

# **Updates to the Alberta Drug Benefit List**

**Effective December 1, 2021**



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**Website:** <https://www.alberta.ca/drug-benefit-list-and-drug-review-process.aspx>

Administered by Alberta Blue Cross  
on behalf of Alberta Health.

The Drug Benefit List (DBL) is a list of drugs for which coverage may be provided to program participants. The DBL is not intended to be, and must not be used as a diagnostic or prescribing tool. Inclusion of a drug on the DBL does not mean or imply that the drug is fit or effective for any specific purpose. Prescribing professionals must always use their professional judgment and should refer to product monographs and any applicable practice guidelines when prescribing drugs. The product monograph contains information that may be required for the safe and effective use of the product.

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## Special Authorization

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The following drug product(s) will be considered for coverage by Special Authorization effective December 1, 2021 for patients covered under Alberta government-sponsored drug programs.

### New Drug Product(s) Available by Special Authorization

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
MAYZENT 0.25 MG TABLET	SIPONIMOD	00002496429	NOV
MAYZENT 2 MG TABLET	SIPONIMOD	00002496437	NOV

### Additional Brand(s) and/or Strength(s) of Drug Product(s) Available by Special Authorization

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
IDACIO (40 MG / 0.8 ML) 40 MG / SYRINGE INJECTION	ADALIMUMAB	00002502682	FKC
JAMP PIRFENIDONE 267 MG TABLET	PIRFENIDONE	00002514702	JPC
JAMP PIRFENIDONE 801 MG TABLET	PIRFENIDONE	00002514710	JPC
LACOSAMIDE 50 MG TABLET	LACOSAMIDE	00002512874	SNS
LACOSAMIDE 100 MG TABLET	LACOSAMIDE	00002512882	SNS
LACOSAMIDE 150 MG TABLET	LACOSAMIDE	00002512890	SNS
LACOSAMIDE 200 MG TABLET	LACOSAMIDE	00002512904	SNS
OCTREOTIDE 10 MG / VIAL INJECTION	OCTREOTIDE ACETATE	00002503751	TEV
OCTREOTIDE 20 MG / VIAL INJECTION	OCTREOTIDE ACETATE	00002503778	TEV
OCTREOTIDE 30 MG / VIAL INJECTION	OCTREOTIDE ACETATE	00002503786	TEV
RIABNI 10 MG / ML INJECTION	RITUXIMAB	00002513447	AMG

## Drug Product(s) with Changes to Benefit Status

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The following drug product(s) previously covered through Special Authorization will now be covered as regular benefits effective December 1, 2021.

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
SUBLOCADE 100 MG / SYRINGE INJECTION	BUPRENORPHINE	00002483084	IUK
SUBLOCADE 300 MG / SYRINGE INJECTION	BUPRENORPHINE	00002483092	IUK

## Added Product(s)

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<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
NRA-HYDROXYCHLOROQUINE 200 MG TABLET	HYDROXYCHLOROQUINE SULFATE	00002511886	NRA
PMS-LEVETIRACETAM 250 MG TABLET	LEVETIRACETAM	00002296101	PMS

## Added Product(s), continued

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
PMS-LEVETIRACETAM 500 MG TABLET	LEVETIRACETAM	00002296128	PMS
PMS-LEVETIRACETAM 750 MG TABLET	LEVETIRACETAM	00002296136	PMS
RIVA-CLINDAMYCIN 150 MG CAPSULE	CLINDAMYCIN HCL	00002468476	RIV
RIVA-CLINDAMYCIN 300 MG CAPSULE	CLINDAMYCIN HCL	00002468484	RIV
RIVA-DORZOLAMIDE / TIMOLOL 2% / 0.5% OPHTHALMIC SOLUTION	DORZOLAMIDE HCL/ TIMOLOL MALEATE	00002441659	RIV
RIVA-LATANOPROST 0.005 % OPHTHALMIC SOLUTION	LATANOPROST	00002341085	RIV

## New Established Interchangeable (IC) Grouping(s)

The following IC Grouping(s) have been established and LCA pricing will be applied effective December 1, 2021.

