Updates to the Alberta Drug Benefit List

Effective December 1, 2023

Alberta Government

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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

The following drug product(s) will be considered for coverage by Special Authorization effective December 1, 2023 for patients covered under Alberta government-sponsored drug programs.

New Drug Product(s) Available by Special Authorization

Trade Name / Strength / Form	Generic Description	DIN	MFR
KERENDIA 10 MG TABLET	FINERENONE	00002531917	BAI
KERENDIA 20 MG TABLET	FINERENONE	00002531925	BAI
QULIPTA 10 MG TABLET	ATOGEPANT	00002533979	ABV
QULIPTA 30 MG TABLET	ATOGEPANT	00002533987	ABV
QULIPTA 60 MG TABLET	ATOGEPANT	00002533995	ABV
SAPHNELO 150 MG / VIAL INJECTION	ANIFROLUMAB	00002522845	AZC

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

Trade Name / Strength / Form	Generic Description	DIN	MFR
JAMP TOFACITINIB 5 MG TABLET	TOFACITINIB CITRATE	00002522896	JPC
NRA-DONEPEZIL 5 MG TABLET	DONEPEZIL HCL	00002535386	NRA
NRA-DONEPEZIL 10 MG TABLET	DONEPEZIL HCL	00002535394	NRA

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

Trade Name / Strength / Form	Generic Description	DIN	MFR
ATOMOXETINE 10 MG CAPSULE	ATOMOXETINE HCL	00002445883	SIV
ATOMOXETINE 18 MG CAPSULE	ATOMOXETINE HCL	00002445905	SIV
ATOMOXETINE 25 MG CAPSULE	ATOMOXETINE HCL	00002445913	SIV
ATOMOXETINE 40 MG CAPSULE	ATOMOXETINE HCL	00002445948	SIV
ATOMOXETINE 60 MG CAPSULE	ATOMOXETINE HCL	00002445956	SIV
TEVA-ATOMOXETINE 10 MG CAPSULE	ATOMOXETINE HCL	00002314541	TEV
TEVA-ATOMOXETINE 18 MG CAPSULE	ATOMOXETINE HCL	00002314568	TEV
TEVA-ATOMOXETINE 25 MG CAPSULE	ATOMOXETINE HCL	00002314576	TEV
TEVA-ATOMOXETINE 40 MG CAPSULE	ATOMOXETINE HCL	00002314584	TEV
TEVA-ATOMOXETINE 60 MG CAPSULE	ATOMOXETINE HCL	00002314592	TEV
TEVA-ATOMOXETINE 80 MG CAPSULE	ATOMOXETINE HCL	00002362511	TEV

Drug Product(s) with Changes to Criteria for Coverage

Trade Name / Strength / Form	Generic Description	DIN	MFR
ABILIFY MAINTENA 300 MG / VIAL INJECTION	ARIPIPRAZOLE	00002420864	OTS
ABILIFY MAINTENA 400 MG / VIAL INJECTION	ARIPIPRAZOLE	00002420872	OTS
ABRILADA (20 MG / 0.4 ML SYRINGE) 20 MG / SYRINGE INJECTION	ADALIMUMAB	00002511061	PFI
ABRILADA (40 MG / 0.8 ML PEN) 40 MG / SYRINGE INJECTION	ADALIMUMAB	00002511045	PFI
ABRILADA (40 MG / 0.8 ML SYRINGE) 40 MG / SYRINGE INJECTION	ADALIMUMAB	00002511053	PFI
AMGEVITA (20 MG / 0.4 ML SYRINGE) 20 MG / SYRINGE INJECTION	ADALIMUMAB	00002459310	AMG
AMGEVITA (40 MG / 0.8 ML SYRINGE) 40 MG / SYRINGE INJECTION	ADALIMUMAB	00002459299	AMG
AMGEVITA (40 MG / 0.8 ML AUTOINJECTOR PEN) 40 MG / SYRINGE INJECTION	ADALIMUMAB	00002459302	AMG
AVSOLA 100 MG / VIAL INJECTION	INFLIXIMAB	00002496933	AMG
BRENZYS 50 MG / SYRINGE INJECTION	ETANERCEPT	00002455323	SSB
BRENZYS (AUTO INJECTOR) 50 MG / SYRINGE INJECTION	ETANERCEPT	00002455331	SSB
ENTYVIO 108 MG / SYRINGE INJECTION	VEDOLIZUMAB	00002497875	TAK
ENTYVIO 300 MG / VIAL INJECTION	VEDOLIZUMAB	00002436841	TAK
ENTYVIO (PEN) 108 MG / SYRINGE INJECTION	VEDOLIZUMAB	00002497867	TAK
ERELZI 25 MG / SYRINGE INJECTION	ETANERCEPT	00002462877	SDZ
ERELZI 50 MG / SYRINGE INJECTION	ETANERCEPT	00002462869	SDZ
ERELZI (SENSOREADY AUTO INJECTOR) 50 MG / SYRINGE INJECTION	ETANERCEPT	00002462850	SDZ
HADLIMA (40 MG / 0.8 ML PEN) 40 MG / SYRINGE INJECTION	ADALIMUMAB	00002473100	SSB
HADLIMA (40 MG / 0.8 ML SYRINGE) 40 MG / SYRINGE INJECTION	ADALIMUMAB	00002473097	SSB
HULIO (20 MG / 0.4 ML SYRINGE) 20 MG / SYRINGE INJECTION	ADALIMUMAB	00002502380	BGP
HULIO (40 MG / 0.8 ML PEN) 40 MG / SYRINGE INJECTION	ADALIMUMAB	00002502402	BGP
HULIO (40 MG / 0.8 ML SYRINGE) 40 MG / SYRINGE INJECTION	ADALIMUMAB	00002502399	BGP
HYRIMOZ (20 MG / 0.4 ML SYRINGE) 20 MG / SYRINGE INJECTION	ADALIMUMAB	00002505258	SDZ
HYRIMOZ (40 MG / 0.8 ML PEN) 40 MG / SYRINGE INJECTION	ADALIMUMAB	00002492156	SDZ

