAQUE PSORIASIS

"Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:

- Have a total PASI of 10 or more and a DLQI of more than 10, OR
- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory to or intolerant to:

at least THREE of the following:
- adalimumab
- bimekizumab
- etanercept
- infliximab
- ixekizumab
- risankizumab
- secukinumab
- tildrakizumab

AND

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
- Cyclosporine (6 weeks treatment); AND
- Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

- Initial coverage may be approved for three doses of 45 mg (90 mg for patients weighing greater than 100 kg) at weeks 0, 4 and 16.
- Patients will be limited to receiving one dose per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage, the patient must meet all of the following criteria:
1) The patient must be assessed by a Dermatology Specialist after the initial 16 weeks of therapy to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Greater than or equal to 75% reduction in PASI score, OR
- Greater than or equal to 50% reduction in PASI score AND improvement of greater than or

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equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for 45 mg (90 mg for patients weighing greater than 100 kg) every 12 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for ustekinumab for Plaque Psoriasis must be completed using the Adalimumab/Bimekizumab/Etanercept/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Tildrakizumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

45 MG INJECTION VIAL OR SYRINGE				
00002320673	STELARA (0.5 ML VIAL OR SYRINGE)	JAI	$	4465.5800
For this product - pricing has been established on a per vial or syringe basis.				
90 MG / SYR INJECTION SYRINGE				
00002320681	STELARA (1 ML SYRINGE)	JAI	$	4465.5800

VARENICLINE TARTRATE

For subsequent prescriptions, patients may obtain this product via special authorization with the following criteria for coverage:

"For use in patients 18 years of age and older for smoking cessation treatment in conjunction with smoking cessation counseling.

Special authorization coverage may be granted for a maximum of 24 weeks of therapy per year."

This product is not eligible for auto-renewal.

0.5 MG (BASE) ORAL TABLET				
00002419882	**APO-VARENICLINE**	**APX**	$	**0.9237**
00002426226	**TEVA-VARENICLINE**	**TEV**	$	**0.9237**
00002291177	CHAMPIX	PFI	$	1.8437
1 MG (BASE) ORAL TABLET				
00002419890	**APO-VARENICLINE**	**APX**	$	**0.9235**
00002426234	**TEVA-VARENICLINE**	**TEV**	$	**0.9235**
00002291185	CHAMPIX	PFI	$	1.8432

VARENICLINE TARTRATE/ VARENICLINE TARTRATE

For subsequent prescriptions, patients may obtain this product via special authorization with the following criteria for coverage:

"For use in patients 18 years of age and older for smoking cessation treatment in conjunction with smoking cessation counseling.

Special authorization coverage may be granted for a maximum of 24 weeks of therapy per year."

This product is not eligible for auto-renewal.

0.5 MG * 1 MG ORAL TABLET

00002435675	**APO-VARENICLINE (STARTER PACK)**	**APX**	$	**0.9203**
00002426781	**TEVA-VARENICLINE (STARTER PACK)**	**TEV**	$	**0.9203**
00002298309	CHAMPIX (STARTER PACK)	PFI	$	1.8370

VEDOLIZUMAB

Ulcerative Colitis

"Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:
- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks
AND
- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:
i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

For coverage, this drug must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross ('Specialist').

Initial coverage may be approved for three doses of 300 mg of vedolizumab intravenous (IV) with one dose dispensed at 0, 2 and 6 weeks OR two doses of 300 mg of vedolizumab IV with one dose dispensed at 0 and 2 weeks, followed by 108 mg vedolizumab subcutaneous (SC) at 6, 8, 10 and 12 weeks.

- Patients will be limited to receiving one dose of vedolizumab IV OR two doses of vedolizumab SC per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:
1) The patient must be assessed by a Specialist between weeks 10 and 12 after the initiation of therapy to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for a dose of 300 mg IV every 8 weeks or 108 mg SC every 2 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist in Gastroenterology to determine response;
2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of vedolizumab therapy."

All requests (including renewal requests) for vedolizumab for Ulcerative Colitis must be

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completed using the Adalimumab/Golimumab/Infliximab/Tofacitinib/Vedolizumab for Ulcerative Colitis Special Authorization Request Form (ABC 60008).

Moderately to Severely Active Crohn's Disease

"Special authorization coverage may be approved for coverage of vedolizumab for the reduction in signs and symptoms and induction and maintenance of clinical remission of Moderately to Severely Active Crohn's Disease in patients who meet the following criteria:

- vedolizumab must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross for coverage for the treatment of Moderately to Severely Active Crohn's Disease patients ('Specialist').
- Patients must be 18 years of age or older to be considered for coverage of vedolizumab.
- Patients will be limited to receiving one dose of vedolizumab intravenous (IV) OR two doses of vedolizumab subcutaneous (SC) per prescription at their pharmacy.
- Patients may be allowed to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy (both primary loss of response and secondary loss of response) or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

Prior to initiation of vedolizumab therapy for New Patients:
'New Patients' are patients who have never been treated with vedolizumab by any health care provider.

