Updates to the Alberta Drug Benefit List

Effective December 1, 2020

Alberta Government

Inquiries should be directed to:

Pharmacy Services
Alberta Blue Cross
10009 108 Street NW
Edmonton AB T5J 3C5

Telephone Number: (780) 498-8370 (Edmonton)
(403) 294-4041 (Calgary)
1-800-361-9632 (Toll Free)

FAX Number: (780) 498-8406
1-877-305-9911 (Toll Free)

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

Administered by Alberta Blue Cross
on behalf of Alberta Health.

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

Copies of the *Alberta Drug Benefit List* are available from Pharmacy Services, Alberta Blue Cross at the address shown above.

Binder and contents: **$42.00** ($40.00 + $2.00 G.S.T.)
Contents only: **$36.75** ($35.00 + $1.75 G.S.T.)

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Special Authorization

The following drug product(s) will be considered for coverage by Special Authorization 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
NIVESTYM 0.3 MG / ML INJECTION	FILGRASTIM	00002485591	PFI
NIVESTYM (0.5 ML SYRINGE) 0.3 MG / SYRINGE INJECTION	FILGRASTIM	00002485575	PFI
NIVESTYM 0.48 MG / ML INJECTION	FILGRASTIM	00002485656	PFI
NIVESTYM (0.8 ML SYRINGE) 0.48 MG / SYRINGE INJECTION	FILGRASTIM	00002485583	PFI
TAKHZYRO 150 MG / ML INJECTION	LANADELUMAB	00002480948	SHB
XELJANZ 10 MG TABLET	TOFACITINIB CITRATE	00002480786	PFI

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

Trade Name / Strength / Form	Generic Description	DIN	MFR
AG-CELECOXIB 100 MG CAPSULE	CELECOXIB	00002437570	AGP
AG-CELECOXIB 200 MG CAPSULE	CELECOXIB	00002437589	AGP
GLN-EZETIMIBE 10 MG TABLET	EZETIMIBE	00002460750	GLM
NRA-CELECOXIB 100 MG CAPSULE	CELECOXIB	00002479737	NRA
NRA-CELECOXIB 200 MG CAPSULE	CELECOXIB	00002479745	NRA

Drug Product(s) with Changes to Criteria for Coverage

Trade Name / Strength / Form	Generic Description	DIN	MFR
FIRAZYR 30 MG / SYRINGE INJECTION	ICATIBANT ACETATE	00002425696	SOT
GRASTOFIL (0.5 ML SYRINGE) 0.3 MG / SYRINGE INJECTION	FILGRASTIM	00002441489	APX
GRASTOFIL (0.8 ML SYRINGE) 0.48 MG / SYRINGE INJECTION	FILGRASTIM	00002454548	APX
HUMIRA 40 MG / 0.8 ML SYRINGE INJECTION	ADALIMUMAB	00002258595	ABV
INFLECTRA 100 MG / VIAL INJECTION	INFLIXIMAB	00002419475	CHH
NEUPOGEN 0.3 MG / ML INJECTION	FILGRASTIM	00001968017	AMG
REMICADE 100 MG / VIAL INJECTION	INFLIXIMAB	00002244016	JAI
RENFLEXIS 100 MG / VIAL INJECTION	INFLIXIMAB	00002470373	SSB
SIMPONI 50 MG / SYRINGE INJECTION	GOLIMUMAB	00002324776	JAI

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

Trade Name / Strength / Form	Generic Description	DIN	MFR
SIMPONI (AUTO INJECTOR) 50 MG / SYRINGE INJECTION	GOLIMUMAB	00002324784	JAI
SIMPONI 100 MG / SYRINGE INJECTION	GOLIMUMAB	00002413175	JAI
SIMPONI (AUTO INJECTOR) 100 MG / SYRINGE INJECTION	GOLIMUMAB	00002413183	JAI
STELARA (0.5 ML VIAL OR SYRINGE) 45 MG INJECTION	USTEKINUMAB	00002320673	JAI
STELARA (1 ML SYRINGE) 90 MG / SYRINGE INJECTION	USTEKINUMAB	00002320681	JAI
XELJANZ 5 MG TABLET	TOFACITINIB CITRATE	00002423898	PFI

Added Product(s)

Trade Name / Strength / Form	Generic Description	DIN	MFR
AG-DULOXETINE 30 MG DELAYED-RELEASE CAPSULE	DULOXETINE HYDROCHLORIDE	00002475308	AGP
AG-DULOXETINE 60 MG DELAYED-RELEASE CAPSULE	DULOXETINE HYDROCHLORIDE	00002475316	AGP
AG-TOPIRAMATE 25 MG TABLET	TOPIRAMATE	00002475936	AGP
AG-TOPIRAMATE 100 MG TABLET	TOPIRAMATE	00002475944	AGP
METHOTREXATE SUBCUTANEOUS 15 MG / SYRINGE INJECTION	METHOTREXATE SODIUM	00002491311	MDX
MINT-DICLOFENAC 0.1% OPHTHALMIC SOLUTION	DICLOFENAC SODIUM	00002475197	MPI
NRA-ATORVASTATIN 10 MG TABLET	ATORVASTATIN CALCIUM	00002476517	NRA
NRA-ATORVASTATIN 20 MG TABLET	ATORVASTATIN CALCIUM	00002476525	NRA
NRA-ATORVASTATIN 40 MG TABLET	ATORVASTATIN CALCIUM	00002476533	NRA
NRA-ATORVASTATIN 80 MG TABLET	ATORVASTATIN CALCIUM	00002476541	NRA
NRA-AZITHROMYCIN 250 MG TABLET	AZITHROMYCIN	00002479680	NRA
NRA-CLINDAMYCIN 150 MG CAPSULE	CLINDAMYCIN HCL	00002493748	NRA
NRA-CLINDAMYCIN 300 MG CAPSULE	CLINDAMYCIN HCL	00002493756	NRA
RIVA LEUCOVORIN 5 MG TABLET	LEUCOVORIN CALCIUM	00002493357	RIV

New Established Interchangeable (IC) Grouping(s)

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

Generic Description	Strength / Form	New LCA Price
LEUCOVORIN	5 MG TABLET	5.5164

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 change, will be effective December 1, 2020. Please review the online **Interactive Drug Benefit List** for further information.*

Generic Description	Strength / Form	New LCA Price
CEFPROZIL	250 MG TABLET	1.0220

Product(s) with a Price Change

The following product(s) had a Price Change. The previous higher price will be recognized until December 31, 2020. For products within an established IC Grouping, the LCA price may apply.

Trade Name / Strength / Form	Generic Description	DIN	MFR
RAN-CEFPROZIL 250 MG TABLET	CEFPROZIL	00002293528	RAN
RIXIMYO 10 MG / ML INJECTION	RITUXIMAB	00002498316	SDZ

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, 2020, 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, 2021 claims will no longer pay for these product(s).