Drug Product(s) with Changes to Criteria for Coverage, continued

Trade Name / Strength / Form	Generic Description	DIN	MFR
HYRIMOZ (40 MG / 0.8 ML SYRINGE) 40 MG / SYRINGE INJECTION	ADALIMUMAB	00002492164	SDZ
IDACIO (40 MG / 0.8 ML PEN) 40 MG / SYRINGE INJECTION	ADALIMUMAB	00002502674	FKC
IDACIO (40 MG / 0.8 ML SYRINGE) 40 MG / SYRINGE INJECTION	ADALIMUMAB	00002502682	FKC
INFLECTRA 100 MG / VIAL INJECTION	INFLIXIMAB	00002419475	CHH
INVEGA SUSTENNA (0.5 ML SYRINGE) 50 MG / SYRINGE INJECTION	PALIPERIDONE PALMITATE	00002354217	JAI
INVEGA SUSTENNA (0.75 ML SYRINGE) 75 MG / SYRINGE INJECTION	PALIPERIDONE PALMITATE	00002354225	JAI
INVEGA SUSTENNA (1 ML SYRINGE) 100 MG / SYRINGE INJECTION	PALIPERIDONE PALMITATE	00002354233	JAI
INVEGA SUSTENNA (1.5 ML SYRINGE) 150 MG / SYRINGE INJECTION	PALIPERIDONE PALMITATE	00002354241	JAI
INVEGA TRINZA (0.875 ML SYRINGE) 175 MG / SYRINGE INJECTION	PALIPERIDONE PALMITATE	00002455943	JAI
INVEGA TRINZA (1.315 ML SYRINGE) 263 MG / SYRINGE INJECTION	PALIPERIDONE PALMITATE	00002455986	JAI
INVEGA TRINZA (1.75 ML SYRINGE) 350 MG / SYRINGE INJECTION	PALIPERIDONE PALMITATE	00002455994	JAI
INVEGA TRINZA (2.625 ML SYRINGE) 525 MG / SYRINGE INJECTION	PALIPERIDONE PALMITATE	00002456001	JAI
RENFLEXIS 100 MG / VIAL INJECTION	INFLIXIMAB	00002470373	SSB
RISPERDAL CONSTA 25 MG / VIAL INJECTION	RISPERIDONE	00002255707	JAI
RISPERDAL CONSTA 37.5 MG / VIAL INJECTION	RISPERIDONE	00002255723	JAI
RISPERDAL CONSTA 50 MG / VIAL INJECTION	RISPERIDONE	00002255758	JAI
SIMLANDI (40 MG / 0.4 ML AUTO-INJECTOR PEN) 40 MG / SYRINGE INJECTION	ADALIMUMAB	00002523957	JPC
SIMLANDI (40 MG / 0.4 ML SYRINGE) 40 MG / SYRINGE INJECTION	ADALIMUMAB	00002523949	JPC
SIMLANDI (80 MG / 0.8 ML SYRINGE) 80 MG / SYRINGE INJECTION	ADALIMUMAB	00002523965	JPC
YUFLYMA (40 MG / 0.4 ML PEN) 40 MG / SYRINGE INJECTION	ADALIMUMAB	00002523779	CHC

Restricted Benefit(s)

Additional Brand(s) and/or Strength(s) of Drug Product(s) Available by Restricted Benefit

Trade Name / Strength / Form	Generic Description	DIN	MFR
TEVA-AMPHETAMINE XR (5 MG) 1.25 MG / 1.25 MG / 1.25 MG / 1.25 MG EXTENDED-RELEASE CAPSULE	AMPHETAMINE SULFATE/ AMPHETAMINE ASPARTATE/ DEXTROAMPHETAMINE SULFATE/ DEXTROAMPHETAMINE SACCHARATE	00002439247	TEV
TEVA-AMPHETAMINE XR (10 MG) 2.5 MG / 2.5 MG / 2.5 MG / 2.5 MG EXTENDED-RELEASE CAPSULE	AMPHETAMINE SULFATE/ AMPHETAMINE ASPARTATE/ DEXTROAMPHETAMINE SULFATE/ DEXTROAMPHETAMINE SACCHARATE	00002439255	TEV
TEVA-AMPHETAMINE XR (15 MG) 3.75 MG / 3.75 MG / 3.75 MG / 3.75 MG EXTENDED-RELEASE CAPSULE	AMPHETAMINE SULFATE/ AMPHETAMINE ASPARTATE/ DEXTROAMPHETAMINE SULFATE/ DEXTROAMPHETAMINE SACCHARATE	00002439263	TEV
TEVA-AMPHETAMINE XR (20 MG) 5 MG / 5 MG / 5 MG / 5 MG EXTENDED-RELEASE CAPSULE	AMPHETAMINE SULFATE/ AMPHETAMINE ASPARTATE/ DEXTROAMPHETAMINE SULFATE/ DEXTROAMPHETAMINE SACCHARATE	00002439298	TEV
TEVA-AMPHETAMINE XR (30 MG) 7.5 MG / 7.5 MG / 7.5 MG / 7.5 MG EXTENDED-RELEASE CAPSULE	AMPHETAMINE SULFATE/ AMPHETAMINE ASPARTATE/ DEXTROAMPHETAMINE SULFATE/ DEXTROAMPHETAMINE SACCHARATE	00002439239	TEV

Added Product(s)