<u>Generic Description</u>	<u>Strength / Form</u>	<u>New LCA Price</u>
OCTREOTIDE ACETATE	10 MG / VIAL INJECTION	990.6975
OCTREOTIDE ACETATE	20 MG / VIAL INJECTION	1279.9350
OCTREOTIDE ACETATE	30 MG / VIAL INJECTION	1642.1400

## Least Cost Alternative (LCA) Price Change(s)

The following established IC Grouping(s) are affected and a revised LCA price has been established. Groupings affected by a price decrease, will be effective January 1, 2022. Please review the online [Interactive Drug Benefit List](#) for further information.

<u>Generic Description</u>	<u>Strength / Form</u>	<u>New LCA Price</u>
BROMAZEPAM	3 MG TABLET	0.0897
BROMAZEPAM	6 MG TABLET	0.1310
METHOTREXATE SODIUM	25 MG / ML INJECTION	3.1200
RIZATRIPTAN BENZOATE	5 MG TABLET	7.4100

## Product(s) with a Price Change

The following product(s) had a Price Change. The previous higher price will be recognized until December 31, 2021. For products within an established IC Grouping, the LCA price may apply.

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
APO-BROMAZEPAM 3 MG TABLET	BROMAZEPAM	00002177161	APX
APO-BROMAZEPAM 6 MG TABLET	BROMAZEPAM	00002177188	APX
APO-RIZATRIPTAN 5 MG TABLET	RIZATRIPTAN BENZOATE	00002393468	APX
JAMP-RIZATRIPTAN IR 5 MG TABLET	RIZATRIPTAN BENZOATE	00002429233	JPC

## Product(s) with a Price Change, continued

The following product(s) had a Price Change. The previous higher price will be recognized until December 31, 2021. For products within an established IC Grouping, the LCA price may apply.

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
METHOTREXATE (PRESERVED) 25 MG / ML INJECTION	METHOTREXATE SODIUM	00002464365	AHI
METHOTREXATE SODIUM (PRESERVED) 25 MG / ML INJECTION	METHOTREXATE SODIUM	00002182777	PFI
SANDOZ TIMOLOL MALEATE 0.25 % OPHTHALMIC SOLUTION	TIMOLOL MALEATE	00002166712	SDZ
TEVA-BROMAZEPAM 3 MG TABLET	BROMAZEPAM	00002230584	TEV
TEVA-BROMAZEPAM 6 MG TABLET	BROMAZEPAM	00002230585	TEV

## Discontinued Listing(s)

Notification of discontinuation has been received from the manufacturer(s). The Alberta government-sponsored drug programs previously covered the following drug product(s). Effective December 1, 2021, the listed product(s) will no longer be a benefit and where applicable, will not be considered for coverage by Special Authorization. A transition period will be applied and as of January 1, 2022 claims will no longer pay for these product(s).