Trade Name / Strength / Form	Generic Description	DIN	MFR
APO-DIPYRIDAMOLE (FC) 25 MG TABLET	DIPYRIDAMOLE	00000895644	APX
APO-DIPYRIDAMOLE (FC) 50 MG TABLET	DIPYRIDAMOLE	00000895652	APX
APO-DIPYRIDAMOLE (FC) 75 MG TABLET	DIPYRIDAMOLE	00000895660	APX
AVANDIA 8 MG TABLET	ROSIGLITAZONE MALEATE	00002241114	GSK
CEFTIN 250 MG TABLET	CEFUROXIME AXETIL	00002212277	GSK
CEFTIN 500 MG TABLET	CEFUROXIME AXETIL	00002212285	GSK
CYCLEN (21 DAY) 0.25 MG / 0.035 MG ORAL TABLET	NORGESTIMATE/ ETHINYL ESTRADIOL	00001968440	JAI
CYCLEN (28 DAY) 0.25 MG / 0.035 MG ORAL TABLET	NORGESTIMATE/ ETHINYL ESTRADIOL	00001992872	JAI
DAKLINZA 30 MG TABLET	DACLATASVIR DIHYDROCHLORIDE	00002444747	BMS
DAKLINZA 60 MG TABLET	DACLATASVIR DIHYDROCHLORIDE	00002444755	BMS
DICLOFENAC SODIUM 50 MG ENTERIC-COATED TABLET	DICLOFENAC SODIUM	00002352397	SNS
DIPROSALIC 0.5 MG / ML / 20 MG / ML TOPICAL LOTION	BETAMETHASONE DIPROPIONATE/ SALICYLIC ACID	00000578428	MFC
INHIBACE 2.5 MG TABLET	CILAZAPRIL	00001911473	CAG

Discontinued Listing(s), continued

Trade Name / Strength / Form	Generic Description	DIN	MFR
KETOPROFEN 50 MG CAPSULE	KETOPROFEN	00000790427	AAP
MINT-IRBESARTAN / HCTZ 150 / 12.5 MG TABLET	IRBESARTAN/ HYDROCHLOROTHIAZIDE	00002392992	MPI
MINT-IRBESARTAN / HCTZ 300 / 12.5 MG TABLET	IRBESARTAN/ HYDROCHLOROTHIAZIDE	00002393018	MPI
MINT-IRBESARTAN / HCTZ 300 / 25 MG TABLET	IRBESARTAN/ HYDROCHLOROTHIAZIDE	00002393026	MPI
MORPHINE SR 15 MG SUSTAINED-RELEASE TABLET	MORPHINE SULFATE	00002350815	SNS
MORPHINE SR 30 MG SUSTAINED-RELEASE TABLET	MORPHINE SULFATE	00002350890	SNS
OXYCODONE / ACET 5 MG / 325 MG ORAL TABLET	OXYCODONE HCL/ ACETAMINOPHEN	00002361361	SNS
THEOLAIR 80 MG/15 ML ORAL LIQUID	THEOPHYLLINE	00001966219	VCL
TRI-CYCLEN (21 DAY) 0.18 MG / 0.035 MG / 0.215 MG / 0.035 MG / 0.25 MG / 0.035 MG ORAL TABLET	NORGESTIMATE/ ETHINYL ESTRADIOL/ NORGESTIMATE/ ETHINYL ESTRADIOL/ NORGESTIMATE/ ETHINYL ESTRADIOL	00002028700	JAI
TRI-CYCLEN (28 DAY) 0.18 MG / 0.035 MG / 0.215 MG / 0.035 MG / 0.25 MG / 0.035 MG ORAL TABLET	NORGESTIMATE/ ETHINYL ESTRADIOL/ NORGESTIMATE/ ETHINYL ESTRADIOL/ NORGESTIMATE/ ETHINYL ESTRADIOL	00002029421	JAI
TRI-CYCLEN LO 21 0.18 MG / 0.025 MG / 0.215 MG / 0.025 MG / 0.25 MG / 0.025 MG ORAL TABLET	NORGESTIMATE/ ETHINYL ESTRADIOL/ NORGESTIMATE/ ETHINYL ESTRADIOL/ NORGESTIMATE/ ETHINYL ESTRADIOL	00002258560	JAI
TRI-CYCLEN LO 28 0.18 MG / 0.025 MG / 0.285 MG / 0.025 MG / 0.25 MG / 0.025 MG ORAL TABLET	NORGESTIMATE/ ETHINYL ESTRADIOL/ NORGESTIMATE/ ETHINYL ESTRADIOL/ NORGESTIMATE/ ETHINYL ESTRADIOL	00002258587	JAI
TYLENOL NO. 2 15 MG / 300 MG / 15 MG ORAL TABLET	CODEINE PHOSPHATE/ ACETAMINOPHEN/ CAFFEINE	00002163934	JAI
TYLENOL NO. 3 30 MG / 300 MG / 15 MG ORAL TABLET	CODEINE PHOSPHATE/ ACETAMINOPHEN/ CAFFEINE	00002163926	JAI
TYLENOL NO. 4 60 MG / 300 MG ORAL TABLET	CODEINE PHOSPHATE/ ACETAMINOPHEN	00002163918	JAI

Product(s) Removed from the ADBL as Price Policy Requirements not Satisfied

The Alberta government-sponsored drug programs previously covered the following drug product(s). Effective December 1, 2020, the listed product(s) will no longer be a benefit. A transition period will be applied and as of January 1, 2021 claims will no longer pay for tis product.

Trade Name / Strength / Form	Generic Description	DIN	MFR
JAMP-INDAPAMIDE 2.5 MG TABLET	INDAPAMIDE HEMIHYDRATE	00002373912	JPC

PART 2

Drug Additions

ATORVASTATIN CALCIUM

10 MG (BASE) ORAL TABLET				
00002457741	**ACH-ATORVASTATIN**	**AHI**	$	**0.1743**
00002478145	**AG-ATORVASTATIN**	**AGP**	$	**0.1743**
00002295261	**APO-ATORVASTATIN**	**APX**	$	**0.1743**
00002411350	**ATORVASTATIN-10**	**SIV**	$	**0.1743**
00002407256	**AURO-ATORVASTATIN**	**AUR**	$	**0.1743**
00002391058	**JAMP-ATORVASTATIN**	**JPC**	$	**0.1743**
00002454017	**MAR-ATORVASTATIN**	**MAR**	$	**0.1743**
00002479508	**MINT-ATORVASTATIN**	**MPI**	$	**0.1743**
00002392933	**MYLAN-ATORVASTATIN**	**MYP**	$	**0.1743**
00002476517	**NRA-ATORVASTATIN**	**NRA**	$	**0.1743**
00002399377	**PMS-ATORVASTATIN**	**PMS**	$	**0.1743**
00002477149	**PMS-ATORVASTATIN**	**PMS**	$	**0.1743**
00002313707	**RAN-ATORVASTATIN**	**RAN**	$	**0.1743**
00002417936	**REDDY-ATORVASTATIN**	**DRL**	$	**0.1743**
00002324946	**SANDOZ ATORVASTATIN**	**SDZ**	$	**0.1743**
00002310899	**TEVA-ATORVASTATIN**	**TEV**	$	**0.1743**
00002230711	LIPITOR	UJC	$	1.8223
20 MG (BASE) ORAL TABLET				
00002457768	**ACH-ATORVASTATIN**	**AHI**	$	**0.2179**
00002478153	**AG-ATORVASTATIN**	**AGP**	$	**0.2179**
00002295288	**APO-ATORVASTATIN**	**APX**	$	**0.2179**
00002411369	**ATORVASTATIN-20**	**SIV**	$	**0.2179**
00002407264	**AURO-ATORVASTATIN**	**AUR**	$	**0.2179**
00002391066	**JAMP-ATORVASTATIN**	**JPC**	$	**0.2179**
00002454025	**MAR-ATORVASTATIN**	**MAR**	$	**0.2179**
00002479516	**MINT-ATORVASTATIN**	**MPI**	$	**0.2179**
00002392941	**MYLAN-ATORVASTATIN**	**MYP**	$	**0.2179**
00002476525	**NRA-ATORVASTATIN**	**NRA**	$	**0.2179**
00002399385	**PMS-ATORVASTATIN**	**PMS**	$	**0.2179**
00002477157	**PMS-ATORVASTATIN**	**PMS**	$	**0.2179**
00002313715	**RAN-ATORVASTATIN**	**RAN**	$	**0.2179**
00002417944	**REDDY-ATORVASTATIN**	**DRL**	$	**0.2179**
00002324954	**SANDOZ ATORVASTATIN**	**SDZ**	$	**0.2179**
00002310902	**TEVA-ATORVASTATIN**	**TEV**	$	**0.2179**
00002230713	LIPITOR	UJC	$	2.2779
40 MG (BASE) ORAL TABLET				
00002457776	**ACH-ATORVASTATIN**	**AHI**	$	**0.2342**
00002478161	**AG-ATORVASTATIN**	**AGP**	$	**0.2342**
00002295296	**APO-ATORVASTATIN**	**APX**	$	**0.2342**
00002411377	**ATORVASTATIN-40**	**SIV**	$	**0.2342**
00002407272	**AURO-ATORVASTATIN**	**AUR**	$	**0.2342**
00002391074	**JAMP-ATORVASTATIN**	**JPC**	$	**0.2342**
00002454033	**MAR-ATORVASTATIN**	**MAR**	$	**0.2342**
00002479524	**MINT-ATORVASTATIN**	**MPI**	$	**0.2342**
00002392968	**MYLAN-ATORVASTATIN**	**MYP**	$	**0.2342**
00002476533	**NRA-ATORVASTATIN**	**NRA**	$	**0.2342**
00002399393	**PMS-ATORVASTATIN**	**PMS**	$	**0.2342**
00002477165	**PMS-ATORVASTATIN**	**PMS**	$	**0.2342**
00002313723	**RAN-ATORVASTATIN**	**RAN**	$	**0.2342**
00002417952	**REDDY-ATORVASTATIN**	**DRL**	$	**0.2342**
00002324962	**SANDOZ ATORVASTATIN**	**SDZ**	$	**0.2342**
00002310910	**TEVA-ATORVASTATIN**	**TEV**	$	**0.2342**
00002230714	LIPITOR	UJC	$	2.4483