Trade Name / Strength / Form	Generic Description	DIN	MFR
DORZOLAMIDE 2 % OPHTHALMIC SOLUTION	DORZOLAMIDE HCL	00002522373	JPC
IMVEXXY 4 MCG VAGINAL INSERT	ESTRADIOL-17B	00002503689	KTI
IMVEXXY 10 MCG VAGINAL INSERT	ESTRADIOL-17B	00002503697	KTI
JAMP VALPROIC ACID 50 MG / ML ORAL SYRUP	VALPROIC ACID	00002532441	JPC
MINT-ROSUVASTATIN 5 MG TABLET	ROSUVASTATIN CALCIUM	00002397781	MPI
MINT-ROSUVASTATIN 10 MG TABLET	ROSUVASTATIN CALCIUM	00002397803	MPI
MINT-ROSUVASTATIN 20 MG TABLET	ROSUVASTATIN CALCIUM	00002397811	MPI
MINT-ROSUVASTATIN 40 MG TABLET	ROSUVASTATIN CALCIUM	00002397838	MPI
NATCO-CITALOPRAM 20 MG TABLET	CITALOPRAM HYDROBROMIDE	00002443880	NTP
NATCO-CITALOPRAM 40 MG TABLET	CITALOPRAM HYDROBROMIDE	00002443899	NTP
NRA-ROSUVASTATIN 5 MG TABLET	ROSUVASTATIN CALCIUM	00002536595	NRA
NRA-ROSUVASTATIN 10 MG TABLET	ROSUVASTATIN CALCIUM	00002536609	NRA
NRA-ROSUVASTATIN 20 MG TABLET	ROSUVASTATIN CALCIUM	00002536625	NRA
NRA-ROSUVASTATIN 40 MG TABLET	ROSUVASTATIN CALCIUM	00002536633	NRA
TRURAPI 100 UNIT / ML INJECTION	INSULIN ASPART	00002529254	SAV

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, 2024. Please review the online **Interactive Drug Benefit List** for further information.*

Generic Description	Strength / Form	New LCA Price
VALPROIC ACID	50 MG / ML ORAL SYRUP	0.0480

Product(s) with a Price Change

The following product(s) had a Price Change. The previous higher price will be recognized until December 31, 2023. For products within an established IC Grouping, the LCA price may apply.

Trade Name / Strength / Form	Generic Description	DIN	MFR
APO-VALPROIC 50 MG / ML ORAL SYRUP	VALPROIC ACID	00002238370	APX
PMS-VALPROIC ACID 50 MG / ML ORAL SYRUP	VALPROIC ACID	00002236807	PMS

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, 2023, 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, 2024 claims will no longer pay for these product(s).

Trade Name / Strength / Form	Generic Description	DIN	MFR
ADLYXINE 0.05 MG / ML INJECTION	LIXISENATIDE	00002464276	SAV
APO-VENLAFAXINE XR 37.5 MG EXTENDED-RELEASE CAPSULE	VENLAFAXINE HCL	00002331683	APX
APO-VENLAFAXINE XR 75 MG EXTENDED-RELEASE CAPSULE	VENLAFAXINE HCL	00002331691	APX
APO-VENLAFAXINE XR 150 MG EXTENDED-RELEASE CAPSULE	VENLAFAXINE HCL	00002331705	APX
JAMP-MONTELUKAST 4 MG CHEWABLE TABLET	MONTELUKAST SODIUM	00002442353	JPC
MOVAPO 10 MG / ML PRE-FILLED PEN INJECTION	APOMORPHINE HCL	00002459132	PAL
PMS-RABEPRAZOLE EC 10 MG ENTERIC-COATED TABLET	RABEPRAZOLE SODIUM	00002310805	PMS
SANDOZ OMEPRAZOLE 10 MG SUSTAINED-RELEASE CAPSULE	OMEPRAZOLE	00002296438	SDZ
TAZORAC 0.1% TOPICAL GEL	TAZAROTENE	00002230785	ALL

PART 2

Drug Additions

AMPHETAMINE SULFATE/ AMPHETAMINE ASPARTATE/ DEXTROAMPHETAMINE SULFATE/ DEXTROAMPHETAMINE SACCHARATE

RESTRICTED BENEFIT

For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) as a restricted benefit for patients 6 years of age and older.

1.25 MG * 1.25 MG (BASE) * 1.25 MG * 1.25 MG ORAL EXTENDED-RELEASE CAPSULE				
00002445492	**APO-AMPHETAMINE XR (5 MG)**	**APX**	$	**0.5372**
00002457288	**SANDOZ AMPHETAMINE XR (5 MG)**	**SDZ**	$	**0.5372**
00002439239	**TEVA-AMPHETAMINE XR (5 MG)**	**TEV**	$	**0.5372**
2.5 MG * 2.5 MG (BASE) * 2.5 MG * 2.5 MG ORAL EXTENDED-RELEASE CAPSULE				
00002445506	**APO-AMPHETAMINE XR (10 MG)**	**APX**	$	**0.6105**
00002457296	**SANDOZ AMPHETAMINE XR (10 MG)**	**SDZ**	$	**0.6105**
00002439247	**TEVA-AMPHETAMINE XR (10 MG)**	**TEV**	$	**0.6105**
3.75 MG * 3.75 MG (BASE) * 3.75 MG * 3.75 MG ORAL EXTENDED-RELEASE CAPSULE				
00002445514	**APO-AMPHETAMINE XR (15 MG)**	**APX**	$	**0.6838**
00002457318	**SANDOZ AMPHETAMINE XR (15 MG)**	**SDZ**	$	**0.6838**
00002439255	**TEVA-AMPHETAMINE XR (15 MG)**	**TEV**	$	**0.6838**
5 MG * 5 MG (BASE) * 5 MG * 5 MG ORAL EXTENDED-RELEASE CAPSULE				
00002445522	**APO-AMPHETAMINE XR (20 MG)**	**APX**	$	**0.7572**
00002457326	**SANDOZ AMPHETAMINE XR (20 MG)**	**SDZ**	$	**0.7572**
00002439263	**TEVA-AMPHETAMINE XR (20 MG)**	**TEV**	$	**0.7572**
7.5 MG * 7.5 MG (BASE) * 7.5 MG * 7.5 MG ORAL EXTENDED-RELEASE CAPSULE				
00002445549	**APO-AMPHETAMINE XR (30 MG)**	**APX**	$	**0.9038**
00002457342	**SANDOZ AMPHETAMINE XR (30 MG)**	**SDZ**	$	**0.9038**
00002439298	**TEVA-AMPHETAMINE XR (30 MG)**	**TEV**	$	**0.9038**