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
ALPRAZOLAM 0.25 MG TABLET	ALPRAZOLAM	00002349191	SNS
ALPRAZOLAM 0.5 MG TABLET	ALPRAZOLAM	00002349205	SNS
BUPROPION SR 100 MG SUSTAINED-RELEASE TABLET	BUPROPION HCL	00002391562	SNS
BUPROPION SR 150 MG SUSTAINED-RELEASE TABLET	BUPROPION HCL	00002391570	SNS
CEFTRIAXONE SODIUM 1 G / VIAL INJECTION	CEFTRIAXONE SODIUM	00002287633	TEV
CYANOCOBALAMIN 1000 MCG / ML INJECTION	CYANOCOBALAMIN	00002413795	MYP
IBAVYR 400 MG TABLET	RIBAVIRIN	00002425890	PPH
LOPRESOR SR 200 MG SUSTAINED-RELEASE TABLET	METOPROLOL TARTRATE	00000534560	NOV
LORAZEPAM 1 MG TABLET	LORAZEPAM	00002351080	SNS
LORAZEPAM 2 MG TABLET	LORAZEPAM	00002351099	SNS
ODAN PROCTOMYXIN HC 5 MG / 5 MG / 10 MG / 10 MG RECTAL SUPPOSITORY	HYDROCORTISONE/ CINCHOCAINE HCL/ FRAMYCETIN SULFATE/ ESCULIN	00002242528	ODN
RAN-DULOXETINE 30 MG DELAYED-RELEASE CAPSULE	DULOXETINE HYDROCHLORIDE	00002438259	RAN
RAN-DULOXETINE 60 MG DELAYED-RELEASE CAPSULE	DULOXETINE HYDROCHLORIDE	00002438267	RAN
RAN-QUETIAPINE 25 MG TABLET	QUETIAPINE FUMARATE	00002397099	RAN

## Discontinued Listing(s), continued

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
RAN-RANITIDINE 150 MG TABLET	RANITIDINE HCL	00002336480	RAN
RAN-RANITIDINE 300 MG TABLET	RANITIDINE HCL	00002336502	RAN
SANDOZ CITALOPRAM 40 MG TABLET	CITALOPRAM HYDROBROMIDE	00002248171	SDZ
SANDOZ SUMATRIPTAN 50 MG TABLET	SUMATRIPTAN SUCCINATE	00002263025	SDZ
SANDOZ SUMATRIPTAN 100 MG TABLET	SUMATRIPTAN SUCCINATE	00002263033	SDZ
TERAZOSIN 5 MG TABLET	TERAZOSIN HCL	00002350491	SNS
TERAZOSIN 10 MG TABLET	TERAZOSIN HCL	00002350505	SNS
TEVA-CHLOROQUINE 250 MG TABLET	CHLOROQUINE PHOSPHATE	00000021261	TEV
TEVA-LOSARTAN / HCTZ 100 MG / 12.5 MG TABLET	LOSARTAN POTASSIUM/ HYDROCHLOROTHIAZIDE	00002377144	TEV
TEVA-LOSARTAN / HCTZ 100 MG / 25 MG TABLET	LOSARTAN POTASSIUM/ HYDROCHLOROTHIAZIDE	00002377152	TEV
ZOFRAN 2 MG / ML INJECTION	ONDANSETRON HCL DIHYDRATE	00002213745	NOV

## Product(s) Removed from the Alberta Drug Benefit List

*The Alberta government-sponsored drug programs previously covered the following drug product(s). Effective December 1, 2021, the listed product(s) will no longer be a benefit. A transition period will be applied and as of January 1, 2022 claims will no longer pay for this product.*

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
JAMP-RIZATRIPTAN 5 MG TABLET	RIZATRIPTAN BENZOATE	00002380455	JPC

## **PART 2**

# Drug Additions



ALBERTA DRUG BENEFIT LIST UPDATE

**BROMAZEPAM**

3 MG ORAL TABLET				
00002177161	APO-BROMAZEPAM	APX	\$	0.0897
00002230584	TEVA-BROMAZEPAM	TEV	\$	0.0897
6 MG ORAL TABLET				
00002177188	APO-BROMAZEPAM	APX	\$	0.1310
00002230585	TEVA-BROMAZEPAM	TEV	\$	0.1310

**BUPRENORPHINE**

100 MG / SYR INJECTION SYRINGE				
00002483084	SUBLOCADE	IUK	\$	550.0000
300 MG / SYR INJECTION SYRINGE				
00002483092	SUBLOCADE	IUK	\$	550.0000