ATORVASTATIN CALCIUM

80 MG (BASE) ORAL TABLET

00002457784	**ACH-ATORVASTATIN**	**AHI**	$	**0.2342**
00002478188	**AG-ATORVASTATIN**	**AGP**	$	**0.2342**
00002295318	**APO-ATORVASTATIN**	**APX**	$	**0.2342**
00002411385	**ATORVASTATIN-80**	**SIV**	$	**0.2342**
00002407280	**AURO-ATORVASTATIN**	**AUR**	$	**0.2342**
00002391082	**JAMP-ATORVASTATIN**	**JPC**	$	**0.2342**
00002454041	**MAR-ATORVASTATIN**	**MAR**	$	**0.2342**
00002392976	**MYLAN-ATORVASTATIN**	**MYP**	$	**0.2342**
00002476541	**NRA-ATORVASTATIN**	**NRA**	$	**0.2342**
00002399407	**PMS-ATORVASTATIN**	**PMS**	$	**0.2342**
00002477173	**PMS-ATORVASTATIN**	**PMS**	$	**0.2342**
00002313758	**RAN-ATORVASTATIN**	**RAN**	$	**0.2342**
00002417960	**REDDY-ATORVASTATIN**	**DRL**	$	**0.2342**
00002324970	**SANDOZ ATORVASTATIN**	**SDZ**	$	**0.2342**
00002310929	**TEVA-ATORVASTATIN**	**TEV**	$	**0.2342**
00002243097	LIPITOR	UJC	$	2.4483

AZITHROMYCIN

250 MG ORAL TABLET

00002480700	**AG-AZITHROMYCIN**	**AGP**	$	**0.9410**
00002415542	**APO-AZITHROMYCIN Z**	**APX**	$	**0.9410**
00002330881	**AZITHROMYCIN**	**SNS**	$	**0.9410**
00002442434	**AZITHROMYCIN**	**SIV**	$	**0.9410**
00002452308	**JAMP-AZITHROMYCIN**	**JPC**	$	**0.9410**
00002452324	**MAR-AZITHROMYCIN**	**MAR**	$	**0.9410**
00002267845	**NOVO-AZITHROMYCIN**	**TEV**	$	**0.9410**
00002479680	**NRA-AZITHROMYCIN**	**NRA**	$	**0.9410**
00002261634	**PMS-AZITHROMYCIN**	**PMS**	$	**0.9410**
00002265826	**SANDOZ AZITHROMYCIN**	**SDZ**	$	**0.9410**
00002212021	ZITHROMAX	PFI	$	5.2318

CEFPROZIL

250 MG ORAL TABLET

00002293528	RAN-CEFPROZIL	RAN	$	1.0220

CLINDAMYCIN HCL

150 MG (BASE) ORAL CAPSULE

00002436906	**AURO-CLINDAMYCIN**	**AUR**	$	**0.2217**
00002483734	**JAMP CLINDAMYCIN**	**JPC**	$	**0.2217**
00002493748	**NRA-CLINDAMYCIN**	**NRA**	$	**0.2217**
00002241709	**TEVA-CLINDAMYCIN**	**TEV**	$	**0.2217**

300 MG (BASE) ORAL CAPSULE

00002436914	**AURO-CLINDAMYCIN**	**AUR**	$	**0.4434**
00002483742	**JAMP CLINDAMYCIN**	**JPC**	$	**0.4434**
00002493756	**NRA-CLINDAMYCIN**	**NRA**	$	**0.4434**
00002241710	**TEVA-CLINDAMYCIN**	**TEV**	$	**0.4434**

DICLOFENAC SODIUM

0.1 % OPHTHALMIC SOLUTION

00002441020	**APO-DICLOFENAC OPHTHALMIC**	**APX**	$	**1.2397**
00002475065	**DICLOFENAC**	**PSL**	$	**1.2397**
00002475197	**MINT-DICLOFENAC**	**MPI**	$	**1.2397**
00002454807	**SANDOZ DICLOFENAC OPHTHA**	**SDZ**	$	**1.2397**
00001940414	VOLTAREN OPHTHA	NOV	$	2.6860

DIVALPROEX SODIUM (VALPROIC ACID EQUIV.)