CITALOPRAM HYDROBROMIDE

20 MG (BASE) ORAL TABLET				
00002246056	**APO-CITALOPRAM**	**APX**	$	**0.1332**
00002275562	**AURO-CITALOPRAM**	**AUR**	$	**0.1332**
00002459914	**CCP-CITALOPRAM**	**CEL**	$	**0.1332**
00002353660	**CITALOPRAM**	**SNS**	$	**0.1332**
00002387956	**CITALOPRAM**	**SIV**	$	**0.1332**
00002430541	**CITALOPRAM**	**JPC**	$	**0.1332**
00002371898	**MAR-CITALOPRAM**	**MAR**	$	**0.1332**
00002429705	**MINT-CITALOPRAM**	**MPI**	$	**0.1332**
00002409011	**NAT-CITALOPRAM**	**NTP**	$	**0.1332**
00002443880	**NATCO-CITALOPRAM**	**NTP**	$	**0.1332**
00002477645	**NRA-CITALOPRAM**	**NRA**	$	**0.1332**
00002248010	**PMS-CITALOPRAM**	**PMS**	$	**0.1332**
00002303264	**RIVA-CITALOPRAM**	**RIV**	$	**0.1332**
00002355272	**SEPTA-CITALOPRAM**	**SEP**	$	**0.1332**
00002293218	**TEVA-CITALOPRAM**	**TEV**	$	**0.1332**
00002239607	CELEXA	LBC	$	1.5234
40 MG (BASE) ORAL TABLET				
00002246057	**APO-CITALOPRAM**	**APX**	$	**0.1332**
00002275570	**AURO-CITALOPRAM**	**AUR**	$	**0.1332**
00002459922	**CCP-CITALOPRAM**	**CEL**	$	**0.1332**
00002353679	**CITALOPRAM**	**SNS**	$	**0.1332**
00002387964	**CITALOPRAM**	**SIV**	$	**0.1332**
00002430568	**CITALOPRAM**	**JPC**	$	**0.1332**
00002371901	**MAR-CITALOPRAM**	**MAR**	$	**0.1332**
00002429713	**MINT-CITALOPRAM**	**MPI**	$	**0.1332**
00002409038	**NAT-CITALOPRAM**	**NTP**	$	**0.1332**
00002443899	**NATCO-CITALOPRAM**	**NTP**	$	**0.1332**
00002477653	**NRA-CITALOPRAM**	**NRA**	$	**0.1332**
00002248011	**PMS-CITALOPRAM**	**PMS**	$	**0.1332**
00002303272	**RIVA-CITALOPRAM**	**RIV**	$	**0.1332**
00002355280	**SEPTA-CITALOPRAM**	**SEP**	$	**0.1332**
00002293226	**TEVA-CITALOPRAM**	**TEV**	$	**0.1332**
00002239608	CELEXA	LBC	$	1.5234

DORZOLAMIDE HCL

2 % (BASE) OPHTHALMIC SOLUTION				
00002522373	**DORZOLAMIDE**	**JPC**	$	**1.4757**
00002453347	**JAMP-DORZOLAMIDE**	**JPC**	$	**1.4757**
00002457210	**MED-DORZOLAMIDE**	**GMP**	$	**1.4757**
00002316307	**SANDOZ DORZOLAMIDE**	**SDZ**	$	**1.4757**
00002216205	TRUSOPT	ELV	$	4.5465
⊠ 00002269090	TRUSOPT (PRESERVATIVE-FREE)	ELV	$	4.5518

ESTRADIOL-17B

4 MCG VAGINAL INSERT				
00002503689	IMVEXXY	KTI	$	3.6288
10 MCG VAGINAL INSERT				
00002503697	IMVEXXY	KTI	$	3.6288

INSULIN ASPART

100 UNIT / ML INJECTION				
⊠ 00002529254	TRURAPI	SAV	$	2.2643
⊠ 00002520974	KIRSTY (PEN)	BGP	$	2.8475
⊠ 00002506564	TRURAPI CARTRIDGE	SAV	$	3.0000
⊠ 00002506572	TRURAPI SOLOSTAR PEN	SAV	$	3.0000