**CLINDAMYCIN HCL**

150 MG (BASE) ORAL CAPSULE				
00002436906	AURO-CLINDAMYCIN	AUR	\$	0.2217
00002483734	JAMP CLINDAMYCIN	JPC	\$	0.2217
00002479923	M-CLINDAMYCIN	MTR	\$	0.2217
00002493748	NRA-CLINDAMYCIN	NRA	\$	0.2217
00002468476	RIVA-CLINDAMYCIN	RIV	\$	0.2217
00002241709	TEVA-CLINDAMYCIN	TEV	\$	0.2217
300 MG (BASE) ORAL CAPSULE				
00002436914	AURO-CLINDAMYCIN	AUR	\$	0.4434
00002483742	JAMP CLINDAMYCIN	JPC	\$	0.4434
00002479931	M-CLINDAMYCIN	MTR	\$	0.4434
00002493756	NRA-CLINDAMYCIN	NRA	\$	0.4434
00002468484	RIVA-CLINDAMYCIN	RIV	\$	0.4434
00002241710	TEVA-CLINDAMYCIN	TEV	\$	0.4434

**DORZOLAMIDE HCL/ TIMOLOL MALEATE**

2 % (BASE) * 0.5 % (BASE) OPHTHALMIC SOLUTION				
00002299615	APO-DORZO-TIMOP	APX	\$	1.9887
00002489635	DORZOLAMIDE AND TIMOLOL	TGT	\$	1.9887
00002457539	JAMP DORZOLAMIDE-TIMOLOL	JPC	\$	1.9887
00002437686	MED-DORZOLAMIDE-TIMOLOL	GMP	\$	1.9887
00002441659	RIVA-DORZOLAMIDE/TIMOLOL	RIV	\$	1.9887
00002344351	SANDOZ DORZOLAMIDE/ TIMOLOL	SDZ	\$	1.9887
<input checked="" type="checkbox"/> 00002258692	COSOPT PRESERVATIVE-FREE	ELV	\$	2.6930
00002240113	COSOPT	ELV	\$	6.6560

**HYDROXYCHLOROQUINE SULFATE**

200 MG ORAL TABLET				
00002246691	APO-HYDROXYQUINE	APX	\$	0.1576
00002491427	JAMP HYDROXYCHLOROQUINE SULFATE	JPC	\$	0.1576
00002424991	MINT-HYDROXYCHLOROQUINE	MPI	\$	0.1576
00002511886	NRA-HYDROXYCHLOROQUINE	NRA	\$	0.1576
00002017709	PLAQUENIL SULFATE	SAV	\$	0.6302

ALBERTA DRUG BENEFIT LIST UPDATE

**LATANOPROST**

0.005 % OPHTHALMIC SOLUTION

00002296527	APO-LATANOPROST	APX	\$	3.6320
00002373041	GD-LATANOPROST	UJC	\$	3.6320
00002453355	JAMP-LATANOPROST	JPC	\$	3.6320
00002489570	LATANOPROST	TGT	\$	3.6320
00002426935	MED-LATANOPROST	GMP	\$	3.6320
00002341085	RIVA-LATANOPROST	RIV	\$	3.6320
00002367335	SANDOZ LATANOPROST	SDZ	\$	3.6320
00002254786	TEVA-LATANOPROST	TEV	\$	3.6320
00002231493	XALATAN	UJC	\$	12.3960

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ALBERTA DRUG BENEFIT LIST UPDATE