125 MG (BASE) ORAL ENTERIC-COATED TABLET				
00002239698	**APO-DIVALPROEX**	**APX**	$	**0.0724**
00002458926	**MYLAN-DIVALPROEX**	**MYP**	$	**0.0724**
00000596418	EPIVAL	BGP	$	0.3078
250 MG (BASE) ORAL ENTERIC-COATED TABLET				
00002239699	**APO-DIVALPROEX**	**APX**	$	**0.1301**
00002458934	**MYLAN-DIVALPROEX**	**MYP**	$	**0.1301**
00000596426	EPIVAL	BGP	$	0.5533
500 MG (BASE) ORAL ENTERIC-COATED TABLET				
00002239700	**APO-DIVALPROEX**	**APX**	$	**0.2604**
00002459019	**MYLAN-DIVALPROEX**	**MYP**	$	**0.2604**
00000596434	EPIVAL	BGP	$	1.1073

DULOXETINE HYDROCHLORIDE

30 MG (BASE) ORAL DELAYED-RELEASE CAPSULE				
00002475308	**AG-DULOXETINE**	**AGP**	$	**0.4814**
00002440423	**APO-DULOXETINE**	**APX**	$	**0.4814**
00002436647	**AURO-DULOXETINE**	**AUR**	$	**0.4814**
00002453630	**DULOXETINE**	**SIV**	$	**0.4814**
00002490889	**DULOXETINE**	**SNS**	$	**0.4814**
00002437082	**DULOXETINE DR**	**TEV**	$	**0.4814**
00002451913	**JAMP-DULOXETINE**	**JPC**	$	**0.4814**
00002446081	**MAR-DULOXETINE**	**MAR**	$	**0.4814**
00002438984	**MINT-DULOXETINE**	**MPI**	$	**0.4814**
00002429446	**PMS-DULOXETINE**	**PMS**	$	**0.4814**
00002438259	**RAN-DULOXETINE**	**RAN**	$	**0.4814**
00002439948	**SANDOZ DULOXETINE**	**SDZ**	$	**0.4814**
00002456753	**TEVA-DULOXETINE**	**TEV**	$	**0.4814**
00002301482	CYMBALTA	LIL	$	2.0217
60 MG (BASE) ORAL DELAYED-RELEASE CAPSULE				
00002475316	**AG-DULOXETINE**	**AGP**	$	**0.9769**
00002440431	**APO-DULOXETINE**	**APX**	$	**0.9769**
00002436655	**AURO-DULOXETINE**	**AUR**	$	**0.9769**
00002453649	**DULOXETINE**	**SIV**	$	**0.9769**
00002490897	**DULOXETINE**	**SNS**	$	**0.9769**
00002437090	**DULOXETINE DR**	**TEV**	$	**0.9769**
00002451921	**JAMP-DULOXETINE**	**JPC**	$	**0.9769**
00002446103	**MAR-DULOXETINE**	**MAR**	$	**0.9769**
00002438992	**MINT-DULOXETINE**	**MPI**	$	**0.9769**
00002429454	**PMS-DULOXETINE**	**PMS**	$	**0.9769**
00002438267	**RAN-DULOXETINE**	**RAN**	$	**0.9769**
00002439956	**SANDOZ DULOXETINE**	**SDZ**	$	**0.9769**
00002456761	**TEVA-DULOXETINE**	**TEV**	$	**0.9769**
00002301490	CYMBALTA	LIL	$	4.1029

LEUCOVORIN CALCIUM

5 MG (BASE) ORAL TABLET				
00002493357	**RIVA LEUCOVORIN**	**RIV**	$	**5.5164**
00002170493	LEDERLE LEUCOVORIN CALCIUM	PFI	$	7.2466

METHOTREXATE SODIUM

15 MG / SYR (BASE) INJECTION SYRINGE				
00002491311	**METHOTREXATE SUBCUTANEOUS**	**AHI**	$	**24.5700**
☒ 00002454858	METOJECT SUBCUTANEOUS	MDX	$	24.5700

TOPIRAMATE

25 MG ORAL TABLET				
00002475936	**AG-TOPIRAMATE**	**AGP**	$	**0.2433**
00002279614	**APO-TOPIRAMATE**	**APX**	$	**0.2433**
00002345803	**AURO-TOPIRAMATE**	**AUR**	$	**0.2433**
00002315645	**MINT-TOPIRAMATE**	**MPI**	$	**0.2433**
00002263351	**MYLAN-TOPIRAMATE**	**MYP**	$	**0.2433**
00002262991	**PMS-TOPIRAMATE**	**PMS**	$	**0.2433**
00002431807	**SANDOZ TOPIRAMATE**	**SDZ**	$	**0.2433**
00002248860	**TEVA-TOPIRAMATE**	**TEV**	$	**0.2433**
00002356856	**TOPIRAMATE**	**SNS**	$	**0.2433**
00002389460	**TOPIRAMATE**	**SIV**	$	**0.2433**
00002395738	**TOPIRAMATE**	**AHI**	$	**0.2433**
00002230893	TOPAMAX	JAI	$	1.4816
100 MG ORAL TABLET				
00002475944	**AG-TOPIRAMATE**	**AGP**	$	**0.4583**
00002279630	**APO-TOPIRAMATE**	**APX**	$	**0.4583**
00002345838	**AURO-TOPIRAMATE**	**AUR**	$	**0.4583**
00002315653	**MINT-TOPIRAMATE**	**MPI**	$	**0.4583**
00002263378	**MYLAN-TOPIRAMATE**	**MYP**	$	**0.4583**
00002263009	**PMS-TOPIRAMATE**	**PMS**	$	**0.4583**
00002431815	**SANDOZ TOPIRAMATE**	**SDZ**	$	**0.4583**
00002248861	**TEVA-TOPIRAMATE**	**TEV**	$	**0.4583**
00002356864	**TOPIRAMATE**	**SNS**	$	**0.4583**
00002389487	**TOPIRAMATE**	**SIV**	$	**0.4583**
00002395746	**TOPIRAMATE**	**AHI**	$	**0.4583**
00002230894	TOPAMAX	JAI	$	2.7825

PART 3

Special Authorization

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Ankylosing Spondylitis

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

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

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

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

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

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

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

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

Hidradenitis Suppurativa

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

- 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

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

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

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

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

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

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

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

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

Moderately to Severe 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 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.

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Moderately to Severely Active Crohn's Disease:

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

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

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

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

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

Coverage Criteria for Moderately to Severely Active Crohn's Disease

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

Induction Dosing for New Patients:

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

Maintenance Dosing:

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

Maintenance Dosing for New Patients after Completion of Induction Dosing:

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

Maintenance Dosing for Existing Patients:

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

Continued Coverage for Maintenance Dosing:

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

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

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

Plaque Psoriasis

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

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

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

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

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

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

Polyarticular Juvenile Idiopathic Arthritis

"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

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due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from abatacept to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

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

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

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

Psoriatic Arthritis

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

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

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

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

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

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

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

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

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

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

Rheumatoid Arthritis

"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

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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.

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

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

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

All requests (including renewal requests) for adalimumab for Rheumatoid Arthritis must be

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

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

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

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

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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				
00002258595	HUMIRA (40 MG/0.8 ML INJ SYR)	ABV	$	785.4500

ASENAPINE MALEATE

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

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

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

These products are eligible for auto-renewal.

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

CELECOXIB

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

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

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

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

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

100 MG ORAL CAPSULE

00002420155	**ACT CELECOXIB**	**APH**	$	**0.1279**
00002437570	**AG-CELECOXIB**	**AGP**	$	**0.1279**
00002418932	**APO-CELECOXIB**	**APX**	$	**0.1279**
00002445670	**AURO-CELECOXIB**	**AUR**	$	**0.1279**
00002426382	**BIO-CELECOXIB**	**BMD**	$	**0.1279**
00002429675	**CELECOXIB**	**SIV**	$	**0.1279**
00002424533	**JAMP-CELECOXIB**	**JPC**	$	**0.1279**
00002420058	**MAR-CELECOXIB**	**MAR**	$	**0.1279**
00002412497	**MINT-CELECOXIB**	**MPI**	$	**0.1279**
00002479737	**NRA-CELECOXIB**	**NRA**	$	**0.1279**
00002355442	**PMS-CELECOXIB**	**PMS**	$	**0.1279**
00002412373	**RAN-CELECOXIB**	**RAN**	$	**0.1279**
00002442639	**SDZ CELECOXIB**	**SDZ**	$	**0.1279**
00002239941	CELEBREX	UJC	$	0.6992