ROSUVASTATIN CALCIUM

5 MG (BASE) ORAL TABLET				
00002438917	**ACH-ROSUVASTATIN**	**AHI**	$	**0.1284**
00002477033	**AG-ROSUVASTATIN**	**AGP**	$	**0.1284**
00002337975	**APO-ROSUVASTATIN**	**APX**	$	**0.1284**
00002442574	**AURO-ROSUVASTATIN**	**AUR**	$	**0.1284**
00002498332	**JAMP ROSUVASTATIN CALCIUM**	**JPC**	$	**0.1284**
00002391252	**JAMP-ROSUVASTATIN**	**JPC**	$	**0.1284**
00002496534	**M-ROSUVASTATIN**	**MTR**	$	**0.1284**
00002413051	**MAR-ROSUVASTATIN**	**MAR**	$	**0.1284**
00002397781	**MINT-ROSUVASTATIN**	**MPI**	$	**0.1284**
00002477483	**NRA-ROSUVASTATIN**	**NRA**	$	**0.1284**
00002536595	**NRA-ROSUVASTATIN**	**NRA**	$	**0.1284**
00002378523	**PMS-ROSUVASTATIN**	**PMS**	$	**0.1284**
00002505576	**PRZ-ROSUVASTATIN**	**PCI**	$	**0.1284**
00002405628	**ROSUVASTATIN**	**SNS**	$	**0.1284**
00002411628	**ROSUVASTATIN-5**	**SIV**	$	**0.1284**
00002338726	**SANDOZ ROSUVASTATIN**	**SDZ**	$	**0.1284**
00002382644	**TARO-ROSUVASTATIN**	**SPG**	$	**0.1284**
00002354608	**TEVA-ROSUVASTATIN**	**TEV**	$	**0.1284**
00002265540	CRESTOR	AZC	$	1.3871
10 MG (BASE) ORAL TABLET				
00002438925	**ACH-ROSUVASTATIN**	**AHI**	$	**0.1354**
00002477041	**AG-ROSUVASTATIN**	**AGP**	$	**0.1354**
00002337983	**APO-ROSUVASTATIN**	**APX**	$	**0.1354**
00002442582	**AURO-ROSUVASTATIN**	**AUR**	$	**0.1354**
00002498340	**JAMP ROSUVASTATIN CALCIUM**	**JPC**	$	**0.1354**
00002391260	**JAMP-ROSUVASTATIN**	**JPC**	$	**0.1354**
00002496542	**M-ROSUVASTATIN**	**MTR**	$	**0.1354**
00002413078	**MAR-ROSUVASTATIN**	**MAR**	$	**0.1354**
00002397803	**MINT-ROSUVASTATIN**	**MPI**	$	**0.1354**
00002477491	**NRA-ROSUVASTATIN**	**NRA**	$	**0.1354**
00002536609	**NRA-ROSUVASTATIN**	**NRA**	$	**0.1354**
00002378531	**PMS-ROSUVASTATIN**	**PMS**	$	**0.1354**
00002505584	**PRZ-ROSUVASTATIN**	**PCI**	$	**0.1354**
00002405636	**ROSUVASTATIN**	**SNS**	$	**0.1354**
00002411636	**ROSUVASTATIN-10**	**SIV**	$	**0.1354**
00002338734	**SANDOZ ROSUVASTATIN**	**SDZ**	$	**0.1354**
00002382652	**TARO-ROSUVASTATIN**	**SPG**	$	**0.1354**
00002354616	**TEVA-ROSUVASTATIN**	**TEV**	$	**0.1354**
00002247162	CRESTOR	AZC	$	1.4408
20 MG (BASE) ORAL TABLET				
00002438933	**ACH-ROSUVASTATIN**	**AHI**	$	**0.1692**
00002477068	**AG-ROSUVASTATIN**	**AGP**	$	**0.1692**
00002337991	**APO-ROSUVASTATIN**	**APX**	$	**0.1692**
00002442590	**AURO-ROSUVASTATIN**	**AUR**	$	**0.1692**
00002498359	**JAMP ROSUVASTATIN CALCIUM**	**JPC**	$	**0.1692**
00002391279	**JAMP-ROSUVASTATIN**	**JPC**	$	**0.1692**
00002496550	**M-ROSUVASTATIN**	**MTR**	$	**0.1692**
00002413086	**MAR-ROSUVASTATIN**	**MAR**	$	**0.1692**
00002397811	**MINT-ROSUVASTATIN**	**MPI**	$	**0.1692**
00002477505	**NRA-ROSUVASTATIN**	**NRA**	$	**0.1692**
00002536625	**NRA-ROSUVASTATIN**	**NRA**	$	**0.1692**
00002378558	**PMS-ROSUVASTATIN**	**PMS**	$	**0.1692**
00002505592	**PRZ-ROSUVASTATIN**	**PCI**	$	**0.1692**
00002405644	**ROSUVASTATIN**	**SNS**	$	**0.1692**
00002411644	**ROSUVASTATIN-20**	**SIV**	$	**0.1692**
00002338742	**SANDOZ ROSUVASTATIN**	**SDZ**	$	**0.1692**
00002382660	**TARO-ROSUVASTATIN**	**SPG**	$	**0.1692**
00002354624	**TEVA-ROSUVASTATIN**	**TEV**	$	**0.1692**
00002247163	CRESTOR	AZC	$	1.8007

ROSUVASTATIN CALCIUM

40 MG (BASE) ORAL TABLET

00002438941	**ACH-ROSUVASTATIN**	**AHI**	$	**0.1990**
00002477076	**AG-ROSUVASTATIN**	**AGP**	$	**0.1990**
00002338009	**APO-ROSUVASTATIN**	**APX**	$	**0.1990**
00002442604	**AURO-ROSUVASTATIN**	**AUR**	$	**0.1990**
00002498367	**JAMP ROSUVASTATIN CALCIUM**	**JPC**	$	**0.1990**
00002391287	**JAMP-ROSUVASTATIN**	**JPC**	$	**0.1990**
00002496569	**M-ROSUVASTATIN**	**MTR**	$	**0.1990**
00002413108	**MAR-ROSUVASTATIN**	**MAR**	$	**0.1990**
00002397838	**MINT-ROSUVASTATIN**	**MPI**	$	**0.1990**
00002477513	**NRA-ROSUVASTATIN**	**NRA**	$	**0.1990**
00002536633	**NRA-ROSUVASTATIN**	**NRA**	$	**0.1990**
00002378566	**PMS-ROSUVASTATIN**	**PMS**	$	**0.1990**
00002505606	**PRZ-ROSUVASTATIN**	**PCI**	$	**0.1990**
00002405652	**ROSUVASTATIN**	**SNS**	$	**0.1990**
00002411652	**ROSUVASTATIN-40**	**SIV**	$	**0.1990**
00002338750	**SANDOZ ROSUVASTATIN**	**SDZ**	$	**0.1990**
00002382679	**TARO-ROSUVASTATIN**	**SPG**	$	**0.1990**
00002354632	**TEVA-ROSUVASTATIN**	**TEV**	$	**0.1990**
00002247164	CRESTOR	AZC	$	2.1080

VALPROIC ACID

50 MG / ML ORAL SYRUP

00002238370	**APO-VALPROIC**	**APX**	$	**0.0480**
00002532441	**JAMP VALPROIC ACID**	**JPC**	$	**0.0480**
00002236807	**PMS-VALPROIC ACID**	**PMS**	$	**0.0480**
00000443832	DEPAKENE	BGP	$	0.1305

PART 3

Special Authorization

ADALIMUMAB

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 12 months. After 12 months, in order to be considered for continued coverage, the patient must be re-assessed every 24 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

☒ 00002511061	ABRILADA (20 MG/0.4 ML SYRINGE)	PFI	$	235.6300
☒ 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 24 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 24 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; OR 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.

