Updates to the Alberta Drug Benefit List

Effective March 1, 2021

Alberta Government

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Administered by Alberta Blue Cross
on behalf of Alberta Health.

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

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Special Authorization

The following drug product(s) will be considered for coverage by Special Authorization 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
AVSOLA 100 MG / VIAL INJECTION	INFLIXIMAB	00002496933	AMG
HUMIRA (20 MG / 0.2 ML) 20 MG / SYRINGE INJECTION	ADALIMUMAB	00002474263	ABV
ONPATTRO 2 MG / ML VIAL INJECTION	PATISIRAN SODIUM	00002489252	ANT
TEGSEDI 284 MG / SYRINGE INJECTION	INOTERSEN SODIUM	00002481383	AKC

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

Trade Name / Strength / Form	Generic Description	DIN	MFR
JAMP DIENOGEST 2 MG TABLET	DIENOGEST	00002498189	JPC

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

Trade Name / Strength / Form	Generic Description	DIN	MFR
NRA-MONTELUKAST 10 MG TABLET	MONTELUKAST SODIUM	00002489821	NRA

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

Trade Name / Strength / Form	Generic Description	DIN	MFR
ACT PIOGLITAZONE 45 MG TABLET	PIOGLITAZONE HCL	00002302896	TEV

Drug Product(s) with Changes to Criteria for Coverage

Trade Name / Strength / Form	Generic Description	DIN	MFR
BRENZYS (AUTO INJECTOR) 50 MG / SYRINGE INJECTION	ETANERCEPT	00002455331	SSB
BRENZYS 50 MG / SYRINGE INJECTION	ETANERCEPT	00002455323	SSB
ENBREL 25 MG / VIAL INJECTION	ETANERCEPT	00002242903	AMG
ENBREL 50 MG / SYRINGE INJECTION	ETANERCEPT	00002274728	AMG
ERELZI 25 MG / SYRINGE INJECTION	ETANERCEPT	00002462877	SDZ
ERELZI 50 MG / SYRINGE INJECTION	ETANERCEPT	00002462869	SDZ

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

Trade Name / Strength / Form	Generic Description	DIN	MFR
ERELZI (SENSOREADY AUTO INJECTOR) 50 MG / SYRINGE INJECTION	ETANERCEPT	00002462850	SDZ
MAVIRET 40 MG / 100 MG TABLET	PIBRENTASVIR/ GLECAPREVIR	00002467550	ABV
RUXIENCE 10 MG / ML INJECTION	RITUXIMAB	00002495724	PFI
SOVALDI 400 MG TABLET	SOFOSBUVIR	00002418355	GIL
TRUXIMA 10 MG / ML (10 ML) INJECTION	RITUXIMAB	00002478382	CTC
TRUXIMA 10 MG / ML (50 ML) INJECTION	RITUXIMAB	00002478390	CTC

Optional Special Authorization

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

*Please refer to **Section 3A** of the online Alberta Drug Benefit List for further information regarding the Optional Special Authorization of Select Drug Products criteria and related forms.*

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

Trade Name / Strength / Form	Generic Description	DIN	MFR
NRA-CIPROFLOXACIN 500 MG TABLET	CIPROFLOXACIN HCL	00002492008	NRA

Added Product(s)

Trade Name / Strength / Form	Generic Description	DIN	MFR
ENTECAVIR 0.5 MG TABLET	ENTECAVIR	00002453797	STR
JAMP FLECAINIDE 50 MG TABLET	FLECAINIDE ACETATE	00002493705	JPC
JAMP FLECAINIDE 100 MG TABLET	FLECAINIDE ACETATE	00002493713	JPC
JAMP TELMISARTAN 40 MG TABLET	TELMISARTAN	00002386755	JPC
JAMP TELMISARTAN 80 MG TABLET	TELMISARTAN	00002386763	JPC
JAMP TELMISARTAN-HCT 80 MG / 12.5 MG TABLET	TELMISARTAN/ HYDROCHLOROTHIAZIDE	00002389940	JPC
JAMP TELMISARTAN-HCT 80 MG / 25 MG TABLET	TELMISARTAN/ HYDROCHLOROTHIAZIDE	00002389959	JPC
JAMP-METHADONE CONCENTRATE 10 MG / ML LIQUID	METHADONE HYDROCHLORIDE	00002495783	JPC
JAMP-TOPIRAMATE 100 MG TABLET	TOPIRAMATE	00002435616	JPC
JAMP-TOPIRAMATE 200 MG TABLET	TOPIRAMATE	00002435624	JPC
JAMP-TOPIRAMATE 25 MG TABLET	TOPIRAMATE	00002435608	JPC

Added Product(s), continued

Trade Name / Strength / Form	Generic Description	DIN	MFR
LANSOPRAZOLE 15 MG DELAYED-RELEASE CAPSULE	LANSOPRAZOLE	00002357682	SNS
MINT-LEUCOVORIN 5 MG TABLET	LEUCOVORIN CALCIUM	00002496828	MPI
MIRTAZAPINE 15 MG TABLET	MIRTAZAPINE	00002496666	SIV
NRA-CLOPIDOGREL 75 MG TABLET	CLOPIDOGREL BISULFATE	00002482037	NRA
NRA-DULOXETINE 30 MG DELAYED-RELEASE CAPSULE	DULOXETINE HYDROCHLORIDE	00002482126	NRA
NRA-DULOXETINE 60 MG DELAYED-RELEASE CAPSULE	DULOXETINE HYDROCHLORIDE	00002482134	NRA
NRA-EZETIMIBE 10 MG TABLET	EZETIMIBE	00002481669	NRA
NRA-OMEPRAZOLE 20 MG SUSTAINED-RELEASE TABLET	OMEPRAZOLE	00002501880	NRA
NRA-PANTOPRAZOLE 40 MG ENTERIC-COATED TABLET	PANTOPRAZOLE SODIUM	00002471825	NRA
NRA-PAROXETINE 20 MG TABLET	PAROXETINE HCL	00002479761	NRA
NRA-PAROXETINE 30 MG TABLET	PAROXETINE HCL	00002479788	NRA
NRA-PERINDOPRIL 2 MG TABLET	PERINDOPRIL ERBUMINE	00002489015	NRA
NRA-PERINDOPRIL 4 MG TABLET	PERINDOPRIL ERBUMINE	00002489023	NRA
NRA-PERINDOPRIL 8 MG TABLET	PERINDOPRIL ERBUMINE	00002489031	NRA
OLMESARTAN 20 MG TABLET	OLMESARTAN MEDOXOMIL	00002481057	SNS
OLMESARTAN 40 MG TABLET	OLMESARTAN MEDOXOMIL	00002481065	SNS
TARO-CIPROFLOXACIN / DEXAMETHASONE 0.3% / 0.1% OTIC SUSPENSION	CIPROFLOXACIN HYDROCHLORIDE/ DEXAMETHASONE	00002481901	TAR
TARO-TESTOSTERONE CYPIONATE 100 MG / ML INJECTION	TESTOSTERONE CYPIONATE	00002496003	TAR
TEVA-LIOTHYRONINE 5 MCG TABLET	LIOTHYRONINE SODIUM	00002494337	TEV
TEVA-LIOTHYRONINE 25 MCG TABLET	LIOTHYRONINE SODIUM	00002494345	TEV
TRINTELLIX 5 MG TABLET	VORTIOXETINE HYDROBROMIDE	00002432919	LBC
TRINTELLIX 10 MG TABLET	VORTIOXETINE HYDROBROMIDE	00002432927	LBC
TRINTELLIX 20 MG TABLET	VORTIOXETINE HYDROBROMIDE	00002432943	LBC

New Established Interchangeable (IC) Grouping(s)

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

Generic Description	Strength / Form	New LCA Price
CIPROFLOXACIN/DEXAMETHASONE	0.3% / 0.1% OTIC SUSPENSION	2.8840
LIOTHYRONINE	5 MCG TABLET	1.1587
LIOTHYRONINE	25 MCG TABLET	1.2595
TESTOSTERONE CYPIONATE	100 MG / ML INJECTION	3.4878

Least Cost Alternative (LCA) Price Change(s)

*The following established IC Grouping(s) are affected and a revised LCA price has been established. Groupings affected by a price decrease, will be effective April 1, 2021. Please review the online **Interactive Drug Benefit List** for further information.*

Generic Description	Strength / Form	New LCA Price
DIENOGEST	2 MG TABLET	1.0231
FLECAINIDE	50 MG TABLET	0.1389
FLECAINIDE	100 MG TABLET	0.1389
GRANISETRON	1 MG TABLET	4.5000
LEUCOVORIN	5 MG TABLET	3.6776
LEVOCARNITINE	100 MG / ML ORAL SOLUTION	0.3809
PILOCARPINE	5 MG TABLET	1.1713
RALOXIFENE	60 MG TABLET	1.0268