200 MG ORAL CAPSULE

00002420163	**ACT CELECOXIB**	**APH**	$	**0.2558**
00002437589	**AG-CELECOXIB**	**AGP**	$	**0.2558**
00002418940	**APO-CELECOXIB**	**APX**	$	**0.2558**
00002445689	**AURO-CELECOXIB**	**AUR**	$	**0.2558**
00002426390	**BIO-CELECOXIB**	**BMD**	$	**0.2558**
00002429683	**CELECOXIB**	**SIV**	$	**0.2558**
00002424541	**JAMP-CELECOXIB**	**JPC**	$	**0.2558**
00002420066	**MAR-CELECOXIB**	**MAR**	$	**0.2558**
00002412500	**MINT-CELECOXIB**	**MPI**	$	**0.2558**
00002479745	**NRA-CELECOXIB**	**NRA**	$	**0.2558**
00002355450	**PMS-CELECOXIB**	**PMS**	$	**0.2558**
00002412381	**RAN-CELECOXIB**	**RAN**	$	**0.2558**
00002442647	**SDZ CELECOXIB**	**SDZ**	$	**0.2558**
00002239942	CELEBREX	UJC	$	1.3988

EZETIMIBE

"For the treatment of hypercholesterolemia in patients who are intolerant to statins or in whom a statin is contraindicated and who are at high cardiovascular risk*; or

For the treatment of hypercholesterolemia when used in combination with a statin in patients failing to achieve target LDL with a statin at maximum tolerable dose or maximum recommended dose as per respective product monograph and who are at high cardiovascular risk*:

* High cardiovascular risk is defined as possessing one of the following:
1) Pre-existing cardiovascular disease and/or cerebrovascular disease, or
2) Diabetes, or
3) Familial hypercholesterolemia, or
4) Greater than or equal to 20% risk as defined by the Framingham Risk Assessment Tool, or
5) Three or more of the following risk factors:
- Family history of premature cardiovascular disease
- Smoking
- Hypertension
- Obesity
- Glucose intolerance
- Renal disease.

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

All requests for ezetimibe must be completed using the Ezetimibe Special Authorization Request Form (ABC 60036).

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

10 MG ORAL TABLET

00002425610	**ACH-EZETIMIBE**	**AHI**	$	**0.1811**
00002475898	**AG-EZETIMIBE**	**AGP**	$	**0.1811**
00002427826	**APO-EZETIMIBE**	**APX**	$	**0.1811**
00002469286	**AURO-EZETIMIBE**	**AUR**	$	**0.1811**
00002429659	**EZETIMIBE**	**SIV**	$	**0.1811**
00002431300	**EZETIMIBE**	**SNS**	$	**0.1811**
00002460750	**GLN-EZETIMIBE**	**GLM**	$	**0.1811**
00002423235	**JAMP-EZETIMIBE**	**JPC**	$	**0.1811**
00002422662	**MAR-EZETIMIBE**	**MAR**	$	**0.1811**
00002423243	**MINT-EZETIMIBE**	**MPI**	$	**0.1811**
00002416409	**PMS-EZETIMIBE**	**PMS**	$	**0.1811**
00002419548	**RAN-EZETIMIBE**	**RAN**	$	**0.1811**
00002416778	**SANDOZ EZETIMIBE**	**SDZ**	$	**0.1811**
00002354101	**TEVA-EZETIMIBE**	**TEV**	$	**0.1811**

FILGRASTIM

Effective April 1, 2017, all Special Authorization requests for filgrastim will be assessed for coverage with Grastofil or Nivestym. Neupogen will not be approved for new filgrastim starts or repeat treatments (i.e. new course of chemotherapy); however, coverage for Neupogen will continue for pediatric patients with congenital, cyclic or idiopathic neutropenia who are currently maintained on Neupogen.

"In patients with non-myeloid malignancies, receiving myelosuppressive anti-neoplastic drugs with curative intent, to decrease the incidence of infection, as manifested by febrile neutropenia."

"Following induction and consolidation treatment for acute myeloid leukemia, for the reduction in the duration of neutropenia, fever, antibiotic use and hospitalization."

"In patients with a diagnosis of congenital, cyclic or idiopathic neutropenia, to increase neutrophil counts and to reduce the incidence and duration of infection."

Please note for the first criterion: Coverage cannot be considered for palliative patients.

All requests for filgrastim must be completed using the Filgrastim/Pegfilgrastim/Plerixafor Special Authorization Request Form (ABC 60013).

0.3 MG / ML INJECTION				
☒ 00002485591	NIVESTYM	PFI	$	144.3100
☒ 00001968017	NEUPOGEN	AMG	$	176.1330
0.48 MG / ML INJECTION				
00002485656	NIVESTYM	PFI	$	144.3100
0.3 MG / SYR INJECTION SYRINGE				
☒ 00002485575	NIVESTYM (0.5 ML SYRINGE)	PFI	$	144.3100
☒ 00002441489	GRASTOFIL (0.5 ML SYRINGE)	APX	$	144.3135
0.48 MG / SYR INJECTION SYRINGE				
☒ 00002485583	NIVESTYM (0.8 ML SYRINGE)	PFI	$	230.9000
☒ 00002454548	GRASTOFIL (0.8 ML SYRINGE)	APX	$	230.9017

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

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

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

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

Psoriatic Arthritis

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

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

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

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

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

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

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

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

All requests (including renewal requests) for golimumab for Psoriatic Arthritis must be

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completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Ixekizumab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

Rheumatoid Arthritis

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

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

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

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

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

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

Following this assessment, continued coverage may be approved for 50 mg per month, for a further 12 month period. Should continued coverage criteria be met, coverage will

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

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

Ulcerative Colitis

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

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

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

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

Initial coverage may be approved for 200 mg of golimumab administered by subcutaneous injection at Week 0, followed by 100 mg at Week 2. As an interim measure, an additional dose of 50 mg of golimumab will be provided at weeks 6 and 10 to allow time to determine whether the patient meets coverage criteria for maintenance dosing, see below.
- Patients will be limited to receiving a one-month supply of golimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition

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for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by a Specialist between week 12 and week 14 to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for a dose of 50 mg every 4 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist to determine response;
2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of golimumab therapy

Note: For patients who showed a response to induction therapy then experienced secondary loss of response while on maintenance dosing with 50 mg, the maintenance dose may be adjusted from 50 mg to 100 mg by making an additional special authorization request to Alberta Blue Cross for the increased dose.

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

50 MG / SYR INJECTION SYRINGE

☒	00002324776	SIMPONI	JAI	$ 1516.0000
☒	00002324784	SIMPONI (AUTO INJECTOR)	JAI	$ 1516.0000

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Ulcerative Colitis

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

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

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

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

Initial coverage may be approved for 200 mg of golimumab administered by subcutaneous injection at Week 0, followed by 100 mg at Week 2. As an interim measure, an additional dose of 50 mg of golimumab will be provided at weeks 6 and 10 to allow time to determine whether the patient meets coverage criteria for maintenance dosing, see below.
- Patients will be limited to receiving a one-month supply of golimumab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by a Specialist between week 12 and week 14 to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for a dose of 50 mg every 4 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist to determine response;
2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of golimumab therapy

Note: For patients who showed a response to induction therapy then experienced

GOLIMUMAB

secondary loss of response while on maintenance dosing with 50 mg, the maintenance dose may be adjusted from 50 mg to 100 mg by making an additional special authorization request to Alberta Blue Cross for the increased dose.