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:

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'Maintenance Dosing' means one 40 mg dose of adalimumab per patient provided no more often than every other week starting at Week 4 for an initial period of 12 months with subsequent renewals of 24 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 (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 24 months, if the following criteria are met at the end of each 24 month period:

-The New Patient or the Existing Patient must be assessed by a Specialist (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 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

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

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"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 12 months. After 12 months, in order to be considered for continued coverage, the patient must be re-assessed every 24 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 adalimumab for Polyarticular Juvenile

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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 an initial period of 12 months with subsequent renewals of 24 months.
Ongoing coverage may be considered if the following criteria are met at the end of each 24-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

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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/Guselkumab/Infliximab/Ixekizumab/Secukinumab/Upadacitinib 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 for which it is being prescribed.

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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 an initial period of 12 months and subsequent renewals of 24 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 24-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/Upadacitinib 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 160 mg, followed by an 80 mg

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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 an initial period of 12 months and subsequent renewals of 24 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 24-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 INJ SYR)	JPC	$	471.2700
☒ 00002523779	YUFLYMA (40 MG/0.4 ML INJ 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 24 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; OR 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.

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.

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-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 an initial period of 12 months with subsequent renewals of 24 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 (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 24 months, if the following criteria are met at the end of each 24 month period:

-The New Patient or the Existing Patient must be assessed by a Specialist (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

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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 24 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/Bimekizumab/Etanercept/Guselkumab/Infliximab/Ixekizumab/Risankizumab/Secukinumab/Tildrakizumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

ULCERATIVE COLITIS

"Special authorization coverage may be provided for the reduction in signs and

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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 an initial period of 12 months and subsequent renewals of 24 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 24-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 INJ SYR)	JPC	$	942.5400

ANIFROLUMAB

"Special authorization coverage may be provided for the treatment of moderate to severe systemic lupus erythematosus (SLE) in adult patients who meet the following criteria:
- Patient has moderate to severe SLE (defined as Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) score of at least 6) prior to treatment initiation with anifrolumab and
- Is inadequately controlled with oral corticosteroids (OCS) dose of at least 10 mg/day of prednisone or its equivalent in addition to standard therapy*

* Standard therapy includes an antimalarial drug (e.g., hydroxychloroquine) or immunosuppressive agents (e.g., azathioprine, methotrexate, mycophenolate mofetil) with or without nonsteroidal anti-inflammatory drugs (NSAIDs)

A SLEDAI-2K pre-treatment baseline score must be provided. If a British Isles Lupus Activity Group (BILAG)-2004 will be used for renewal assessment, a BILAG-2004 pre-treatment baseline assessment of organ systems must also be provided. The same scale should be used on all subsequent renewals.

Coverage will not be provided for patients with any of the following:
- severe or unstable neuropsychiatric SLE or
- active severe SLE nephritis.

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

Initial coverage may be approved for a period of 12 months at a dosage of 300 mg administered every 4 weeks.
-Patients will be limited to receiving one dose of anifrolumab per prescription at their pharmacy.

For continued coverage, the patient must meet the following criteria:
- OCS dose decreased to </= 7.5 mg/day of prednisone or its equivalent and
- Reduction in disease activity measured by:
--reducing the SLEDAI-2K score to 5 or less OR
--BILAG-2004 improvement in organ systems and no new worsening. This is interpreted as a reduction of all severe (BILAG-2004 A) or moderately severe (BILAG-2004 B) to lower rating levels AND no worsening in other organ systems (worsening was defined as one or more new A item or two or more new B items).

Following this assessment, continued coverage may be considered at a dosage of 300 mg administered every 4 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed every 12 months and has maintained a response to therapy.

Coverage cannot be provided for anifrolumab when this medication is intended for use in combination with other biologics for the treatment of SLE."

All requests (including renewal requests) for anifrolumab must be completed using the Anifrolumab for Systemic Lupus Erythematosus Special Authorization Request Form (ABC 60110).

150 MG / VIAL INJECTION

00002522845	SAPHNELO	AZC	$	1687.2100

ARIPIPRAZOLE

"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 aripiprazole therapy;
AND
Is refractory to a trial of at least one other antipsychotic therapy.

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

ATOGEPANT

''Special authorization coverage may be provided for the prevention of episodic 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.

'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 up to a maximum daily dose of 60 mg 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 month supply of atogepant 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 up to a maximum daily dose of 60 mg 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 atogepant (including renewal requests) must be completed using the Atogepant/Eptinezumab/Fremanezumab/Galcanezumab for Migraine Prevention Special Authorization Request Form (ABC 60095).

10 MG ORAL TABLET				
00002533979	QULIPTA	ABV	$	18.4400
30 MG ORAL TABLET				
00002533987	QULIPTA	ABV	$	18.4400
60 MG ORAL TABLET				
00002533995	QULIPTA	ABV	$	18.4400

ATOMOXETINE HCL

STEP THERAPY/SPECIAL AUTHORIZATION

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

FIRST-LINE DRUG PRODUCT(S): SHORT/LONG-ACTING METHYLPHENIDATE AND SHORT/LONG-ACTING AMPHETAMINE

For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years of age and older who are refractory to a short-/long-acting methylphenidate AND a short-/long-acting amphetamine.

"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.

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 atomoxetine must be completed using the Atomoxetine for Attention Deficit Hyperactivity Disorder (ADHD) Special Authorization Request Form (ABC 60109).