Product(s) with a Price Change

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

Trade Name / Strength / Form	Generic Description	DIN	MFR
ACCEL-PILOCARPINE 5 MG TABLET	PILOCARPINE HCL	00002496119	ACP
APO-FLECAINIDE 50 MG TABLET	FLECAINIDE ACETATE	00002275538	APX
APO-FLECAINIDE 100 MG TABLET	FLECAINIDE ACETATE	00002275546	APX
APO-GRANISETRON 1 MG TABLET	GRANISETRON HCL	00002308894	APX
ASPEN-DIENOGEST 2 MG TABLET	DIENOGEST	00002493055	APC
AURO-FLECAINIDE 50 MG TABLET	FLECAINIDE ACETATE	00002459957	AUR
AURO-FLECAINIDE 100 MG TABLET	FLECAINIDE ACETATE	00002459965	AUR
CUBICIN RF 500 MG / VIAL INJECTION	DAPTOMYCIN	00002465493	CUB

Product(s) with a Price Change, continued

Trade Name / Strength / Form	Generic Description	DIN	MFR
NAT-GRANISETRON 1 MG TABLET	GRANISETRON HCL	00002452359	NTP
ODAN LEVOCARNITINE 100 MG / ML ORAL SOLUTION	LEVOCARNITINE	00002492105	ODN
RIVA LEUCOVORIN 5 MG TABLET	LEUCOVORIN CALCIUM	00002493357	RIV

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 March 1, 2021, the listed product(s) will no longer be a benefit and where applicable, will not be considered for coverage by Special Authorization. A transition period will be applied and as of April 1, 2021 claims will no longer pay for these product(s).

Trade Name / Strength / Form	Generic Description	DIN	MFR
SANDOZ DICLOFENAC 100 MG RECTAL SUPPOSITORY	DICLOFENAC SODIUM	00002261936	SDZ
SANDOZ DILTIAZEM T 120 MG ORAL EXTENDED-RELEASE CAPSULE	DILTIAZEM HCL	00002245918	SDZ
SANDOZ FENOFIBRATE S 100 MG ORAL TABLET	FENOFIBRATE	00002288044	SDZ

Product(s) Removed from the Alberta Drug Benefit List

The Alberta government-sponsored drug programs previously covered the following drug product(s). Effective March 1, 2021, the listed product(s) will no longer be a benefit. A transition period will be applied and as of March 31, 2021 claims will no longer pay for this product.

Trade Name / Strength / Form	Generic Description	DIN	MFR
RITUXAN 10 MG / ML INJECTION	RITUXIMAB	00002241927	HLR

PART 2

Drug Additions

CIPROFLOXACIN HCL/ DEXAMETHASONE

0.3 % * 0.1 % OTIC SUSPENSION

00002481901	**TARO-CIPROFLOXACIN/DEXAMETHASONE**	**TAR**	$	**2.8840**
00002252716	CIPRODEX	NOV	$	3.7693

CLOPIDOGREL BISULFATE

75 MG (BASE) ORAL TABLET

00002252767	**APO-CLOPIDOGREL**	**APX**	$	**0.2631**
00002416387	**AURO-CLOPIDOGREL**	**AUR**	$	**0.2631**
00002385813	**CLOPIDOGREL**	**SIV**	$	**0.2631**
00002400553	**CLOPIDOGREL**	**SNS**	$	**0.2631**
00002415550	**JAMP-CLOPIDOGREL**	**JPC**	$	**0.2631**
00002422255	**MAR-CLOPIDOGREL**	**MAR**	$	**0.2631**
00002482037	**NRA-CLOPIDOGREL**	**NRA**	$	**0.2631**
00002348004	**PMS-CLOPIDOGREL**	**PMS**	$	**0.2631**
00002379813	**RAN-CLOPIDOGREL**	**RAN**	$	**0.2631**
00002359316	**SANDOZ CLOPIDOGREL**	**SDZ**	$	**0.2631**
00002293161	**TEVA-CLOPIDOGREL**	**TEV**	$	**0.2631**
00002238682	PLAVIX	SAV	$	2.7125

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**
00002451913	**JAMP-DULOXETINE**	**JPC**	$	**0.4814**
00002446081	**MAR-DULOXETINE**	**MAR**	$	**0.4814**
00002438984	**MINT-DULOXETINE**	**MPI**	$	**0.4814**
00002482126	**NRA-DULOXETINE**	**NRA**	$	**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**
00002451921	**JAMP-DULOXETINE**	**JPC**	$	**0.9769**
00002446103	**MAR-DULOXETINE**	**MAR**	$	**0.9769**
00002438992	**MINT-DULOXETINE**	**MPI**	$	**0.9769**
00002482134	**NRA-DULOXETINE**	**NRA**	$	**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

ENTECAVIR

RESTRICTED BENEFIT - This product is a benefit for the treatment of chronic hepatitis B when prescribed by a Specialist in Internal Medicine or a designated prescriber.

0.5 MG ORAL TABLET

00002479907	**ACCEL-ENTECAVIR**	**ACP**	$	**4.4000**
00002448777	**AURO-ENTECAVIR**	**AUR**	$	**4.4000**
00002396955	APO-ENTECAVIR	APX	$	5.5000
00002453797	ENTECAVIR	STR	$	5.5000
00002467232	JAMP-ENTECAVIR	JPC	$	5.5000
00002485907	MINT-ENTECAVIR	MPI	$	5.5000
00002430576	PMS-ENTECAVIR	PMS	$	5.5000
00002282224	BARACLUDE	BMS	$	22.6601

EZETIMIBE

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**
00002481669	**NRA-EZETIMIBE**	**NRA**	$	**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**
00002247521	EZETROL	MFC	$	1.9180

FLECAINIDE ACETATE

50 MG ORAL TABLET

00002275538	**APO-FLECAINIDE**	**APX**	$	**0.1389**
00002459957	**AURO-FLECAINIDE**	**AUR**	$	**0.1389**
00002493705	**JAMP FLECAINIDE**	**JPC**	$	**0.1389**

100 MG ORAL TABLET

00002275546	**APO-FLECAINIDE**	**APX**	$	**0.2779**
00002459965	**AURO-FLECAINIDE**	**AUR**	$	**0.2779**
00002493713	**JAMP FLECAINIDE**	**JPC**	$	**0.2779**

GRANISETRON HCL

1 MG (BASE) ORAL TABLET

00002308894	**APO-GRANISETRON**	**APX**	$	**4.5000**
00002452359	**NAT-GRANISETRON**	**NTP**	$	**4.5000**

LANSOPRAZOLE

15 MG ORAL DELAYED-RELEASE CAPSULE

00002293811	APO-LANSOPRAZOLE	APX	***$ 0.0669***	$	0.5000
00002357682	LANSOPRAZOLE	SNS	***$ 0.0669***	$	0.5000
00002385767	LANSOPRAZOLE	SIV	***$ 0.0669***	$	0.5000
00002433001	LANSOPRAZOLE	PMS	***$ 0.0669***	$	0.5000
00002353830	MYLAN-LANSOPRAZOLE	MYP	***$ 0.0669***	$	0.5000
00002402610	RAN-LANSOPRAZOLE	RAN	***$ 0.0669***	$	0.5000
00002385643	SANDOZ LANSOPRAZOLE	SDZ	***$ 0.0669***	$	0.5000
00002165503	PREVACID	BGP	***$ 0.0669***	$	2.0998

MAC pricing will be applied based on the LCA Price for Rabeprazole Sodium 1 X 10 mg enteric-coated tablet.