**LEVETIRACETAM**

250 MG ORAL TABLET

00002285924	APO-LEVETIRACETAM	APX	\$	0.3210
00002375249	AURO-LEVETIRACETAM	AUR	\$	0.3210
00002403005	JAMP-LEVETIRACETAM	JPC	\$	0.3210
00002353342	LEVETIRACETAM	SNS	\$	0.3210
00002399776	LEVETIRACETAM	AHI	\$	0.3210
00002442531	LEVETIRACETAM	SIV	\$	0.3210
00002454653	LEVETIRACETAM	PMS	\$	0.3210
00002442388	MINT-LEVETIRACETAM	MPI	\$	0.3210
00002440202	NAT-LEVETIRACETAM	NTP	\$	0.3210
00002499193	NRA-LEVETIRACETAM	NRA	\$	0.3210
00002296101	PMS-LEVETIRACETAM	PMS	\$	0.3210
00002482274	RIVA-LEVETIRACETAM	RIV	\$	0.3210
00002461986	SANDOZ LEVETIRACETAM	SDZ	\$	0.3210
00002274183	TEVA-LEVETIRACETAM	APH	\$	0.3210
00002247027	KEPPRA	UCB	\$	1.7252

500 MG ORAL TABLET

00002285932	APO-LEVETIRACETAM	APX	\$	0.3911
00002375257	AURO-LEVETIRACETAM	AUR	\$	0.3911
00002403021	JAMP-LEVETIRACETAM	JPC	\$	0.3911
00002353350	LEVETIRACETAM	SNS	\$	0.3911
00002399784	LEVETIRACETAM	AHI	\$	0.3911
00002442558	LEVETIRACETAM	SIV	\$	0.3911
00002454661	LEVETIRACETAM	PMS	\$	0.3911
00002442396	MINT-LEVETIRACETAM	MPI	\$	0.3911
00002440210	NAT-LEVETIRACETAM	NTP	\$	0.3911
00002499207	NRA-LEVETIRACETAM	NRA	\$	0.3911
00002296128	PMS-LEVETIRACETAM	PMS	\$	0.3911
00002482282	RIVA-LEVETIRACETAM	RIV	\$	0.3911
00002461994	SANDOZ LEVETIRACETAM	SDZ	\$	0.3911
00002274191	TEVA-LEVETIRACETAM	APH	\$	0.3911
00002247028	KEPPRA	UCB	\$	2.1213

750 MG ORAL TABLET

00002285940	APO-LEVETIRACETAM	APX	\$	0.5416
00002375265	AURO-LEVETIRACETAM	AUR	\$	0.5416
00002403048	JAMP-LEVETIRACETAM	JPC	\$	0.5416
00002353369	LEVETIRACETAM	SNS	\$	0.5416
00002399792	LEVETIRACETAM	AHI	\$	0.5416
00002442566	LEVETIRACETAM	SIV	\$	0.5416
00002454688	LEVETIRACETAM	PMS	\$	0.5416
00002442418	MINT-LEVETIRACETAM	MPI	\$	0.5416
00002440229	NAT-LEVETIRACETAM	NTP	\$	0.5416
00002499215	NRA-LEVETIRACETAM	NRA	\$	0.5416
00002296136	PMS-LEVETIRACETAM	PMS	\$	0.5416
00002482290	RIVA-LEVETIRACETAM	RIV	\$	0.5416
00002462001	SANDOZ LEVETIRACETAM	SDZ	\$	0.5416
00002274205	TEVA-LEVETIRACETAM	APH	\$	0.5416
00002247029	KEPPRA	UCB	\$	2.9371

**METHOTREXATE SODIUM**

25 MG / ML (BASE) INJECTION

00002182777	METHOTREXATE SOD. (PRESERVED)	PFI	\$	3.1200
00002464365	METHOTREXATE (PRESERVED)	AHI	\$	3.1220

ALBERTA DRUG BENEFIT LIST UPDATE

**RIZATRIPTAN BENZOATE**

RESTRICTED BENEFIT - This product is a benefit for patients 18 to 64 years of age inclusive for the treatment of acute migraine attacks in patients where standard therapy has failed. (Refer to Criteria for Special Authorization of Select Drug Products of the List for eligibility in patients 65 years of age and older; and Criteria for Special Authorization of Select Drug Products of the Alberta Human Services Drug Benefit Supplement for eligibility in Alberta Human Services clients.)