10 MG (BASE) ORAL CAPSULE				
00002318024	**APO-ATOMOXETINE**	**APX**	$	**0.5106**
00002445883	**ATOMOXETINE**	**SIV**	$	**0.5106**
00002506807	**JAMP ATOMOXETINE**	**JPC**	$	**0.5106**
00002381028	**PMS-ATOMOXETINE**	**PMS**	$	**0.5106**
00002386410	**SANDOZ ATOMOXETINE**	**SDZ**	$	**0.5106**
00002314541	**TEVA-ATOMOXETINE**	**TEV**	$	**0.5106**
18 MG (BASE) ORAL CAPSULE				
00002318032	**APO-ATOMOXETINE**	**APX**	$	**0.5748**
00002445905	**ATOMOXETINE**	**SIV**	$	**0.5748**
00002506815	**JAMP ATOMOXETINE**	**JPC**	$	**0.5748**
00002381036	**PMS-ATOMOXETINE**	**PMS**	$	**0.5748**
00002386429	**SANDOZ ATOMOXETINE**	**SDZ**	$	**0.5748**
00002314568	**TEVA-ATOMOXETINE**	**TEV**	$	**0.5748**
25 MG (BASE) ORAL CAPSULE				
00002318040	**APO-ATOMOXETINE**	**APX**	$	**0.6420**
00002445913	**ATOMOXETINE**	**SIV**	$	**0.6420**
00002506823	**JAMP ATOMOXETINE**	**JPC**	$	**0.6420**
00002381044	**PMS-ATOMOXETINE**	**PMS**	$	**0.6420**
00002386437	**SANDOZ ATOMOXETINE**	**SDZ**	$	**0.6420**
00002314576	**TEVA-ATOMOXETINE**	**TEV**	$	**0.6420**
40 MG (BASE) ORAL CAPSULE				
00002318059	**APO-ATOMOXETINE**	**APX**	$	**0.7369**
00002445948	**ATOMOXETINE**	**SIV**	$	**0.7369**
00002506831	**JAMP ATOMOXETINE**	**JPC**	$	**0.7369**
00002381052	**PMS-ATOMOXETINE**	**PMS**	$	**0.7369**
00002386445	**SANDOZ ATOMOXETINE**	**SDZ**	$	**0.7369**
00002314584	**TEVA-ATOMOXETINE**	**TEV**	$	**0.7369**

ATOMOXETINE HCL

60 MG (BASE) ORAL CAPSULE				
00002318067	**APO-ATOMOXETINE**	**APX**	$	**0.8092**
00002445956	**ATOMOXETINE**	**SIV**	$	**0.8092**
00002506858	**JAMP ATOMOXETINE**	**JPC**	$	**0.8092**
00002381060	**PMS-ATOMOXETINE**	**PMS**	$	**0.8092**
00002386453	**SANDOZ ATOMOXETINE**	**SDZ**	$	**0.8092**
00002314592	**TEVA-ATOMOXETINE**	**TEV**	$	**0.8092**
80 MG (BASE) ORAL CAPSULE				
00002318075	**APO-ATOMOXETINE**	**APX**	$	**1.2193**
00002506866	**JAMP ATOMOXETINE**	**JPC**	$	**1.2193**
00002386461	**SANDOZ ATOMOXETINE**	**SDZ**	$	**1.2193**
00002362511	**TEVA-ATOMOXETINE**	**TEV**	$	**1.2193**

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

00002402645	**ACH-DONEPEZIL**	**AHI**	$	**0.4586**
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**
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**
00002535386	**NRA-DONEPEZIL**	**NRA**	$	**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

00002402653	**ACH-DONEPEZIL**	**AHI**	$	**0.4586**
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**
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**
00002535394	**NRA-DONEPEZIL**	**NRA**	$	**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

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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 24 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 24 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/Bimekizumab/Etanercept/Guselkumab/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

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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 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 12 months. After 12 months, in order to be considered for continued coverage, the patient must be re-assessed every 24 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

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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:
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 an initial period of 12 months and subsequent renewals of 24 months. Ongoing coverage may be considered if the following criteria are met at the end of each 24-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/Guselkumab/Infliximab/Ixekizumab/Secukinumab/Upadacitinib 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

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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.
'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 an initial period of 12 months and subsequent renewals of 24 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 24-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/Upadacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

ETANERCEPT

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 24 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 24 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/Bimekizumab/Etanercept/Guselkumab/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

ETANERCEPT

- 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):
- 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 12 months. After 12 months, in order to be considered for continued coverage, the patient must be re-assessed every 24 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

ETANERCEPT

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:
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 an initial period of 12 months and subsequent renewals of 24 months. Ongoing coverage may be considered if the following criteria are met at the end of each 24-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/Guselkumab/Infliximab/Ixekizumab/Secukinumab/Upadacitinib 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

ETANERCEPT

- 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.

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 an initial period of 12 months and subsequent renewals of 24 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 24-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/Upadacitinib 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

ETANERCEPT

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 24 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)

ETANERCEPT

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 24 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/Bimekizumab/Etanercept/Guselkumab/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).

ETANERCEPT

- 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 12 months. After 12 months, in order to be considered for continued coverage, the patient must be re-assessed every 24 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

ETANERCEPT

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 an initial period of 12 months and subsequent renewals of 24 months. Ongoing coverage may be considered if the following criteria are met at the end of each 24-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/Guselkumab/Infliximab/Ixekizumab/Secukinumab/Upadacitinib 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

ETANERCEPT

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 an initial period of 12 months and subsequent renewals of 24 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 24-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/Upadacitinib 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.

ETANERCEPT

'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 24 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.

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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 24 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/Bimekizumab/Etanercept/Guselkumab/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

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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 12 months. After 12 months, in order to be considered for continued coverage, the patient must be re-assessed every 24 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

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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 an initial period of 12 months and subsequent renewals of 24 months. Ongoing coverage may be considered if the following criteria are met at the end of each 24-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/Guselkumab/Infliximab/Ixekizumab/Secukinumab/Upadacitinib 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

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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 an initial period of 12 months and subsequent renewals of 24 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 24-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/Upadacitinib 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.