LEUCOVORIN CALCIUM

5 MG (BASE) ORAL TABLET

00002496828	**MINT-LEUCOVORIN**	**MPI**	$	**3.6776**
00002493357	**RIVA LEUCOVORIN**	**RIV**	$	**3.6776**
00002170493	LEDERLE LEUCOVORIN CALCIUM	PFI	$	7.2466

LIOTHYRONINE SODIUM

5 MCG (BASE) ORAL TABLET

00002494337	**TEVA-LIOTHYRONINE**	**TEV**	$	**1.1587**
00001919458	CYTOMEL	PFI	$	1.3632

25 MCG (BASE) ORAL TABLET

00002494345	**TEVA-LIOTHYRONINE**	**TEV**	$	**1.2595**
00001919466	CYTOMEL	PFI	$	1.4818

METHADONE HCL

10 MG / ML ORAL LIQUID

☒ 00002495783	JAMP-METHADONE CONCENTRATE	JPC	$	0.0525
☒ 00002481979	METHADONE HYDROCHLORIDE	SDZ	$	0.1125
☒ 00002394596	METHADOSE	MAL	$	0.1125
☒ 00002394618	METHADOSE SUGAR FREE	MAL	$	0.1125
☒ 00002244290	METADOL-D	PAL	$	0.1500
☒ 00002241377	METADOL CONCENTRATE	PAL	$	0.4112

MIRTAZAPINE

15 MG ORAL TABLET

00002411695	**AURO-MIRTAZAPINE**	**AUR**	$	**0.0974**
00002496666	**MIRTAZAPINE**	**SIV**	$	**0.0974**
00002256096	**MYLAN-MIRTAZAPINE**	**MYP**	$	**0.0974**
00002273942	**PMS-MIRTAZAPINE**	**PMS**	$	**0.0974**

MONTELUKAST SODIUM

10 MG (BASE) ORAL TABLET

00002374609	**APO-MONTELUKAST**	**APX**	$	**0.4231**
00002401274	**AURO-MONTELUKAST**	**AUR**	$	**0.4231**
00002391422	**JAMP-MONTELUKAST**	**JPC**	$	**0.4231**
00002399997	**MAR-MONTELUKAST**	**MAR**	$	**0.4231**
00002408643	**MINT-MONTELUKAST**	**MPI**	$	**0.4231**
00002379333	**MONTELUKAST**	**SNS**	$	**0.4231**
00002382474	**MONTELUKAST**	**SIV**	$	**0.4231**
00002379236	**MONTELUKAST SODIUM**	**AHI**	$	**0.4231**
00002489821	**NRA-MONTELUKAST**	**NRA**	$	**0.4231**
00002373947	**PMS-MONTELUKAST FC**	**PMS**	$	**0.4231**
00002389517	**RAN-MONTELUKAST**	**RAN**	$	**0.4231**
00002328593	**SANDOZ MONTELUKAST**	**SDZ**	$	**0.4231**
00002355523	**TEVA-MONTELUKAST**	**TEV**	$	**0.4231**
00002238217	SINGULAIR	MFC	$	2.4823

RESTRICTED BENEFIT - This product is a benefit for patients 6 to 18 years of age inclusive for the prophylaxis and treatment of asthma. (For eligibility in patients over 18 years of age refer to Criteria for Special Authorization of Select Drug Products of the List, and Criteria for Special Authorization of Select Drug Products in the Alberta Human Services Drug Benefit Supplement for eligibility for Alberta Human Services clients.)

OLMESARTAN MEDOXOMIL

20 MG ORAL TABLET

00002456311	**ACH-OLMESARTAN**	**AHI**	$	**0.3019**
00002442191	**ACT OLMESARTAN**	**APH**	$	**0.3019**
00002453452	**APO-OLMESARTAN**	**APX**	$	**0.3019**
00002443864	**AURO-OLMESARTAN**	**AUR**	$	**0.3019**
00002469812	**GLN-OLMESARTAN**	**GLM**	$	**0.3019**
00002461641	**JAMP-OLMESARTAN**	**JPC**	$	**0.3019**
00002499258	**NRA-OLMESARTAN**	**NRA**	$	**0.3019**
00002481057	**OLMESARTAN**	**SNS**	$	**0.3019**
00002461307	**PMS-OLMESARTAN**	**PMS**	$	**0.3019**
00002443414	**SANDOZ OLMESARTAN**	**SDZ**	$	**0.3019**
00002318660	OLMETEC	MFC	$	1.1441

40 MG ORAL TABLET

00002456338	**ACH-OLMESARTAN**	**AHI**	$	**0.3019**
00002442205	**ACT OLMESARTAN**	**APH**	$	**0.3019**
00002453460	**APO-OLMESARTAN**	**APX**	$	**0.3019**
00002443872	**AURO-OLMESARTAN**	**AUR**	$	**0.3019**
00002469820	**GLN-OLMESARTAN**	**GLM**	$	**0.3019**
00002461668	**JAMP-OLMESARTAN**	**JPC**	$	**0.3019**
00002499266	**NRA-OLMESARTAN**	**NRA**	$	**0.3019**
00002481065	**OLMESARTAN**	**SNS**	$	**0.3019**
00002461315	**PMS-OLMESARTAN**	**PMS**	$	**0.3019**
00002443422	**SANDOZ OLMESARTAN**	**SDZ**	$	**0.3019**
00002318679	OLMETEC	MFC	$	1.1441

OMEPRAZOLE

20 MG ORAL CAPSULE/SUSTAINED-RELEASE TABLET

00002245058	APO-OMEPRAZOLE (DELAYED-RELEASE CAPSULE)	APX	***$ 0.1875***	$	0.2287
00002420198	JAMP-OMEPRAZOLE DR (DELAYED-RELEASE TABLET)	JPC	***$ 0.1875***	$	0.2287
00002439549	NAT-OMEPRAZOLE DR (DELAYED-RELEASE TABLET)	NTP	***$ 0.1875***	$	0.2287
00002501880	NRA-OMEPRAZOLE (SUSTAINED-RELEASE TABLET)	NRA	***$ 0.1875***	$	0.2287
00002348691	OMEPRAZOLE (DELAYED-RELEASE CAPSULE)	SNS	***$ 0.1875***	$	0.2287
00002416549	OMEPRAZOLE (DELAYED-RELEASE TABLET)	AHI	***$ 0.1875***	$	0.2287
00002411857	OMEPRAZOLE-20 (DELAYED-RELEASE CAPSULE)	SIV	***$ 0.1875***	$	0.2287
00002320851	PMS-OMEPRAZOLE (SUSTAINED-RELEASE CAP)	PMS	***$ 0.1875***	$	0.2287
00002296446	SANDOZ OMEPRAZOLE (SUSTAINED-RELEASE CAP)	SDZ	***$ 0.1875***	$	0.2287
00002295415	TEVA-OMEPRAZOLE (DELAYED-RELEASE TABLET)	TEV	***$ 0.1875***	$	0.2287
00000846503	LOSEC (SUSTAINED-RELEASE CAPSULE)	CAG	***$ 0.1875***	$	1.1320
00002190915	LOSEC (SUSTAINED-RELEASE TABLET)	CAG	***$ 0.1875***	$	2.3820

MAC pricing will be applied based on the LCA Price for Pantoprazole Magnesium 1 X 40 mg enteric-coated tablet.

PANTOPRAZOLE SODIUM

40 MG ORAL ENTERIC-COATED TABLET

00002481588	AG-PANTOPRAZOLE SODIUM	AGP	***$ 0.1875***	$	0.2016
00002292920	APO-PANTOPRAZOLE	APX	***$ 0.1875***	$	0.2016
00002415208	AURO-PANTOPRAZOLE	AUR	***$ 0.1875***	$	0.2016
00002357054	JAMP-PANTOPRAZOLE	JPC	***$ 0.1875***	$	0.2016
00002467372	M-PANTOPRAZOLE	MTR	***$ 0.1875***	$	0.2016
00002416565	MAR-PANTOPRAZOLE	MAR	***$ 0.1875***	$	0.2016
00002417448	MINT-PANTOPRAZOLE	MPI	***$ 0.1875***	$	0.2016
00002370808	PANTOPRAZOLE	SNS	***$ 0.1875***	$	0.2016
00002437945	PANTOPRAZOLE	PMS	***$ 0.1875***	$	0.2016
00002428180	PANTOPRAZOLE-40	SIV	***$ 0.1875***	$	0.2016
00002307871	PMS-PANTOPRAZOLE	PMS	***$ 0.1875***	$	0.2016
00002305046	RAN-PANTOPRAZOLE	RAN	***$ 0.1875***	$	0.2016
00002301083	SANDOZ PANTOPRAZOLE	SDZ	***$ 0.1875***	$	0.2016
00002285487	TEVA-PANTOPRAZOLE	TEV	***$ 0.1875***	$	0.2016
00002229453	PANTOLOC	TAK	***$ 0.1875***	$	2.0803

MAC pricing will be applied based on the LCA Price for Pantoprazole Magnesium 1 X 40 mg enteric-coated tablet.