Moderately to Severely Active Crohn's Disease:
Prior to initiation of vedolizumab therapy, New Patients must have a current Modified (without the physical exam) Harvey Bradshaw Index score of greater than or equal to 7 (New Patient's Baseline Score), AND be Refractory.

Refractory is defined as one or more of the following:
1) Serious adverse effects or reactions to the treatments specified below; OR
2) Contraindications (as defined in product monographs) to the treatments specified below; OR
3) Previous documented lack of effect at doses and for duration of all treatments specified below:
a) mesalamine: minimum of 3 grams/day for a minimum of 6 weeks; AND refractory to, or dependent on, glucocorticoids: following at least one tapering dosing schedule of 40 mg/day, tapering by 5 mg each week to 20 mg, then tapering by 2.5 mg each week to zero, or similar.
[Note: Patients who have used the above treatments in combination will not be required to be challenged with individual treatments as monotherapy]

AND
b) Immunosuppressive therapy as follows:
- Azathioprine: minimum of 2 mg/kg/day for a minimum of 3 months; OR
- 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 3 months; OR
- Methotrexate: minimum or 15 mg/week for a minimum of 3 months.
OR
- Immunosuppressive therapy discontinued at less than 3 months due to serious adverse effects or reactions.

Applications for coverage must include information regarding the dosages and duration of trial of each treatment the patient received, a description of any adverse effects, reactions, contraindications and/or lack of effect, as well as any other information requested by Alberta Blue Cross.

Coverage Criteria for Moderately to Severely Active Crohn's Disease

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- New Patients must meet the criteria above prior to being considered for approval.
- All approvals are also subject to the following applicable criteria.

Induction Dosing for New Patients:
- Coverage for Induction Dosing may only be approved for New Patients (those who have never been treated with vedolizumab by any health care provider).
- 'Induction Dosing' means a maximum of one 300 mg dose of vedolizumab IV per New Patient at 0, 2 and 6 weeks (for a maximum total of three doses) OR one 300 mg dose of vedolizumab IV per New Patient at 0 and 2 weeks, followed by one 108 mg dose of vedolizumab SC at 6, 8, 10, 12 and 14 weeks.
- New Patients are eligible to receive Induction Dosing only once, after which time the Maintenance Dosing for New Patients and Continued Coverage for Maintenance Dosing criteria will apply.

Maintenance Dosing:
'Maintenance Dosing' means one 300 mg dose of vedolizumab IV per patient every eight (8) weeks OR one 108 mg dose of vedolizumab SC per patient every 2 weeks for a period of 12 months to:
- New Patients following the completion of Induction Dosing; OR
- Existing Patients, who are patients that are being treated, or have previously been treated, with vedolizumab.

Maintenance Dosing for New Patients after Completion of Induction Dosing:
- The New Patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of Induction Dosing to determine response by obtaining a Modified Harvey Bradshaw Index score for patients with Moderately to Severely Active Crohn's Disease; AND
- The Specialist must confirm the Modified Harvey Bradshaw Index score shows a decrease from the New Patient's Baseline Score of greater than or equal to 3 points for patients with Moderately to Severely Active Crohn's.

Maintenance Dosing for Existing Patients:
- The patient must be assessed by a Specialist at least 4 to 8 weeks after the day the last dose of vedolizumab IV was administered to the patient and prior to the administration of the next dose, or within 2 weeks after a dose of vedolizumab SC was administered, to obtain a Modified Harvey Bradshaw Index Score (Existing Patient's Baseline Score) for Moderately to Severely Active Crohn's; AND
- these measures must be provided to Alberta Blue Cross for assessment for continued coverage for maintenance dosing.

Continued Coverage for Maintenance Dosing:
-Continued coverage may be considered for one 300 mg dose of vedolizumab IV per patient provided no more often than every 8 weeks OR two 108 mg doses of vedolizumab SC per patient provided no more often than every 4 weeks for a period of 12 months, if the following criteria are met at the end of each 12 month period:

- The New Patient or the Existing Patient must be assessed by a Specialist at least 4 to 6 weeks after the day the last dose of vedolizumab IV was administered to the patient and prior to the administration of the next dose, or within 2 weeks after a dose of vedolizumab SC was administered, to obtain a Modified Harvey Bradshaw Index Score for Moderately to Severely Active Crohn's; AND
- For New Patients: The Specialist must confirm that the patient has maintained a greater than or equal to 3 point decrease from the New Patient's Baseline Score for Moderately to Severely Active Crohn's; OR
- For Existing Patients: The Specialist must confirm that the patient has maintained the Existing Patient's Baseline Score."