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

100 MG / SYR	INJECTION	SYRINGE		
☒ 00002413175	SIMPONI		JAI	$ 1516.0000
☒ 00002413183	SIMPONI (AUTO INJECTOR)		JAI	$ 1516.0000

ICATIBANT ACETATE

"For the treatment of acute attacks of confirmed Type 1 or Type 2 hereditary angioedema (HAE) in patients with C1-esterase inhibitor deficiency. Icatibant is to be used for:
- acute non-laryngeal attack(s) of at least moderate severity, or
- acute laryngeal attack(s) of any severity

This medication must be prescribed by, or in consultation with, a physician experienced in the treatment of HAE.

Special authorization may be granted for 12 months.

Patients will be limited to a maximum of two doses of icatibant per prescription at their pharmacy."

This product is eligible for auto-renewal.

All requests for icatibant must be completed using the Icatibant/Lanadelumab for HAE Type I or II Special Authorization Request Form (ABC 60083).

30 MG / SYR (BASE)	INJECTION		
00002425696	FIRAZYR	SOT	$ 2700.0000

INFLIXIMAB

100 MG / VIAL INJECTION

☒	00002470373	RENFLEXIS	SSB	$	493.0000

Ankylosing Spondylitis

Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

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

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

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

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

- Initial coverage may be approved for three doses as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

Following this assessment, continued coverage may be approved for one 5 mg/kg dose of infliximab every 6 to 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

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

Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease

***Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for

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new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.***

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

Prior to initiation of infliximab therapy for New Patients:

'New Patients' are patients who have never been treated with infliximab by any health care provider.

Moderately to Severely Active Crohn's Disease:

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

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

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

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

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

Fistulizing Crohn's Disease:

Prior to initiation of infliximab therapy, New Patients must have actively draining perianal or enterocutaneous fistula(s) that have recurred or persisted despite:

a) A course of an appropriate dose of antibiotic therapy (e.g. ciprofloxacin or metronidazole) for a

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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.
- All approvals are also subject to the following applicable criteria.

Induction Dosing for New Patients:

- Coverage for Induction Dosing may only be approved for New Patients (those who have never been treated with infliximab by any health care provider).
- 'Induction Dosing' means a maximum of one 5 mg/kg dose of infliximab per New Patient at each 0, 2 and 6 weeks (for a maximum total of three doses).
- New Patients are eligible to receive Induction Dosing only once, after which time the Maintenance Dosing for New Patients and Continued Coverage for Maintenance Dosing criteria will apply.

Maintenance Dosing:

'Maintenance Dosing' means one 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks for a period of 12 months to:
- New Patients following the completion of Induction Dosing; OR
- Existing Patients, who are patients that are being treated, or have previously been treated, with infliximab.

Maintenance Dosing for New Patients after Completion of Induction Dosing:

- The New Patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of Induction Dosing to determine response by obtaining a Modified Harvey Bradshaw Index score for patients with Moderately to Severely Active Crohn's Disease and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND
- The Specialist must confirm the Modified Harvey Bradshaw Index score shows a decrease from the New Patient's Baseline Score of greater than or equal to 3 points for patients with Moderately to Severely Active Crohn's and/or confirm closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

Maintenance Dosing for Existing Patients:

- The patient must be assessed by a Specialist at least 4 to 8 weeks after the day the last dose of infliximab was administered to the patient and prior to administration of the next dose to obtain: a Modified Harvey Bradshaw Index Score (Existing Patient's Baseline Score) for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND

- these measures must be provided to Alberta Blue Cross for assessment for continued coverage for maintenance dosing.

(For existing patients with Moderately to Severely Active Crohn's Disease with an incomplete response or for existing patients with Fistulizing Crohn's who respond then lose their response, the dose may be adjusted to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.)

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Continued Coverage for Maintenance Dosing:

Continued coverage may be considered for one 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks for a period of 12 months, if the following criteria are met at the end of each 12 month period:

- The New Patient or the Existing Patient must be assessed by a Specialist at least 4 to 6 weeks after the day the last dose of infliximab was administered to the patient and prior to the administration of the next dose to obtain a Modified Harvey Bradshaw Index Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND
- For New Patients: The Specialist must confirm that the patient has maintained a greater than or equal to 3 point decrease from the New Patient's Baseline Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; OR
- For Existing Patients: The Specialist must confirm that the patient has maintained the Existing Patient's Baseline Score and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

(For new and existing patients with Moderately to Severely Active Crohn's Disease with an incomplete response or for new and existing patients with Fistulizing Crohn's who respond then lose their response, the maintenance dose may be adjusted to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.)"

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

Plaque Psoriasis

Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

"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

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mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

Following this assessment, continued coverage may be considered for one 5 mg/kg dose of infliximab every 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

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

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

Psoriatic Arthritis

Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

"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

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

Following this assessment, continued coverage may be approved for one 5 mg/kg dose every 8 weeks, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

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

Rheumatoid Arthritis

Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

"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

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by additional 3 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

Following this assessment, continued coverage may be approved for one 3 mg/kg dose every 8 weeks for a period of 12 months [Note: For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg and/or treating as often as every 4 weeks]. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- confirmation of maintenance of ACR20, OR
- maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

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

Ulcerative Colitis

Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

"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.

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'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

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

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

Initial coverage may be approved for three doses of 5 mg/kg of infliximab at 0, 2 and 6 weeks.

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

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of therapy to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for dose of 5 mg/kg every 8 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist in Gastroenterology to determine response;
2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of infliximab therapy

Note: For patients who showed a response to induction therapy then experienced secondary loss of response while on maintenance dosing with 5 mg/kg, the maintenance dose may be adjusted from 5 mg/kg to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose."

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

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Ankylosing Spondylitis

Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

"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

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

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

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

- Initial coverage may be approved for three doses as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

Following this assessment, continued coverage may be approved for one 5 mg/kg dose of infliximab every 6 to 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

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

Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease

Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

"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 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

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

Prior to initiation of infliximab therapy for New Patients:

'New Patients' are patients who have never been treated with infliximab by any health care provider.

Moderately to Severely Active Crohn's Disease:

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

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

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

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

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

Fistulizing Crohn's Disease:

Prior to initiation of infliximab therapy, New Patients must have actively draining perianal or enterocutaneous fistula(s) that have recurred or persisted despite:

a) A course of an appropriate dose of antibiotic therapy (e.g. ciprofloxacin or metronidazole) for a minimum of 3 weeks; AND
b) Immunosuppressive therapy:
- Azathioprine: minimum of 2 mg/kg/day for a minimum of 6 weeks; OR
- 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 6 weeks; OR
- Immunosuppressive therapy discontinued at less than 6 weeks due to serious adverse effects or reactions.

[Note: Patients who have used the above treatments in combination for the treatment of Fistulizing Crohn's will not be required to be challenged with individual treatments as monotherapy]

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

Coverage Criteria for Moderately to Severely Active Crohn's Disease AND/OR Fistulizing Crohn's 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 a period of 12 months to:
- New Patients following the completion of Induction Dosing; OR
- Existing Patients, who are patients that are being treated, or have previously been treated, with infliximab.

Maintenance Dosing for New Patients after Completion of Induction Dosing:

- The New Patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of Induction Dosing to determine response by obtaining a Modified Harvey Bradshaw Index score for patients with Moderately to Severely Active Crohn's Disease and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND
- The Specialist must confirm the Modified Harvey Bradshaw Index score shows a decrease from the New Patient's Baseline Score of greater than or equal to 3 points for patients with Moderately to Severely Active Crohn's and/or confirm closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

Maintenance Dosing for Existing Patients:

- The patient must be assessed by a Specialist at least 4 to 8 weeks after the day the last dose of infliximab was administered to the patient and prior to administration of the next dose to obtain: a Modified Harvey Bradshaw Index Score (Existing Patient's Baseline Score) for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND

- these measures must be provided to Alberta Blue Cross for assessment for continued coverage for maintenance dosing.