PAROXETINE HCL

20 MG (BASE) ORAL TABLET

00002475545	**AG-PAROXETINE**	**AGP**	$	**0.3250**
00002240908	**APO-PAROXETINE**	**APX**	$	**0.3250**
00002383284	**AURO-PAROXETINE**	**AUR**	$	**0.3250**
00002368870	**JAMP-PAROXETINE**	**JPC**	$	**0.3250**
00002411954	**MAR-PAROXETINE**	**MAR**	$	**0.3250**
00002421380	**MINT-PAROXETINE**	**MPI**	$	**0.3250**
00002479761	**NRA-PAROXETINE**	**NRA**	$	**0.3250**
00002282852	**PAROXETINE**	**SNS**	$	**0.3250**
00002388235	**PAROXETINE**	**SIV**	$	**0.3250**
00002247751	**PMS-PAROXETINE**	**PMS**	$	**0.3250**
00002248557	**TEVA-PAROXETINE**	**TEV**	$	**0.3250**
00001940481	PAXIL	GSK	$	1.8959

30 MG (BASE) ORAL TABLET

00002475553	**AG-PAROXETINE**	**AGP**	$	**0.3453**
00002240909	**APO-PAROXETINE**	**APX**	$	**0.3453**
00002383292	**AURO-PAROXETINE**	**AUR**	$	**0.3453**
00002368889	**JAMP-PAROXETINE**	**JPC**	$	**0.3453**
00002411962	**MAR-PAROXETINE**	**MAR**	$	**0.3453**
00002421399	**MINT-PAROXETINE**	**MPI**	$	**0.3453**
00002479788	**NRA-PAROXETINE**	**NRA**	$	**0.3453**
00002282860	**PAROXETINE**	**SNS**	$	**0.3453**
00002388243	**PAROXETINE**	**SIV**	$	**0.3453**
00002247752	**PMS-PAROXETINE**	**PMS**	$	**0.3453**
00001940473	PAXIL	GSK	$	2.0140

PERINDOPRIL ERBUMINE

2 MG ORAL TABLET

00002481677	**AG-PERINDOPRIL**	**AGP**	$	**0.1632**
00002289261	**APO-PERINDOPRIL**	**APX**	$	**0.1632**
00002459817	**AURO-PERINDOPRIL**	**AUR**	$	**0.1632**
00002477009	**JAMP PERINDOPRIL**	**JPC**	$	**0.1632**
00002474824	**MAR-PERINDOPRIL**	**MAR**	$	**0.1632**
00002476762	**MINT-PERINDOPRIL**	**MPI**	$	**0.1632**
00002489015	**NRA-PERINDOPRIL**	**NRA**	$	**0.1632**
00002479877	**PERINDOPRIL ERBUMINE**	**SIV**	$	**0.1632**
00002481634	**PERINDOPRIL ERBUMINE**	**SNS**	$	**0.1632**
00002470675	**PMS-PERINDOPRIL**	**PMS**	$	**0.1632**
00002470225	**SANDOZ PERINDOPRIL ERBUMINE**	**SDZ**	$	**0.1632**
00002464985	**TEVA-PERINDOPRIL**	**TEV**	$	**0.1632**
00002123274	COVERSYL	SEV	$	0.7014

4 MG ORAL TABLET

00002481685	AG-PERINDOPRIL	AGP	***$ 0.1945***	$	0.2042
00002289288	APO-PERINDOPRIL	APX	***$ 0.1945***	$	0.2042
00002459825	AURO-PERINDOPRIL	AUR	***$ 0.1945***	$	0.2042
00002477017	JAMP PERINDOPRIL	JPC	***$ 0.1945***	$	0.2042
00002474832	MAR-PERINDOPRIL	MAR	***$ 0.1945***	$	0.2042
00002476770	MINT-PERINDOPRIL	MPI	***$ 0.1945***	$	0.2042
00002489023	NRA-PERINDOPRIL	NRA	***$ 0.1945***	$	0.2042
00002479885	PERINDOPRIL ERBUMINE	SIV	***$ 0.1945***	$	0.2042
00002481642	PERINDOPRIL ERBUMINE	SNS	***$ 0.1945***	$	0.2042
00002470683	PMS-PERINDOPRIL	PMS	***$ 0.1945***	$	0.2042
00002470233	SANDOZ PERINDOPRIL ERBUMINE	SDZ	***$ 0.1945***	$	0.2042
00002464993	TEVA-PERINDOPRIL	TEV	***$ 0.1945***	$	0.2042
00002123282	COVERSYL	SEV	***$ 0.1945***	$	0.8781

MAC pricing will be applied based on the LCA Price for Lisinopril 1 x 20 mg tablet.

PERINDOPRIL ERBUMINE

8 MG ORAL TABLET

00002481693	AG-PERINDOPRIL	AGP	***$ 0.1945***	$	0.2831
00002289296	APO-PERINDOPRIL	APX	***$ 0.1945***	$	0.2831
00002459833	AURO-PERINDOPRIL	AUR	***$ 0.1945***	$	0.2831
00002477025	JAMP PERINDOPRIL	JPC	***$ 0.1945***	$	0.2831
00002474840	MAR-PERINDOPRIL	MAR	***$ 0.1945***	$	0.2831
00002476789	MINT-PERINDOPRIL	MPI	***$ 0.1945***	$	0.2831
00002489031	NRA-PERINDOPRIL	NRA	***$ 0.1945***	$	0.2831
00002479893	PERINDOPRIL ERBUMINE	SIV	***$ 0.1945***	$	0.2831
00002481650	PERINDOPRIL ERBUMINE	SNS	***$ 0.1945***	$	0.2831
00002470691	PMS-PERINDOPRIL	PMS	***$ 0.1945***	$	0.2831
00002470241	SANDOZ PERINDOPRIL ERBUMINE	SDZ	***$ 0.1945***	$	0.2831
00002465000	TEVA-PERINDOPRIL	TEV	***$ 0.1945***	$	0.2831
00002246624	COVERSYL	SEV	***$ 0.1945***	$	1.2295

MAC pricing will be applied based on the LCA Price for Lisinopril 1 x 20 mg tablet.

PILOCARPINE HCL

5 MG ORAL TABLET

00002496119	**ACCEL-PILOCARPINE**	**ACP**	$	**1.1713**
00002216345	SALAGEN	AMD	$	1.2445

TELMISARTAN

40 MG ORAL TABLET

00002453568	**AURO-TELMISARTAN**	**AUR**	$	**0.2161**
00002386755	**JAMP TELMISARTAN**	**JPC**	$	**0.2161**
00002486369	**MINT-TELMISARTAN**	**MPI**	$	**0.2161**
00002375958	**SANDOZ TELMISARTAN**	**SDZ**	$	**0.2161**
00002388944	**TELMISARTAN**	**SNS**	$	**0.2161**
00002390345	**TELMISARTAN**	**SIV**	$	**0.2161**
00002407485	**TELMISARTAN**	**AHI**	$	**0.2161**
00002320177	**TEVA-TELMISARTAN**	**TEV**	$	**0.2161**
00002240769	MICARDIS	BOE	$	1.2474

80 MG ORAL TABLET

00002453576	**AURO-TELMISARTAN**	**AUR**	$	**0.2161**
00002386763	**JAMP TELMISARTAN**	**JPC**	$	**0.2161**
00002486377	**MINT-TELMISARTAN**	**MPI**	$	**0.2161**
00002375966	**SANDOZ TELMISARTAN**	**SDZ**	$	**0.2161**
00002388952	**TELMISARTAN**	**SNS**	$	**0.2161**
00002390353	**TELMISARTAN**	**SIV**	$	**0.2161**
00002407493	**TELMISARTAN**	**AHI**	$	**0.2161**
00002320185	**TEVA-TELMISARTAN**	**TEV**	$	**0.2161**
00002240770	MICARDIS	BOE	$	1.2474

TELMISARTAN/ HYDROCHLOROTHIAZIDE

80 MG * 12.5 MG ORAL TABLET

00002419114	**ACH-TELMISARTAN HCTZ**	**AHI**	$	**0.2098**
00002456389	**AURO-TELMISARTAN HCTZ**	**AUR**	$	**0.2098**
00002389940	**JAMP TELMISARTAN-HCT**	**JPC**	$	**0.2098**
00002393557	**SANDOZ TELMISARTAN HCT**	**SDZ**	$	**0.2098**
00002390302	**TELMISARTAN HCTZ**	**SIV**	$	**0.2098**
00002395355	**TELMISARTAN/HCTZ**	**SNS**	$	**0.2098**
00002330288	**TEVA-TELMISARTAN HCTZ**	**TEV**	$	**0.2098**
00002244344	MICARDIS PLUS	BOE	$	1.2474