All requests (including renewal requests) for vedolizumab for Moderately to Severely Active Crohn's Disease must be completed using the Adalimumab/Vedolizumab for Crohn's/Infliximab for Crohn's/Fistulizing Crohn's Special Authorization Request Form (ABC 60031).

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300 MG / VIAL INJECTION				
00002436841	ENTYVIO	TAK	$	3401.8600
108 MG / SYR INJECTION SYRINGE				
⊠ 00002497875	ENTYVIO	TAK	$	850.4600
⊠ 00002497867	ENTYVIO (PEN)	TAK	$	850.4600

VELAGLUCERASE ALFA

For long-term enzyme replacement therapy (ERT) for pediatric and adult patients with type 1 Gaucher disease (GD) when the following criteria are met:

1. The diagnosis of GD must have been established by the demonstration of specific deficiency of glucocerebrosidase (GCase) in tissue or cultured skin fibroblasts, or by demonstration of the presence, in tissue or peripheral blood leukocytes, of mutations in the GCase gene known to result in severe enzyme deficiency.

2. Other potentially confounding diagnoses, such as Hodgkin disease or other storage disorders, must have been ruled out. The symptoms experienced by the patient should be shown to be attributable to GD and not some other condition that might mimic it. A trial of therapy would normally be considered in situations of uncertainty only if the symptoms were accompanied by objective evidence (hematological or imaging changes consistent with complaints).

3. The patient should not have any GD-related or other medical condition that might reasonably be expected to compromise their response to treatment. In some patients with GD, secondary pathologic changes, such as avascular necrosis of bone, may already have occurred that would not be expected to respond to enzyme replacement. In such patients, reversal of the pathology is unlikely. Treatment of patients with significant secondary pathology would be directed at preventing further progression of the disease. In these cases, the extent to which symptoms, such as bone pain, are due to active progression of the disease, rather than the secondary pathology, may only be established by a trial of therapy.

4. Treatment should be provided under the care of a specialist with experience in the diagnosis and management of GD.

5. None of the following exclusion criteria apply:
a. The presence of any GD-related condition that might reasonably be expected to compromise a response to therapy
b. The presence of another medical condition that might reasonably be expected to compromise a response to therapy
c. Asymptomatic GD
d. The presence of primary neurological disease due to GD

6. Patients must have the following baseline parameters assessed prior to initiating therapy on velaglucerase alfa:
a. Hemoglobin level and platelet count
b. Presence of splenic infarction, bone crises, radiographic or MRI evidence of incipient destruction of any major joint, spontaneous fractures, chronic bone pain, major joint replacement, liver synthetic dysfunction, symptomatic hepatosplenomegaly, progressive pulmonary disease due to GD, or growth failure in children.

Notes:
- Pregnancy is not considered a contraindication to ERT.
- Patients to be considered for reimbursement of drug costs for ERT must be willing to participate in the long term evaluation of the efficacy of treatment by periodic medical assessment. Failure to comply with recommended medical assessment and investigations may result in withdrawal of financial support of drug therapy.

Initial coverage may be approved at a dosage of up to 60 units/kg every 2 weeks for a period of 6 months.

Ongoing coverage may be considered for up to 60 units/kg every 2 weeks for a period of 6 months at a time during the first 2 years of treatment, and thereafter for 12-month periods, only if the following criteria are met:

- The patient demonstrates all of the following expected treatment outcomes, where applicable:
1. For patients with baseline hemoglobin <85% of lower limit of age- and sex-appropriate normal: Increase hemoglobin levels to >110 g/L for women and children and >120 g/L for men
2. For patients with a baseline platelet count <50 x 10^9/L on two separate occasions at least