(For existing patients with Moderately to Severely Active Crohn's Disease with an incomplete response or for existing patients with Fistulizing Crohn's who respond then lose their response, the dose may be adjusted to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.)

Continued Coverage for Maintenance Dosing:

Continued coverage may be considered for one 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks for a period of 12 months, if the following criteria are met at the end of each 12 month period:

- The New Patient or the Existing Patient must be assessed by a Specialist at least 4 to 6 weeks after the day the last dose of infliximab was administered to the patient and prior to the administration of the next dose to obtain a Modified Harvey Bradshaw Index Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND
- For New Patients: The Specialist must confirm that the patient has maintained a greater than or equal to 3 point decrease from the New Patient's Baseline Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite 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

Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

"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

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- Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for one 5 mg/kg dose of infliximab every 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

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

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

Psoriatic Arthritis

Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

"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

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correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for one 5 mg/kg dose every 8 weeks, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

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

Rheumatoid Arthritis

Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

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

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

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

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

- Initial coverage may be approved for three doses as follows: An initial dose of 3 mg/kg, followed by additional 3 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following

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criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place];
AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for one 3 mg/kg dose every 8 weeks for a period of 12 months [Note: For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg and/or treating as often as every 4 weeks]. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- confirmation of maintenance of ACR20, OR
- maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

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

Ulcerative Colitis

Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

"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

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

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of therapy to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for dose of 5 mg/kg every 8 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist in Gastroenterology to determine response;
2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of infliximab therapy

Note: For patients who showed a response to induction therapy then experienced secondary loss of response while on maintenance dosing with 5 mg/kg, the maintenance dose may be adjusted from 5 mg/kg to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose."

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

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100 MG / VIAL INJECTION

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Ankylosing Spondylitis

Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

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

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

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

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

- Initial coverage may be approved for three doses as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from another biologic agent to infliximab following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to infliximab if previously trialed and deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

Following this assessment, continued coverage may be approved for one 5 mg/kg dose of infliximab every 6 to 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

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

Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease

***Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for

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new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.***

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

Prior to initiation of infliximab therapy for New Patients:

'New Patients' are patients who have never been treated with infliximab by any health care provider.

Moderately to Severely Active Crohn's Disease:

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

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

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

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

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

Fistulizing Crohn's Disease:

Prior to initiation of infliximab therapy, New Patients must have actively draining perianal or enterocutaneous fistula(s) that have recurred or persisted despite:

a) A course of an appropriate dose of antibiotic therapy (e.g. ciprofloxacin or metronidazole) for a

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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.
- All approvals are also subject to the following applicable criteria.

Induction Dosing for New Patients:

- Coverage for Induction Dosing may only be approved for New Patients (those who have never been treated with infliximab by any health care provider).
- 'Induction Dosing' means a maximum of one 5 mg/kg dose of infliximab per New Patient at each 0, 2 and 6 weeks (for a maximum total of three doses).
- New Patients are eligible to receive Induction Dosing only once, after which time the Maintenance Dosing for New Patients and Continued Coverage for Maintenance Dosing criteria will apply.

Maintenance Dosing:

'Maintenance Dosing' means one 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks for a period of 12 months to:
- New Patients following the completion of Induction Dosing; OR
- Existing Patients, who are patients that are being treated, or have previously been treated, with infliximab.

Maintenance Dosing for New Patients after Completion of Induction Dosing:

- The New Patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of Induction Dosing to determine response by obtaining a Modified Harvey Bradshaw Index score for patients with Moderately to Severely Active Crohn's Disease and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND
- The Specialist must confirm the Modified Harvey Bradshaw Index score shows a decrease from the New Patient's Baseline Score of greater than or equal to 3 points for patients with Moderately to Severely Active Crohn's and/or confirm closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

Maintenance Dosing for Existing Patients:

- The patient must be assessed by a Specialist at least 4 to 8 weeks after the day the last dose of infliximab was administered to the patient and prior to administration of the next dose to obtain: a Modified Harvey Bradshaw Index Score (Existing Patient's Baseline Score) for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND

- these measures must be provided to Alberta Blue Cross for assessment for continued coverage for maintenance dosing.

(For existing patients with Moderately to Severely Active Crohn's Disease with an incomplete response or for existing patients with Fistulizing Crohn's who respond then lose their response, the dose may be adjusted to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.)

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Continued Coverage for Maintenance Dosing:

Continued coverage may be considered for one 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks for a period of 12 months, if the following criteria are met at the end of each 12 month period:

- The New Patient or the Existing Patient must be assessed by a Specialist at least 4 to 6 weeks after the day the last dose of infliximab was administered to the patient and prior to the administration of the next dose to obtain a Modified Harvey Bradshaw Index Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND
- For New Patients: The Specialist must confirm that the patient has maintained a greater than or equal to 3 point decrease from the New Patient's Baseline Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; OR
- For Existing Patients: The Specialist must confirm that the patient has maintained the Existing Patient's Baseline Score and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

(For new and existing patients with Moderately to Severely Active Crohn's Disease with an incomplete response or for new and existing patients with Fistulizing Crohn's who respond then lose their response, the maintenance dose may be adjusted to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.)"

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

Plaque Psoriasis

Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

"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

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mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from another biologic agent to infliximab following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to infliximab if previously trialed and deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

Following this assessment, continued coverage may be considered for one 5 mg/kg dose of infliximab every 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

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

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

Psoriatic Arthritis

Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

"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

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trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to infliximab if previously trialed and deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.
Following this assessment, continued coverage may be approved for one 5 mg/kg dose every 8 weeks, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

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

Rheumatoid Arthritis

Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

"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.

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

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

Continued coverage may be approved for one 3 mg/kg dose every 8 weeks for a period of 12 months [Note: For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg and/or treating as often as every 4 weeks]. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- confirmation of maintenance of ACR20, OR
- maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

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

Ulcerative Colitis

Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

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.

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

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

Initial coverage may be approved for three doses of 5 mg/kg of infliximab at 0, 2 and 6 weeks.

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

For continued coverage beyond three doses, the patient must meet the following criteria:
1) The patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of therapy to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for dose of 5 mg/kg every 8 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist in Gastroenterology to determine response;
2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of infliximab therapy

Note: For patients who showed a response to induction therapy then experienced secondary loss of response while on maintenance dosing with 5 mg/kg, the maintenance dose may be adjusted from 5 mg/kg to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.

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

LANADELUMAB

For the routine prevention of attacks of confirmed Type 1 or Type 2 hereditary angioedema (HAE) in patients 12 years of age or older who have had at least three HAE attacks that required the use of an acute injectable treatment within any four-week period in the three months before initiating lanadelumab therapy.

This medication must be prescribed by, or in consultation with, a physician experienced in the treatment of HAE. A record of the baseline total of HAE attacks requiring use of an acute injectable treatment in the three months prior to initiating lanadelumab is required.

Initial coverage may be approved for 3 months. The patient must be assessed after the initial three months to determine response. Patients who have a response to initial treatment* may receive continued coverage with lanadelumab for six months, and should be assessed for continued response** every six months.