80 MG * 25 MG ORAL TABLET

00002419122	**ACH-TELMISARTAN HCTZ**	**AHI**	$	**0.2098**
00002456397	**AURO-TELMISARTAN HCTZ**	**AUR**	$	**0.2098**
00002389959	**JAMP TELMISARTAN-HCT**	**JPC**	$	**0.2098**
00002393565	**SANDOZ TELMISARTAN HCT**	**SDZ**	$	**0.2098**
00002390310	**TELMISARTAN HCTZ**	**SIV**	$	**0.2098**
00002395363	**TELMISARTAN/HCTZ**	**SNS**	$	**0.2098**
00002379252	**TEVA-TELMISARTAN HCTZ**	**TEV**	$	**0.2098**
00002318709	MICARDIS PLUS	BOE	$	1.2474

TESTOSTERONE CYPIONATE

100 MG / ML INJECTION

00002496003	**TARO-TESTOSTERONE CYPIONATE**	**TAR**	$	**3.4878**
00000030783	DEPO-TESTOSTERONE CYPIONATE	PFI	$	4.4681

TOPIRAMATE

25 MG ORAL TABLET

00002475936	**AG-TOPIRAMATE**	**AGP**	$	**0.2433**
00002279614	**APO-TOPIRAMATE**	**APX**	$	**0.2433**
00002345803	**AURO-TOPIRAMATE**	**AUR**	$	**0.2433**
00002435608	**JAMP-TOPIRAMATE**	**JPC**	$	**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**
00002435616	**JAMP-TOPIRAMATE**	**JPC**	$	**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

TOPIRAMATE

200 MG ORAL TABLET				
00002279649	**APO-TOPIRAMATE**	**APX**	$	**0.6748**
00002345846	**AURO-TOPIRAMATE**	**AUR**	$	**0.6748**
00002435624	**JAMP-TOPIRAMATE**	**JPC**	$	**0.6748**
00002315661	**MINT-TOPIRAMATE**	**MPI**	$	**0.6748**
00002263386	**MYLAN-TOPIRAMATE**	**MYP**	$	**0.6748**
00002263017	**PMS-TOPIRAMATE**	**PMS**	$	**0.6748**
00002431823	**SANDOZ TOPIRAMATE**	**SDZ**	$	**0.6748**
00002248862	**TEVA-TOPIRAMATE**	**TEV**	$	**0.6748**
00002356872	**TOPIRAMATE**	**SNS**	$	**0.6748**
00002395754	**TOPIRAMATE**	**AHI**	$	**0.6748**
00002230896	TOPAMAX	JAI	$	4.1055
25 MG ORAL CAPSULE				
00002239908	TOPAMAX SPRINKLE	JAI	$	1.4595

VORTIOXETINE HYDROBROMIDE

5 MG ORAL TABLET				
00002432919	TRINTELLIX	LBC	$	2.8824
10 MG ORAL TABLET				
00002432927	TRINTELLIX	LBC	$	3.0192
20 MG ORAL TABLET				
00002432943	TRINTELLIX	LBC	$	3.2779

PART 3

Special Authorization

ADALIMUMAB

20 MG / SYR INJECTION SYRINGE

00002474263	HUMIRA (20 MG/0.2 ML INJ SYR)	ABV	$	392.7250

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

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

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

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

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

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

DAPTOMYCIN

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

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

Special Authorization may be granted for 12 months.

500 MG / VIAL INJECTION

00002465493	CUBICIN RF	CUB	$	161.0000

DIENOGEST

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

"Special authorization may be granted for 6 months."

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

2 MG ORAL TABLET

00002493055	**ASPEN-DIENOGEST**	**APC**	$	**1.0231**
00002498189	**JAMP DIENOGEST**	**JPC**	$	**1.0231**
00002374900	VISANNE	BAI	$	2.0461

ETANERCEPT

25 MG / VIAL INJECTION

00002242903	ENBREL	AMG	$	200.7100

Plaque Psoriasis

***All new Special Authorization requests for the treatment of adult Plaque Psoriasis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with Plaque Psoriasis; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis or pediatric Plaque Psoriasis for etanercept-naive patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Brenzys or Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg. Coverage for Enbrel will continue for patients with the indications stated above who are currently well maintained on Enbrel 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 for up to 100 mg per week for 12 weeks.
-Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

Following this assessment, continued coverage may be considered for 50 mg per week for a period

ETANERCEPT

of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

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

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

Polyarticular Juvenile Idiopathic Arthritis

***All new Special Authorization requests for the treatment of adult Plaque Psoriasis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with Plaque Psoriasis; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis or pediatric Plaque Psoriasis for etanercept-naive patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Brenzys or Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg. Coverage for Enbrel will continue for patients with the indications stated above who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria. ***

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

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

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

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

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
- 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,

ETANERCEPT

v. functional ability based on CHAQ scores,
vi. ESR or CRP
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request

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

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

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

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25 MG / SYR INJECTION SYRINGE

00002462877	ERELZI	SDZ	$ 120.5000

Ankylosing Spondylitis

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

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

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

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

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

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

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

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

Plaque Psoriasis

***All new Special Authorization requests for the treatment of adult Plaque Psoriasis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with Plaque Psoriasis; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis or pediatric Plaque Psoriasis for etanercept-naive patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Brenzys or Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg. Coverage for Enbrel will continue for patients with the indications stated above who are currently well maintained on Enbrel and are considered a

ETANERCEPT

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

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

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

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

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

Polyarticular Juvenile Idiopathic Arthritis

***All new Special Authorization requests for the treatment of adult Plaque Psoriasis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with Plaque Psoriasis; however, coverage for Enbrel will continue

ETANERCEPT

for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis or pediatric Plaque Psoriasis for etanercept-naive patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Brenzys or Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg. Coverage for Enbrel will continue for patients with the indications stated above who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria. ***

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

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

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

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

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

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

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

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

Psoriatic Arthritis

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

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

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

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

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

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

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

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

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

Rheumatoid Arthritis

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

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

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

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

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

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

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

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

ETANERCEPT

All requests (including renewal requests) for etanercept 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).

ETANERCEPT

50 MG / SYR INJECTION SYRINGE

✉	00002455323	BRENZYS	SSB	$	241.0000

Ankylosing Spondylitis

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

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

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

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

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

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

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

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

Plaque Psoriasis

***All new Special Authorization requests for the treatment of adult Plaque Psoriasis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with Plaque Psoriasis; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis or pediatric Plaque Psoriasis for etanercept-naive patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Brenzys or Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg. Coverage for Enbrel will continue for patients with the indications stated above who are currently well maintained on Enbrel and are considered a

ETANERCEPT

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

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

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

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

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

Polyarticular Juvenile Idiopathic Arthritis

***All new Special Authorization requests for the treatment of adult Plaque Psoriasis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with Plaque Psoriasis; however, coverage for Enbrel will continue

ETANERCEPT

for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis or pediatric Plaque Psoriasis for etanercept-naive patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Brenzys or Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg. Coverage for Enbrel will continue for patients with the indications stated above who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria. ***

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

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

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

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

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

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

ETANERCEPT

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

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

Psoriatic Arthritis

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

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

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

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

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

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

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

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

ETANERCEPT

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

Rheumatoid Arthritis

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

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

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

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

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

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

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

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

ETANERCEPT

All requests (including renewal requests) for etanercept 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).

☒ 00002455331 BRENZYS (AUTO INJECTOR) SSB $ 241.0000

Ankylosing Spondylitis

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

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

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

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

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

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

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

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

Plaque Psoriasis

***All new Special Authorization requests for the treatment of adult Plaque Psoriasis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with Plaque Psoriasis; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile

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Idiopathic Arthritis or pediatric Plaque Psoriasis for etanercept-naive patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Brenzys or Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg. Coverage for Enbrel will continue for patients with the indications stated above who are currently well maintained on Enbrel 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 for up to 100 mg per week for 12 weeks.
-Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

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

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

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

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Polyarticular Juvenile Idiopathic Arthritis

***All new Special Authorization requests for the treatment of adult Plaque Psoriasis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with Plaque Psoriasis; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis or pediatric Plaque Psoriasis for etanercept-naive patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Brenzys or Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg. Coverage for Enbrel will continue for patients with the indications stated above who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria. ***

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

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

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

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

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

Following this assessment, continued coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly, for a maximum of twelve months. After twelve months, in order to be considered for continued coverage, the patient must be re-assessed every twelve months by a Pediatric Rheumatology Specialist and must meet the following criteria:
1) The patient has been assessed by a Pediatric Rheumatology Specialist to determine response, and

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

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

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

Psoriatic Arthritis

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

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

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

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

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

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

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

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or
- Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal

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

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

Rheumatoid Arthritis

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

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

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

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

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

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

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

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:
1) The patient has been assessed by an RA Specialist to determine response;
2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
- Confirmation of maintenance of ACR20, or

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

All requests (including renewal requests) for etanercept 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).