VELAGLUCERASE ALFA

one month apart:
a. Increase platelet count to level sufficient to prevent spontaneous bleeding
b. Normalization of platelet count in splenectomized patients
c. In patients with intact spleen, an increase of at least 1.5X in baseline platelet count
3. For patients with a prior splenic infarct at baseline:
a. Reduction of spleen volume by at least 50%
b. Prevention of further splenic infarcts
4. Prevention of bone crises
5. For patients with radiographic or MRI evidence of incipient destruction of any major joint at baseline: Improvement in imaging parameters (either MRI, QCSI2, or BMD)
6. Prevention of spontaneous fractures
7. Reduced bone pain in patients with chronic bone pain at baseline
8. Optimize surgical outcome for major joint replacement surgery where required at baseline. No new major joint replacement surgery thereafter.
9. Improvement in liver function in patients with liver synthetic dysfunction at baseline
10. For patients with symptomatic hepatosplenomegaly at baseline:
a. Reduction of spleen volume by at least 50%
b. Reduction in liver volume by at least 30%
11. For patients with progressive pulmonary disease due to GD at baseline:
a. Improvement in pulmonary hypertension
b. Improvement in oxygenation
c. Reversal of hepatopulmonary syndrome
12. For children with growth failure at baseline: Return to normal range on height percentiles

- Treatment should be discontinued if the above treatment outcomes have not been demonstrated, as evidenced by readings consistent over the previous 12-month period at the maximum dosage of 60 units/kg every 2 weeks.

Patients will be limited to receiving a one-month supply of velaglucerase alfa per prescription at their pharmacy.
Coverage cannot be provided for velaglucerase alfa when this medication is intended for use in combination with other ERT.
Patients will not be permitted to switch back to a previously trialed ERT if they were deemed sub-optimally responsive despite maximum doses.

The dosage of velaglucerase alfa prescribed would depend on the severity of the disease and would be at the discretion of the specialist. The efficacy of treatment should be re-evaluated every 6 months and dosage adjustments made as appropriate. If there has been insufficient response to treatment after 6 months on a lower dose, the dosage may be increased to a maximum of 60 units/kg every 2 weeks. In the event of severe drug reaction, treatment may have to be discontinued. ERT has been shown to be well tolerated with minimal toxicity reported.

All requests for Velaglucerase Alfa must be completed using the Velaglucerase Alfa/Taliglucerase Alfa for Gaucher Disease Special Authorization Request Form (ABC 60070).

400 UNIT / VIAL	**INJECTION**		
00002357119	VPRIV	TAK	$ 1955.0000

VORICONAZOLE

(Refer to Section 1 - Restricted Benefits of the Alberta Drug Benefit List for coverage of the product when prescribed by a Specialist in Infectious Diseases or a designated prescriber.)

"For the treatment of invasive aspergillosis for post-hospital discharge only."*

"For treatment of culture proven invasive candidiasis with documented resistance to fluconazole."*

"This medication must be prescribed in consultation with a specialist in Infectious Diseases."

*Special Authorization is only required when the prescriber prescribing the medication is not a Specialist in Infectious Diseases or a designated prescriber.

50 MG ORAL TABLET				
00002525771	**JAMP VORICONAZOLE**	**JPC**	$	**3.3909**
00002399245	**SANDOZ VORICONAZOLE**	**SDZ**	$	**3.3909**
00002396866	**TEVA-VORICONAZOLE**	**TEV**	$	**3.3909**
00002256460	VFEND	PFI	$	13.3516
200 MG ORAL TABLET				
00002525798	**JAMP VORICONAZOLE**	**JPC**	$	**13.2403**
00002399253	**SANDOZ VORICONAZOLE**	**SDZ**	$	**13.2403**
00002396874	**TEVA-VORICONAZOLE**	**TEV**	$	**13.2403**
00002256479	VFEND	PFI	$	53.3843
40 MG / ML ORAL SUSPENSION				
00002279991	VFEND	PFI	$	11.1665
200 MG / VIAL INJECTION				
00002477696	**VORICONAZOLE INJECTION**	**JPC**	$	**136.5800**
00002256487	VFEND	PFI	$	160.0204

ZOLEDRONIC ACID

Osteoporosis:

"For the treatment of osteoporosis in patients who have:

A high 10-year risk (i.e., greater than 20%) of experiencing a major osteoporotic fracture, OR
A moderate 10-year fracture risk (10-20%) and have experienced a prior fragility fracture;

AND

at least one of the following:

1) For whom oral bisphosphonates are contraindicated due to an abnormality of the esophagus which delays esophageal emptying;

OR

2) Who have demonstrated persistent severe gastrointestinal intolerance to a course of therapy with either alendronate or risedronate;

OR

3) Who had an unsatisfactory response (defined as a fragility fracture despite adhering to oral alendronate or risedronate treatment fully for 1 year and evidence of a decline in BMD below pre-treatment baseline level).

Note: The fracture risk can be determined by the World Health Organization's fracture risk assessment tool, FRAX, or the most recent (2010) version of the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) table.

Special Authorization may be granted for 12 months.

-Patients will be limited to receiving one dose of zoledronic acid per prescription at their pharmacy.