<b>5 MG (BASE)</b>	<b>ORAL TABLET</b>			
<b>00002393468</b>	<b>APO-RIZATRIPTAN</b>	<b>APX</b>	<b>\$</b>	<b>7.4100</b>
<b>00002429233</b>	<b>JAMP-RIZATRIPTAN IR</b>	<b>JPC</b>	<b>\$</b>	<b>7.4100</b>

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**TIMOLOL MALEATE**

<b>0.25 % (BASE)</b>	<b>OPHTHALMIC SOLUTION</b>			
<b>00002166712</b>	<b>SANDOZ TIMOLOL MALEATE</b>	<b>SDZ</b>	<b>\$</b>	<b>2.3503</b>

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## **PART 3**

# Special Authorization

## ADALIMUMAB

### Ankylosing Spondylitis

\*\*\*Effective May 1, 2021, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Hidradenitis Suppurativa, Moderately to Severely Active Crohn's Disease, Plaque Psoriasis, Polyarticular Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Rheumatoid Arthritis and Ulcerative Colitis for adalimumab-naïve patients will be assessed for coverage with an adalimumab biosimilar. The originator drug, Humira, will not be approved for new adalimumab starts for patients with the indications stated above; adult patients currently on the originator drug for treatment of the indications stated above, except Polyarticular Juvenile Idiopathic Arthritis, must switch to the biosimilar prior to May 1, 2022 in order to maintain coverage for the molecule through their Alberta government sponsored drug plan. During the switching period, both the originator drug and biosimilar(s) will be covered. As of May 1, 2022, the authorization will only cover the biosimilar(s).\*\*\*

"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

**ALBERTA DRUG BENEFIT LIST UPDATE  
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

**ADALIMUMAB**

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**

\*\*\*Effective May 1, 2021, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Hidradenitis Suppurativa, Moderately to Severely Active Crohn's Disease, Plaque Psoriasis, Polyarticular Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Rheumatoid Arthritis and Ulcerative Colitis for adalimumab-naive patients will be assessed for coverage with an adalimumab biosimilar. The originator drug, Humira, will not be approved for new adalimumab starts for patients with the indications stated above; adult patients currently on the originator drug for treatment of the indications stated above, except Polyarticular Juvenile Idiopathic Arthritis, must switch to the biosimilar prior to May 1, 2022 in order to maintain coverage for the molecule through their Alberta government sponsored drug plan. During the switching period, both the originator drug and biosimilar(s) will be covered. As of May 1, 2022, the authorization will only cover the biosimilar(s).\*\*\*

"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

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**ADALIMUMAB**

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 Severe Active Crohn's Disease**

\*\*\*Effective May 1, 2021, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Hidradenitis Suppurativa, Moderately to Severely Active Crohn's Disease, Plaque Psoriasis, Polyarticular Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Rheumatoid Arthritis and Ulcerative Colitis for adalimumab-naive patients will be assessed for coverage with an adalimumab biosimilar. The originator drug, Humira, will not be approved for new adalimumab starts for patients with the indications stated above; adult patients currently on the originator drug for treatment of the indications stated above, except Polyarticular Juvenile Idiopathic Arthritis, must switch to the biosimilar prior to May 1, 2022 in order to maintain coverage for the molecule through their Alberta government sponsored drug plan. During the switching period, both the originator drug and biosimilar(s) will be covered. As of May 1, 2022, the authorization will only cover the biosimilar(s).\*\*\*

"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 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



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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 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:

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- 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**

\*\*\*Effective May 1, 2021, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Hidradenitis Suppurativa, Moderately to Severely Active Crohn's Disease, Plaque Psoriasis, Polyarticular Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Rheumatoid Arthritis and Ulcerative Colitis for adalimumab-naive patients will be assessed for coverage with an adalimumab biosimilar. The originator drug, Humira, will not be approved for new adalimumab starts for patients with the indications stated above; adult patients currently on the originator drug for treatment of the indications stated above, except Polyarticular Juvenile Idiopathic Arthritis, must switch to the biosimilar prior to May 1, 2022 in order to maintain coverage for the molecule through their Alberta government sponsored drug plan. During the switching period, both the originator drug and biosimilar(s) will be covered. As of May 1, 2022, the authorization will only cover the biosimilar(s).\*\*\*

"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 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.