☒ 00002462869 ERELZI SDZ $ 241.0000

Ankylosing Spondylitis

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

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

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

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

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

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

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

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

Plaque Psoriasis

ETANERCEPT

***All new Special Authorization requests for the treatment of adult Plaque Psoriasis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with Plaque Psoriasis; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis or pediatric Plaque Psoriasis for etanercept-naive patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Brenzys or Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg. Coverage for Enbrel will continue for patients with the indications stated above who are currently well maintained on Enbrel 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 for up to 100 mg per week for 12 weeks.
-Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

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

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

All requests (including renewal requests) for etanercept 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

***All new Special Authorization requests for the treatment of adult Plaque Psoriasis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with Plaque Psoriasis; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis or pediatric Plaque Psoriasis for etanercept-naive patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Brenzys or Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg. Coverage for Enbrel will continue for patients with the indications stated above who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria. ***

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

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

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

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

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
- 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

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

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

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

Psoriatic Arthritis

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

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

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

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

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

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

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

Following this assessment, continued coverage may be approved for 50 mg per week, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of

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

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

Rheumatoid Arthritis

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

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

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

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

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

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

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

Following this assessment, continued coverage may be approved for 50 mg per week, for a period

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

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

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Ankylosing Spondylitis

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

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

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

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

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

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

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

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

Plaque Psoriasis

***All new Special Authorization requests for the treatment of adult Plaque Psoriasis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with Plaque Psoriasis; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis or pediatric Plaque Psoriasis for etanercept-naive patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Brenzys or Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg. Coverage for Enbrel will continue for patients with the indications stated above who are currently well maintained on Enbrel 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 for up to 100 mg per week for 12 weeks.
-Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

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

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

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

Polyarticular Juvenile Idiopathic Arthritis

***All new Special Authorization requests for the treatment of adult Plaque Psoriasis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with Plaque Psoriasis; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis or pediatric Plaque Psoriasis for etanercept-naive patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Brenzys or Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg. Coverage for Enbrel will continue for patients with the indications stated above who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria. ***

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

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

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

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

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.
2) The Pediatric Rheumatology Specialist must confirm in writing that the patient is a responder that meets the following criteria (ACR Pedi 30):
- 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),

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iv. number of joints with limitation of motion,
v. functional ability based on CHAQ scores,
vi. ESR or CRP
3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request

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

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

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

Psoriatic Arthritis

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

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

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

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

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

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

For continued coverage beyond 8 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND

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- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

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

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

Rheumatoid Arthritis

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

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

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

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

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

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

For continued coverage beyond 8 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after treatment to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
- ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place];

ETANERCEPT

AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

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

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

☒ 00002274728 ENBREL AMG $ 401.5400

Plaque Psoriasis

***All new Special Authorization requests for the treatment of adult Plaque Psoriasis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with Plaque Psoriasis; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis or pediatric Plaque Psoriasis for etanercept-naive patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Brenzys or Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg. Coverage for Enbrel will continue for patients with the indications stated above who are currently well maintained on Enbrel 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

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Specialist").

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

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

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

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

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

Polyarticular Juvenile Idiopathic Arthritis

***All new Special Authorization requests for the treatment of adult Plaque Psoriasis for etanercept-naive patients will be assessed for coverage with Brenzys or Erelzi. Enbrel will not be approved for new etanercept starts for patients with Plaque Psoriasis; however, coverage for Enbrel will continue for patients who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria.

In addition, all new Special Authorization requests for the treatment of Polyarticular Juvenile Idiopathic Arthritis or pediatric Plaque Psoriasis for etanercept-naive patients weighing 63 kg (138 pounds) or more will be assessed for coverage with Brenzys or Erelzi. Enbrel will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg. Coverage for Enbrel will continue for patients with the indications stated above who are currently well maintained on Enbrel and are considered a 'responder' as defined in criteria. ***

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

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

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

- Coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their

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

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

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

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

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

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100 MG / VIAL INJECTION

☒ 00002496933 AVSOLA AMG $ 493.0000

Ankylosing Spondylitis

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

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

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

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

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

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

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

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

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

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

- Infliximab must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross for infliximab for coverage for the treatment of Moderately to Severely Active Crohn's Disease and/or Fistulizing Crohn's Disease patients (`Specialist').
- Patients must be 18 years of age or older to be considered for coverage of infliximab.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients may be allowed to switch from one biologic agent to another following an adequate trial of

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

Prior to initiation of infliximab therapy for New Patients:

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

Moderately to Severely Active Crohn's Disease:

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

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

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

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

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

Fistulizing Crohn's Disease:

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

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

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

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

Coverage Criteria for Moderately to Severely Active Crohn's Disease AND/OR Fistulizing Crohn's

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Disease

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

Induction Dosing for New Patients:

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

Maintenance Dosing:

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

Maintenance Dosing for New Patients after Completion of Induction Dosing:

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

Maintenance Dosing for Existing Patients:

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

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

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

Continued Coverage for Maintenance Dosing:

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

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

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gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; OR
- For Existing Patients: The Specialist must confirm that the patient has maintained the Existing Patient's Baseline Score and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

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

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

Plaque Psoriasis

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

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

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

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

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

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

Following this assessment, continued coverage may be considered for one 5 mg/kg dose of infliximab every 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be

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continuing to respond to therapy by meeting criteria as outlined in (2) above."

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

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

Psoriatic Arthritis

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

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

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

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

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

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

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

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correct number of decimal places as indicated above."

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

Rheumatoid Arthritis

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

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

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

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

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

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

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

INFLIXIMAB

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

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

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

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

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

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

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

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

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

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

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).

INFLIXIMAB

INOTERSEN SODIUM

"For the treatment of polyneuropathy in adult patients with a confirmed genetic diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in patients who meet the following criteria:

- Are symptomatic with early-stage neuropathy, defined as polyneuropathy disability [PND] stage I to less than or equal to IIIB or familial amyloidotic polyneuropathy [FAP] stage I or II
And
- do not exhibit severe heart failure symptoms (defined as New York Heart Association [NYHA] class III or IV)
And
-have not previously undergone a liver transplant.

For coverage, this drug must be prescribed by a specialist with experience in the diagnosis and management of hATTR.

Initial coverage may be approved for 284 mg adminstered subcutaneously once weekly for a period of nine months.

Patients will be limited to receiving a four-week supply of inotersen per prescription at their pharmacy.

For renewal of coverage, patients must show continued benefit from treatment with inotersen and must NOT be:
- permanently bedridden and dependent on assistance for basic activities of daily living, NOR
- receiving end-of-life care.

Continued coverage may be approved for 284 mg weekly for a period of six months.

Coverage cannot be provided for use in combination with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat hATTR."

All requests (including renewal requests) for inotersen must be completed using the Inotersen/Patisiran for HATTR-PN Special Authorization Request Form (ABC 60084).

284 MG / SYR (BASE)	INJECTION	SYRINGE		
00002481383	TEGSEDI		AKC	$ 8076.9231

LEVOCARNITINE

"For the treatment of primary carnitine deficiency. Information is required regarding the total plasma carnitine levels."

"For the treatment of patients with an inborn error of metabolism that results in secondary carnitine deficiency. Information is required regarding the patient's diagnosis."

"Special authorization may be granted for 6 months."

In order to comply with the first criteria: Information is required regarding pre-treatment total plasma carnitine levels.

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

100 MG / ML ORAL SOLUTION				
00002492105	**ODAN LEVOCARNITINE**	**ODN**	$	**0.3898**
00002144336	CARNITOR	SGM	$	0.5711

MONTELUKAST SODIUM

(Refer to 48:10.24 of the Alberta Drug Benefit List for coverage of patients 6 to 18 years of age inclusive).

"For the prophylaxis and chronic treatment of asthma in patients over the age of 18 who meet one of the following criteria:
a) when used as adjunctive therapy in patients who do not respond adequately to high doses of inhaled glucocorticosteroids and long-acting beta 2 agonists. Patients must be unable to use long-acting beta 2 agonists or have demonstrated persistent symptoms while on long-acting beta 2 agonists, or
b) cannot operate inhaler devices."

"For the prophylaxis of exercise-induced bronchoconstriction in patients over the age of 18 where tachyphylaxis exists for long-acting beta 2 agonists."

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

In order to comply with the first criteria, information should indicate either
a) current use of inhaled steroids and contraindications or poor response to long-acting beta 2 agonists (e.g. salmeterol or formoterol) or,
b) the nature of the patient's difficulties with using inhaler devices.

In order to comply with the second criteria, information should include the nature of the patient's response to long-acting beta 2 agonists (e.g. salmeterol or formoterol).