-Coverage cannot be provided for two or more osteoporosis medications (alendronate, denosumab, raloxifene, risedronate, zoledronic acid) when these medications are intended for use as combination therapy.

-Requests for other osteoporosis medications covered via special authorization will not be considered until 6 months after the last dose of denosumab 60 mg/syr injection syringe.

-Requests for other osteoporosis medications covered via special authorization will not be considered until 12 months after the last dose of zoledronic acid 0.05 mg/ml injection."

-This product is eligible for auto-renewal for the treatment of osteoporosis.

All requests for zoledronic acid for osteoporosis must be completed using the Denosumab/Zoledronic Acid for Osteoporosis Special Authorization Request Form (ABC 60007).

Paget's Disease:

"For the treatment of Paget's disease. Special Authorization for this criterion may be granted for one dose per 12 month period."

"Coverage cannot be provided for two or more medications used in the treatment of

ZOLEDRONIC ACID

Paget's disease when these medications are intended for use in combination or when therapy with two or more medications overlap."

0.05 MG / ML INJECTION

00002415100	**TARO-ZOLEDRONIC ACID**	**TAR**	$	**3.5601**
00002422433	**ZOLEDRONIC ACID**	**DRL**	$	**3.5601**
00002269198	ACLASTA	SDZ	$	7.4393

"For the treatment of tumor-induced hypercalcemia in patients with documented evidence of intolerance or lack of response to clodronate or pamidronate.

For the prevention of skeletal-related events in patients with metastatic castration-resistant prostate cancer (CRPC) with one or more bony metastases.

Special authorization may be granted for 6 months."

The following product(s) are eligible for auto-renewal.

All requests for zoledronic acid 0.8 mg/mL injection must be submitted using the Zoledronic Acid 0.8 mg/mL (4 mg/5 mL vial) Special Authorization Request Form (60091).

0.8 MG / ML INJECTION

00002482525	**JAMP-ZOLEDRONIC ACID**	**JPC**	$	**38.7856**
00002415186	**TARO-ZOLEDRONIC ACID CONCENTRATE**	**TAR**	$	**38.7856**
00002407639	**ZOLEDRONIC ACID**	**TEV**	$	**38.7856**
00002444739	**ZOLEDRONIC ACID**	**JUN**	$	**38.7856**
00002401606	**ZOLEDRONIC ACID - Z**	**SDZ**	$	**38.7856**
00002422425	**ZOLEDRONIC ACID CONCENTRATE**	**DRL**	$	**38.7856**
00002472805	**ZOLEDRONIC ACID FOR INJECTION**	**MAR**	$	**38.7856**
00002248296	ZOMETA CONCENTRATE	NOV	$	121.5820

ZOLMITRIPTAN

(Refer to 28:32.28 of the Alberta Drug Benefit List for coverage of patients 18 to 64 years of age inclusive.)

"For the treatment of acute migraine attacks in patients 65 years of age and older where other standard therapy has failed."

"For the treatment of acute migraine attacks in patients 65 years of age and older who have been using zolmitriptan prior to turning 65."

"Special authorization for both criteria may be granted for 24 months."

In order to comply with the first criteria, information is required regarding previous medications utilized and the patient's response to therapy.

The following product(s) are eligible for auto-renewal.

2.5 MG ORAL TABLET				
00002481030	**AURO-ZOLMITRIPTAN**	**AUR**	$	**3.5375**
00002458780	**CCP-ZOLMITRIPTAN**	**CEL**	$	**3.5375**
00002477106	**JAMP ZOLMITRIPTAN**	**JPC**	$	**3.5375**
00002421623	**JAMP-ZOLMITRIPTAN**	**JPC**	$	**3.5375**
00002419521	**MINT-ZOLMITRIPTAN**	**MPI**	$	**3.5375**
00002421534	**NAT-ZOLMITRIPTAN**	**NTP**	$	**3.5375**
00002362988	**SANDOZ ZOLMITRIPTAN**	**SDZ**	$	**3.5375**
00002313960	**TEVA-ZOLMITRIPTAN**	**TEV**	$	**3.5375**
00002442655	**ZOLMITRIPTAN**	**SNS**	$	**3.5375**
00002238660	ZOMIG	XPI	$	15.7069
2.5 MG ORAL DISPERSIBLE TABLET				
00002428237	**JAMP-ZOLMITRIPTAN ODT**	**JPC**	$	**1.7532**
00002428474	**SEPTA-ZOLMITRIPTAN-ODT**	**SEP**	$	**1.7532**
00002243045	ZOMIG RAPIMELT	XPI	$	15.7069
5 MG / DOSE NASAL UNIT DOSE SPRAY				
00002248993	ZOMIG	XPI	$	15.7069