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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 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/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

**Polyarticular Juvenile Idiopathic Arthritis**

\*\*\*Effective May 1, 2021, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Hidradenitis Suppurativa, Moderately to Severely Active Crohn's Disease, Plaque Psoriasis, Polyarticular Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Rheumatoid Arthritis and Ulcerative Colitis for adalimumab-naive patients will be assessed for coverage with an adalimumab biosimilar. The originator drug, Humira, will not be approved for new adalimumab starts for patients with the indications stated above; adult patients currently on the originator drug for treatment of the indications stated above, except Polyarticular Juvenile Idiopathic Arthritis, must switch to the biosimilar prior to May 1, 2022 in order to maintain coverage for the molecule through their Alberta government sponsored drug plan. During the switching period, both the originator drug and biosimilar(s) will be covered. As of May 1, 2022, the authorization will only cover the biosimilar(s).\*\*\*

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"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 response, and
- 2) The Pediatric Rheumatology Specialist must confirm in writing that the patient has

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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).

**Psoriatic Arthritis**

\*\*\*Effective May 1, 2021, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Hidradenitis Suppurativa, Moderately to Severely Active Crohn's Disease, Plaque Psoriasis, Polyarticular Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Rheumatoid Arthritis and Ulcerative Colitis for adalimumab-naive patients will be assessed for coverage with an adalimumab biosimilar. The originator drug, Humira, will not be approved for new adalimumab starts for patients with the indications stated above; adult patients currently on the originator drug for treatment of the indications stated above, except Polyarticular Juvenile Idiopathic Arthritis, must switch to the biosimilar prior to May 1, 2022 in order to maintain coverage for the molecule through their Alberta government sponsored drug plan. During the switching period, both the originator drug and biosimilar(s) will be covered. As of May 1, 2022, the authorization will only cover the biosimilar(s).\*\*\*

"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 Humira 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

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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:

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**

\*\*\*Effective May 1, 2021, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Hidradenitis Suppurativa, Moderately to Severely Active Crohn's Disease, Plaque Psoriasis, Polyarticular Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Rheumatoid Arthritis and Ulcerative Colitis for adalimumab-naïve patients will be assessed for coverage with an adalimumab biosimilar. The originator drug, Humira, will not be approved for new adalimumab starts for patients with the indications stated above; adult patients currently on the originator drug for treatment of the indications stated above, except Polyarticular Juvenile Idiopathic Arthritis, must switch to the biosimilar prior to May 1, 2022 in order to maintain coverage for the molecule through their Alberta government sponsored drug plan. During the switching period, both the originator drug and biosimilar(s) will be covered. As of May 1, 2022, the authorization will only cover the biosimilar(s).\*\*\*

"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

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- 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.

**40 MG / SYR INJECTION SYRINGE**

<input checked="" type="checkbox"/> 00002502682	IDACIO (40 MG/0.8 ML INJ SYR)	FKC	\$	471.2700
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**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

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**LACOSAMIDE**

**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

**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

**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.

**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



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**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

ALBERTA DRUG BENEFIT LIST UPDATE  
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

**RITUXIMAB**

10 MG / ML INJECTION

☒ 00002513447 RIABNI AMG \$ 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).

'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.

ALBERTA DRUG BENEFIT LIST UPDATE  
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

**RITUXIMAB**

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).

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**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
00002429233	JAMP-RIZATRIPTAN IR		JPC	\$	7.4100

**ALBERTA DRUG BENEFIT LIST UPDATE  
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

**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
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**2 MG ORAL TABLET**

00002496437	MAYZENT	NOV	\$	89.3150
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