All requests (including renewal requests) for montelukast must be completed using the Montelukast/Zafirlukast Special Authorization Request Form (ABC 60039).

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

10 MG (BASE) ORAL TABLET

00002374609	**APO-MONTELUKAST**	**APX**	$	**0.4231**
00002401274	**AURO-MONTELUKAST**	**AUR**	$	**0.4231**
00002391422	**JAMP-MONTELUKAST**	**JPC**	$	**0.4231**
00002399997	**MAR-MONTELUKAST**	**MAR**	$	**0.4231**
00002408643	**MINT-MONTELUKAST**	**MPI**	$	**0.4231**
00002379333	**MONTELUKAST**	**SNS**	$	**0.4231**
00002382474	**MONTELUKAST**	**SIV**	$	**0.4231**
00002379236	**MONTELUKAST SODIUM**	**AHI**	$	**0.4231**
00002489821	**NRA-MONTELUKAST**	**NRA**	$	**0.4231**
00002373947	**PMS-MONTELUKAST FC**	**PMS**	$	**0.4231**
00002389517	**RAN-MONTELUKAST**	**RAN**	$	**0.4231**
00002328593	**SANDOZ MONTELUKAST**	**SDZ**	$	**0.4231**
00002355523	**TEVA-MONTELUKAST**	**TEV**	$	**0.4231**
00002238217	SINGULAIR	MFC	$	2.4823

PATISIRAN SODIUM

"For the treatment of polyneuropathy in adult patients with a confirmed genetic diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in patients who meet the following criteria:

-Patients are symptomatic with early-stage neuropathy, defined as polyneuropathy disability [PND] stage I to less than or equal to IIIB or familial amyloidotic polyneuropathy [FAP] stage I or II
And
- do not exhibit severe heart failure symptoms (defined as New York Heart Association [NYHA] class III or IV)
And
-have not previously undergone a liver transplant.

For coverage, this drug must be prescribed by a specialist with experience in the diagnosis and management of hATTR.

Initial coverage may be approved 30 mg administered intravenously once every three weeks for a period of nine months.

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

For renewal of coverage, patients must show continued benefit from treatment with patisiran and must NOT be:
- permanently bedridden and dependent on assistance for basic activities of daily living, NOR
- receiving end-of-life care.

Continued coverage may be approved for 30 mg every three weeks for a period of six months.

Coverage cannot be provided for use in combination with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat hATTR."

All requests (including renewal requests) for patisiran must be completed using the Inotersen/Patisiran for HATTR-PN Special Authorization Request Form (ABC 60084).

2 MG / ML (BASE)	INJECTION			
00002489252	ONPATTRO	ANT	$	2100.4813

PIBRENTASVIR/ GLECAPREVIR

"For treatment-naive or treatment-experienced (1) adult patients with chronic hepatitis C infection who meet all of the following criteria:
I) Prescribed by or in consultation with a hepatologist, gastroenterologist or infectious disease specialist (except on a case-by-case basis, in geographic areas where access to these specialties is not available);
AND
II) Laboratory confirmed hepatitis C genotype (2) 1, 2, 3, 4, 5, 6;
AND
III) Laboratory confirmed quantitative HCV RNA value within the last 6 months:
AND
IV) Fibrosis (3) stage of F0 or greater (Metavir scale or equivalent).

Duration of therapy reimbursed:
- Treatment-naive, without cirrhosis: 8 weeks
- Treatment-naive, with compensated cirrhosis (4): 8 weeks
- Treatment-experienced (1) genotype 1, 2, 4, 5, or 6, without cirrhosis: 8 weeks
- Treatment-experienced (1) genotype 1, 2, 4, 5, or 6, with compensated cirrhosis (4): 12 weeks
- NS3/4A protease inhibitor treatment-experienced (5) genotype 1, without cirrhosis or with compensated cirrhosis (4): 12 weeks
- NS5A inhibitor treatment-experienced (6) genotype 1, without cirrhosis or with compensated cirrhosis (4): 16 weeks
- Treatment-experienced (1) genotype 3, without cirrhosis or with compensated cirrhosis (4): 16 weeks

Exclusion criteria:
- Patients currently being treated with another HCV antiviral agent

Notes:
1. Treatment experienced is defined as those who have previously been treated with a regimen containing interferon, peginterferon (P), ribavirin (R), and/or sofosbuvir (e.g. PR, SOF + PR, SOF + R), but have no prior treatment experience with an NS3/4A protease inhibitor or NS5A inhibitor.
2. HCV genotype testing is optional for treatment naive patients.
3. Fibrosis score test is optional. Acceptable methods include liver biopsy, transient elastography (FibroScan), fibrotest and serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.
4. Compensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh A (i.e. score 5 to 6).
5. NS3/4A protease inhibitor treatment-experienced is defined as those who have previously been treated with a regimen containing a non-structural protein 3/4A (NS3/4A) protease inhibitor, but without an NS5A inhibitor.
6. NS5A inhibitor treatment-experienced is defined as those who have previously been treated with a regimen containing an NS5A inhibitor, but without an NS3/4A protease inhibitor, such as daclatasavir + sofosbuvir, ledipasvir/sofosbuvir, or sofosbuvir/velpatasvir.
7. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations."
All requests for pibrentasvir/glecaprevir must be completed using the Antivirals for Chronic Hepatitis C Special Authorization Request Form (ABC 60022).

40 MG * 100 MG ORAL TABLET				
00002467550	MAVIRET	ABV	$	238.0952

PIOGLITAZONE HCL

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

FIRST-LINE DRUG PRODUCT(S): METFORMIN

"For the treatment of Type 2 diabetes in patients who have an inadequate response to a sufficient trial (i.e. a minimum of 6 months) of metformin or who are intolerant to metformin (e.g. dermatologic reactions) or for whom the product is contraindicated."

Special authorization may be granted for 24 months.

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

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

45 MG (BASE) ORAL TABLET

00002339595	**ACH-PIOGLITAZONE**	**AHI**	$	**1.3113**
00002302896	**ACT PIOGLITAZONE**	**TEV**	$	**1.3113**
00002302977	**APO-PIOGLITAZONE**	**APX**	$	**1.3113**
00002365537	**JAMP-PIOGLITAZONE**	**JPC**	$	**1.3113**

RALOXIFENE HCL

Osteoporosis:

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

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

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

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

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

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

60 MG ORAL TABLET

00002358840	**ACT RALOXIFENE**	**APH**	$	**1.0268**
00002279215	**APO-RALOXIFENE**	**APX**	$	**1.0268**
00002239028	EVISTA	LIL	$	1.9593

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10 MG / ML INJECTION

☒ 00002498316 RIXIMYO SDZ $ 29.7000

Rheumatoid Arthritis

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

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

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

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

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

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

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

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

☒ 00002495724 RUXIENCE PFI $ 29.7000

Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA)

"For use in combination with glucocorticoids for the induction of remission of severely active granulomatosis with polyangiitis (GPA, also known as Wegener's granulomatosis) or microscopic polyangiitis (MPA) in adult patients who have:
- Severe active disease that is life- or organ-threatening. The organ(s) and how the organ(s) is (are)

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threatened must be specified;
AND
- A positive serum assay for either proteinase 3-ANCA (anti-neutrophil cytoplasmic antibody) or myeloperoxidase-ANCA. A copy of the lab report must be provided; AND
- Cyclophosphamide cannot be used for ONE of the following reasons:
a) The patient has failed a minimum of six intravenous pulses of cyclophosphamide; OR
b) The patient has failed three months of oral cyclophosphamide therapy; OR
c) The patient has a severe intolerance or an allergy to cyclophosphamide; OR
d) Cyclophosphamide is contraindicated; OR
e) The patient has received a cumulative lifetime dose of at least 25 grams of cyclophosphamide.

- Coverage may be approved for a maximum of 375 mg per square metre of body surface area weekly for 4 weeks.
- Patients will be limited to receiving two doses of rituximab per prescription at their pharmacy.
- For relapse following a remission, coverage may be provided for patients who experience a flare of severe active disease that is life- or organ-threatening; or, who experience worsening symptoms in 2 or more organs even if not life-threatening. Note: For relapse following a rituximab-induced remission, additional coverage may be approved no sooner than 6 months after previous rituximab treatment."

All requests (including renewal requests) for rituximab for Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA) must be completed using the Rituximab for Granulomatosis with Polyangiitis/Microscopic Polyangiitis Special Authorization Request Form (ABC 60018).

Rheumatoid Arthritis

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

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

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

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

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

For coverage for an additional two-dose course of therapy, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after each course of therapy, between 16 and 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

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initial course of rituximab; AND
- An improvement of 0.22 in HAQ score [reported to two (2) decimal places] following the initial course of rituximab.
It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above, AND
3) The patient must have residual disease or disease activity returning to a level above a DAS28 score of 2.6.