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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 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 24 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

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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 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 24 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/Bimekizumab/Etanercept/Guselkumab/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:

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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 12 months. After 12 months, in order to be considered for continued coverage, the patient must be re-assessed every 24 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.

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- 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 an initial period of 12 months and subsequent renewals of 24 months. Ongoing coverage may be considered if the following criteria are met at the end of each 24-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/Guselkumab/Infliximab/Ixekizumab/Secukinumab/Upadacitinib 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.

ETANERCEPT

- 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 an initial period of 12 months and subsequent renewals of 24 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 24-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/Upadacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

FINERENONE

"Special authorization coverage may be provided as an adjunct to standard of care therapy to reduce the risk of end-stage kidney disease or cardiovascular death, fatal myocardial infarction or hospitalization for heart failure in adult patients with chronic kidney disease (CKD) and Type 2 diabetes (T2D), if the following criteria are met:

1) Patients must have:
- an estimated glomerular filtration rate (eGFR) level of at least 25 mL/min/1.73 m2, and
- an albuminuria level of at least 30 mg/g (or 3 mg/mmol)

2) Patients must not have:
- New York Heart Association [NYHA] class II to IV heart failure.

Coverage cannot be provided for use in combination with another mineralocorticoid receptor antagonist (MRA).

For coverage, this drug must be prescribed by a physician who has experience in the diagnosis and management of patients with CKD and T2D.

Special authorization may be granted for 6 months.

Note:
Consider discontinuation of finerenone if the patient has an eGFR less than 15 mL/min/1.73 m2 or urinary albumin-to-creatinine ratio (UACR) increase from baseline level while receiving finerenone."
All requests for finerenone must be completed using the finerenone Special Authorization Request Form (ABC 60111).

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

10 MG ORAL TABLET				
00002531917	KERENDIA	BAI	$	3.3400
20 MG ORAL TABLET				
00002531925	KERENDIA	BAI	$	3.3400

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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 24 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 of

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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; OR 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;

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 Disease

- New Patients must meet the criteria above prior to being considered for approval.

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- 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 an initial period of 12 months with subsequent renewals of 24 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 24 months, if the following criteria are met at the end of each 24 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 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

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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 24 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

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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/Bimekizumab/Etanercept/Guselkumab/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 an initial period of 12 months with subsequent renewals of 24 months. Ongoing coverage may be considered if the following criteria are met at the end of each 24-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 Psoriatic Arthritis must be completed using the
Adalimumab/Certolizumab/Etanercept/Golimumab/Guselkumab/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 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.

Following this assessment, continued coverage may be approved for one 3 mg/kg dose every 8 weeks for an initial period of 12 months with subsequent renewals of 24 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 24-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/Upadacitinib 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 an initial period of 12 months with subsequent renewals of 24 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 24-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

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Authorization Request Form (ABC 60008).

☒	00002470373	RENFLEXIS	SSB	$	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 24 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.

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- 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; OR 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;

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 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 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 an initial period of 12 months with subsequent renewals of 24 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 24 months, if the following criteria are met at the end of each 24 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 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

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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 24 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

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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/Bimekizumab/Etanercept/Guselkumab/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 an initial period of 12 months with subsequent renewals of 24 months. Ongoing coverage may be considered if the following criteria are met at the end of each 24-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

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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/Guselkumab/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 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.

Following this assessment, continued coverage may be approved for one 3 mg/kg dose every 8 weeks for an initial period of 12 months with subsequent renewals of 24 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 24-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

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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/Upadacitinib 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 an initial period of 12 months with subsequent renewals of 24 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 24-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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100 MG / VIAL INJECTION

00002419475	INFLECTRA	CHH	$	525.0000

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 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 24 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 of

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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; OR 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;

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 Disease

- New Patients must meet the criteria above prior to being considered for approval.

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- 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 an initial period of 12 months with subsequent renewals of 24 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 24 months, if the following criteria are met at the end of each 24 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 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

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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 24 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

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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/Bimekizumab/Etanercept/Guselkumab/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 an initial period of 12 months with subsequent renewals of 24 months. Ongoing coverage may be considered if the following criteria are met at the end of each 24-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 Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Guselkumab/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 an initial period of 12 months with subsequent renewals of 24 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 24-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/Upadacitinib 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 an initial period of 12 months with subsequent renewals of 24 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 24-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

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Authorization Request Form (ABC 60008).

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
Is refractory to a trial of at least one other antipsychotic therapy.

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
Is refractory to a trial of at least one other antipsychotic therapy.

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

"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
Is refractory to a trial of at least one other antipsychotic therapy.

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

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
Is refractory to a trial of at least one other antipsychotic therapy.

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

"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
Is refractory to a trial of at least one other antipsychotic therapy.

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

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
Is refractory to a trial of at least one other antipsychotic therapy.

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

"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
Is refractory to a trial of at least one other antipsychotic therapy.

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

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
Is refractory to a trial of at least one other antipsychotic therapy.

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

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
Is refractory to a trial of at least one other antipsychotic therapy.

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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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;

TOFACITINIB CITRATE

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**
00002522896	**JAMP TOFACITINIB**	**JPC**	$	**5.9897**
00002522799	**PMS-TOFACITINIB**	**PMS**	$	**5.9897**
00002511304	**TARO-TOFACITINIB**	**TAR**	$	**5.9897**
00002423898	XELJANZ	PFI	$	24.7733

VEDOLIZUMAB

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; OR 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.

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
- 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

VEDOLIZUMAB

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).

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

VEDOLIZUMAB

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

300 MG / VIAL INJECTION

00002436841	ENTYVIO	TAK	$ 3401.8600

VEDOLIZUMAB

108 MG / SYR INJECTION SYRINGE

☒ 00002497875	ENTYVIO	TAK	$	850.4600
☒ 00002497867	ENTYVIO (PEN)	TAK	$	850.4600