*Response to initial lanadelumab treatment is defined as:
- at least a 50% reduction in the number of HAE attacks requiring use of an acute injectable treatment compared to the three month baseline number of attacks prior to initiation of lanadelumab.

**Continued response is defined as:
- maintenance of a minimum improvement of a 50% reduction in the number of HAE attacks requiring use of an acute injectable treatment compared to the baseline number of attacks observed before initiating treatment with lanadelumab.

Coverage cannot be provided for lanadelumab when used in combination with other medications used for long-term prophylactic treatment of angioedema (e.g., C1-INH).

Coverage may be approved for a dosage of up to 300 mg every two weeks. Patients will be limited to receiving a one-month supply per prescription at their pharmacy.

All requests for lanadelumab must be completed using the Icatibant/Lanadelumab for HAE Type I or II Special Authorization Request Form (ABC 60083).

150 MG / ML INJECTION			
00002480948	TAKHZYRO	SHB	$ 10269.0000

RITUXIMAB

10 MG / ML INJECTION

☒ 00002498316 RIXIMYO SDZ $ 29.7000

Rheumatoid Arthritis

Effective June 1, 2020, all new Special Authorization requests for the treatment of Rheumatoid Arthritis for rituximab naive patients will be assessed for coverage with Riximyo, Ruxience or Truxima. Rituxan will not be approved for new rituximab starts for patients with Rheumatoid Arthritis; however, coverage for Rituxan will continue for patients who completed a previous two-dose course of therapy with Rituxan and are considered a 'responder' as defined in criteria.

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

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

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

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

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

For coverage for an additional two-dose course of therapy, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after each course of therapy, between 16 and 24 weeks after receiving the initial dose of each course of therapy, to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- An improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place] following the initial course of rituximab; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places] following the initial course of rituximab.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above, AND
3) The patient must have residual disease or disease activity returning to a level above a DAS28 score of 2.6.

Subsequent courses of therapy cannot be considered prior to 24 weeks elapsing from the initial dose of the previous course of therapy."

All requests (including renewal requests) for rituximab for Rheumatoid Arthritis must be completed using the Rituximab for Rheumatoid Arthritis Special Authorization Request Form (ABC 60046).

TOFACITINIB CITRATE

Rheumatoid Arthritis

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

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

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

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

- Initial coverage may be approved for three months as follows:
- Tofacitinib 5 mg tablet: one tablet twice daily.
- Tofacitinib 11 mg extended-release tablet: one tablet daily.
- Patients will be limited to receiving a one-month supply of tofacitinib per prescription at their pharmacy.
- Patients will not be permitted to switch back to tofacitinib if they were deemed unresponsive to therapy.

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

Following this assessment, continued coverage may be approved for 5 mg twice daily or 11 mg once daily for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- confirmation of maintenance of ACR20, or
- maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.
It should be noted that the initial score for the DAS28 or HAQ score on record will be 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."

TOFACITINIB CITRATE

All requests (including renewal requests) for tofacitinib for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/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;
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."

TOFACITINIB CITRATE

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**			
00002423898	XELJANZ		PFI	$	23.9589

TOFACITINIB CITRATE

Ulcerative Colitis

"Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:

- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks; AND
- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

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

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

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

Initial coverage may be approved for an initial dose of 10 mg twice daily for 8 weeks. As an interim measure, coverage will be provided for additional doses of 5 mg twice daily for 4 weeks, to allow time to determine whether the New Patient meets coverage criteria for Maintenance Dosing below.

- Patients will be limited to receiving a one-month supply of tofacitinib per prescription at their pharmacy.
- Patients will not be permitted to switch back to tofacitinib if they were deemed unresponsive to therapy.

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:
1) The patient must be assessed by a Specialist after 8 weeks but no longer than 12 weeks after treatment to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- a decrease in the partial Mayo score of greater than or equal to 2 points

Following this assessment, continued coverage may be approved for a dose of 5 mg twice daily for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist in Gastroenterology to determine response;
2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of tofacitinib therapy.

Coverage cannot be provided for tofacitinib when intended for use in combination with a biologic agent."

Note: For patients who showed a response to induction therapy then experienced secondary loss of response while on maintenance dosing with 5 mg, the maintenance

TOFACITINIB CITRATE

dose may be adjusted from 5 mg to 10 mg by making an additional special authorization request to Alberta Blue Cross for the increased dose.

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

10 MG (BASE)	ORAL	TABLET			
00002480786	XELJANZ		PFI	$	42.3426

USTEKINUMAB

Plaque Psoriasis

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

- Have a total PASI of 10 or more and a DLQI of more than 10, OR
- Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
- Who are refractory to or intolerant to:

at least THREE of the following:
- adalimumab
- etanercept
- infliximab
- ixekizumab
- risankizumab
- secukinumab

AND

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

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

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

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

- Initial coverage may be approved for three doses of 45 mg (90 mg for patients weighing greater than 100 kg) at weeks 0, 4 and 16.
- Patients will be limited to receiving one dose per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage, the patient must meet all of the following criteria:
1) The patient must be assessed by a Dermatology Specialist after the initial 16 weeks of therapy to determine response.
2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Greater than or equal to 75% reduction in PASI score, OR
- Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.

USTEKINUMAB

Following this assessment, continued coverage may be considered for 45 mg (90 mg for patients weighing greater than 100 kg) every 12 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

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

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

45 MG INJECTION VIAL OR SYRINGE				
00002320673	STELARA (0.5 ML VIAL OR SYRINGE)	JAI	$	4465.5800
For this product - pricing has been established on a per vial or syringe basis.				
90 MG / SYR INJECTION SYRINGE				
00002320681	STELARA (1 ML SYRINGE)	JAI	$	4465.5800

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

Prior to initiation of vedolizumab therapy for New Patients:
'New Patients' are patients who have never been treated with vedolizumab by any health care provider.
Moderately to Severely Active Crohn's Disease:
Prior to initiation of vedolizumab therapy, New Patients must have a current Modified (without the physical exam) Harvey Bradshaw Index score of greater than or equal to 7 (New Patient's Baseline Score), AND be Refractory.

Refractory is defined as one or more of the following:
1) Serious adverse effects or reactions to the treatments specified below; OR
2) Contraindications (as defined in product monographs) to the treatments specified below; OR
3) Previous documented lack of effect at doses and for duration of all treatments specified below:
a) mesalamine: minimum of 3 grams/day for a minimum of 6 weeks; AND refractory to, or dependent on, glucocorticoids: following at least one tapering dosing schedule of 40 mg/day, tapering by 5 mg each week to 20 mg, then tapering by 2.5 mg each week to zero, or similar.
[Note: Patients who have used the above treatments in combination will not be required to be challenged with individual treatments as monotherapy]

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

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

Coverage Criteria for Moderately to Severely Active Crohn's Disease
- 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 per New Patient at 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 300 mg dose of vedolizumab per patient every eight (8) weeks for a period of 12 months to:
- New Patients following the completion of Induction Dosing; OR
- Existing Patients, who are patients that are being treated, or have previously been treated, with 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 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
- 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 per patient provided no more often than every 8 weeks for a period of 12 months, if the following criteria are met at the end of each 12 month period:

- The New Patient or the Existing Patient must be assessed by a Specialist at least 4 to 6 weeks after the day the last dose of vedolizumab 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
- 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 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

VEDOLIZUMAB

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 at 0, 2 and 6 weeks.

- Patients will be limited to receiving a one dose of vedolizumab 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 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 every 8 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by a Specialist in Gastroenterology to determine response;
2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of 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	$ 3290.0000