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

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

☒ 00002478382 TRUXIMA (10 ML) CTC $ 29.7000

Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA)

"For use in combination with glucocorticoids for the induction of remission of severely active granulomatosis with polyangiitis (GPA, also known as Wegener's granulomatosis) or microscopic polyangiitis (MPA) in adult patients who have:
- Severe active disease that is life- or organ-threatening. The organ(s) and how the organ(s) is (are) threatened must be specified;
AND
- A positive serum assay for either proteinase 3-ANCA (anti-neutrophil cytoplasmic antibody) or myeloperoxidase-ANCA. A copy of the lab report must be provided; AND
- Cyclophosphamide cannot be used for ONE of the following reasons:
a) The patient has failed a minimum of six intravenous pulses of cyclophosphamide; OR
b) The patient has failed three months of oral cyclophosphamide therapy; OR
c) The patient has a severe intolerance or an allergy to cyclophosphamide; OR
d) Cyclophosphamide is contraindicated; OR
e) The patient has received a cumulative lifetime dose of at least 25 grams of cyclophosphamide.

- Coverage may be approved for a maximum of 375 mg per square metre of body surface area weekly for 4 weeks.
- Patients will be limited to receiving two doses of rituximab per prescription at their pharmacy.
- For relapse following a remission, coverage may be provided for patients who experience a flare of severe active disease that is life- or organ-threatening; or, who experience worsening symptoms in 2 or more organs even if not life-threatening. Note: For relapse following a rituximab-induced remission, additional coverage may be approved no sooner than 6 months after previous rituximab treatment."

All requests (including renewal requests) for rituximab for Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA) must be completed using the Rituximab for Granulomatosis with Polyangiitis/Microscopic Polyangiitis Special Authorization Request Form (ABC 60018).

Rheumatoid Arthritis

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

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

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

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

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

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

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

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

☒	00002478390	TRUXIMA (50 ML)	CTC	$	29.7000

Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA)

"For use in combination with glucocorticoids for the induction of remission of severely active granulomatosis with polyangiitis (GPA, also known as Wegener's granulomatosis) or microscopic polyangiitis (MPA) in adult patients who have:
- Severe active disease that is life- or organ-threatening. The organ(s) and how the organ(s) is (are) threatened must be specified;
AND
- A positive serum assay for either proteinase 3-ANCA (anti-neutrophil cytoplasmic antibody) or myeloperoxidase-ANCA. A copy of the lab report must be provided; AND
- Cyclophosphamide cannot be used for ONE of the following reasons:
a) The patient has failed a minimum of six intravenous pulses of cyclophosphamide; OR
b) The patient has failed three months of oral cyclophosphamide therapy; OR
c) The patient has a severe intolerance or an allergy to cyclophosphamide; OR
d) Cyclophosphamide is contraindicated; OR
e) The patient has received a cumulative lifetime dose of at least 25 grams of cyclophosphamide.

- Coverage may be approved for a maximum of 375 mg per square metre of body surface area weekly for 4 weeks.
- Patients will be limited to receiving two doses of rituximab per prescription at their pharmacy.
- For relapse following a remission, coverage may be provided for patients who experience a flare of severe active disease that is life- or organ-threatening; or, who experience worsening symptoms in 2 or more organs even if not life-threatening. Note: For relapse following a rituximab-induced remission, additional coverage may be approved no sooner than 6 months after previous rituximab treatment."

All requests (including renewal requests) for rituximab for Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA) must be completed using the Rituximab for Granulomatosis with Polyangiitis/Microscopic Polyangiitis Special Authorization Request Form (ABC 60018).

RITUXIMAB

Rheumatoid Arthritis

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

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

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

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

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

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

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

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

SOFOSBUVIR

"For use as combination therapy with ribavirin for treatment-naive or treatment-experienced (1) adult patients with chronic hepatitis C (CHC) infection who meet all of the following criteria:

I) Prescribed by or in consultation with a hepatologist, gastroenterologist or infectious disease specialist (except on a case-by-case basis, in geographic areas where access to these specialties is not available);
AND
II) Laboratory confirmed hepatitis C genotype 2 or genotype 3;
AND
III) Laboratory confirmed quantitative HCV RNA value within the last 6 months;
AND
IV) Fibrosis (2) stage of F0 or greater (Metavir scale or equivalent).

Duration of therapy reimbursed:
- Treatment-naive or treatment experienced genotype 2, without cirrhosis or with compensated cirrhosis (3): 12 weeks in combination with ribavirin
- Treatment-naive or treatment-experienced genotype 3, without cirrhosis or with compensated cirrhosis (3), or with decompensated cirrhosis (4), or post-liver transplant: 24 weeks in combination with ribavirin

Exclusion criteria:
- Patients currently being treated with another HCV antiviral agent
- Retreatment for failure or re-infection in patients who have received an adequate prior course of an HCV direct-acting antiviral drug regimen may be considered on an exceptional case-by-case basis
- Combination therapy with elbasvir/grazoprevir will not be considered

Notes:
1. Treatment-experienced are those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor.
2. Fibrosis score test is optional. Acceptable methods include liver biopsy, transient elastography (FibroScan), fibrotest and serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.
3. Compensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh A (i.e. score 5 to 6).
4. Decompensated cirrhosis is defined as cirrhosis with Child-Turcotte-Pugh B or C (i.e. score 7 or above).
5. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations."

All requests for sofosbuvir must be completed using the Antivirals for Chronic Hepatitis C Special Authorization Request Form (ABC 60022).

400 MG ORAL TABLET				
00002418355	SOVALDI	GIL	$	654.7619

PART 3A

Optional Special Authorization

Criteria For Optional Special Authorization Of Select Drug Products

Patient claims for select quinolone prescriptions written by a non-designated prescriber will be subject to a first forgiveness rule, meaning the first claim will be paid. Subsequent claims for the same product (irrespective of strength, route and form) within a 90-day period would require the prescriber to apply for special authorization for coverage on the patient' s behalf.

CIPROFLOXACIN HCL

"For the treatment of:

1) Respiratory Tract Infections:
-end stage COPD with or without bronchiectasis, where there has been documentation of previous Pseudomonas aeruginosa colonization/infection or
- pneumonic illness in cystic fibrosis; or

2) Genitourinary Tract Infections:
- urinary tract infections,
- prostatitis,
- prophylaxis of urinary tract surgical procedures or
- gonococcal infections; or

3) Skin and Soft Tissue/Bone and Joint Infections:
- malignant/invasive otitis externa,
- bone/joint infections due to gram negative organisms or
- therapy/step-down therapy of polymicrobial infections in combination with clindamycin or metronidazole e.g. diabetic foot infection, decubitus ulcers; or

4) Gastrointestinal Tract Infections:
- bacterial gastroenteritis where antimicrobial therapy is indicated,
- typhoid fever (enteric fever), or
- therapy/step-down therapy of polymicrobial infections in combination with clindamycin or metronidazole e.g. intra-abdominal infections; or

5) Other:
- prophylaxis of adult contacts of cases of invasive meningococcal disease,
- therapy/step-down therapy of hospital acquired gram negative infections,
- empiric therapy of febrile neutropenia in combination with other appropriate agents or
- exceptional case of allergy or intolerance to all other appropriate therapies as defined by relevant guidelines/references i.e. AMA CPGs or Bugs and Drugs.
- for use in other current Health Canada approved indications when prescribed by a specialist in Infectious Diseases."

All requests for ciprofloxacin must be completed using the Select Quinolones Special Authorization Request Form (ABC 60042).

500 MG ORAL TABLET

00002247340	**ACT CIPROFLOXACIN**	**APH**	$	**0.5025**
00002381923	**AURO-CIPROFLOXACIN**	**AUR**	$	**0.5025**
00002353326	**CIPROFLOXACIN**	**SNS**	$	**0.5025**
00002386127	**CIPROFLOXACIN**	**SIV**	$	**0.5025**
00002380366	**JAMP-CIPROFLOXACIN**	**JPC**	$	**0.5025**
00002379694	**MAR-CIPROFLOXACIN**	**MAR**	$	**0.5025**
00002492008	**NRA-CIPROFLOXACIN**	**NRA**	$	**0.5025**
00002248438	**PMS-CIPROFLOXACIN**	**PMS**	$	**0.5025**
00002303736	**RAN-CIPROFLOX**	**RAN**	$	**0.5025**
00002248757	**SANDOZ CIPROFLOXACIN**	**SDZ**	$	**0.5025**