Updates to the Alberta Drug Benefit List

Effective May 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.

Table of Contents

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
AMGEVITA (20 MG / 0.4 ML) INJECTION SYRINGE	ADALIMUMAB	00002459310	AMG
AMGEVITA (40 MG / 0.8 ML AUTOINJECTOR) INJECTION SYRINGE	ADALIMUMAB	00002459302	AMG
AMGEVITA 40 MG / 0.8 ML INJECTION SYRINGE	ADALIMUMAB	00002459299	AMG
FASENRA 30 MG / ML PEN INJECTION SYRINGE	BENRALIZUMAB	00002496135	AZC
HADLIMA 40 MG / 0.8 ML AUTO-INJECTOR INJECTION SYRINGE	ADALIMUMAB	00002473100	ABV
HADLIMA 40 MG / 0.8 ML INJECTION SYRINGE	ADALIMUMAB	00002473097	ABV
HULIO 40 MG / 0.8 ML PEN INJECTION SYRINGE	ADALIMUMAB	00002502402	BGP
HULIO 40 MG / 0.8 ML PREFILLED SYRINGE	ADALIMUMAB	00002502399	BGP
HYRIMOZ (20 MG / 0.4 ML) INJECTION SYRINGE	ADALIMUMAB	00002505258	SDZ
HYRIMOZ 40 MG / 0.8 ML INJECTION SYRINGE	ADALIMUMAB	00002492164	SDZ
HYRIMOZ 40 MG / 0.8 ML AUTO-INJECTOR PEN INJECTION SYRINGE	ADALIMUMAB	00002492156	SDZ
IDACIO 40 MG / 0.8 ML PEN INJECTION SYRINGE	ADALIMUMAB	00002502674	FKC
MONOFERRIC 100 MG / ML INJECTION	IRON ISOMALTOSIDE 1000	00002477777	PFI
NYVEPRIA 0.6 ML SYRINGE INJECTION	PEGFILGRASTIM	00002506238	PFI
TAKHZYRO 150 MG / ML INJECTION SYRINGE	LANADELUMAB	00002505614	SHB
VYNDAQEL 20 MG CAPSULE	TAFAMIDIS MEGLUMINE	00002495732	PFI

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

Trade Name / Strength / Form	Generic Description	DIN	MFR
NRA-LACOSAMIDE 50 MG TABLET	LACOSAMIDE	00002499568	NRA
NRA-LACOSAMIDE 100 MG TABLET	LACOSAMIDE	00002499576	NRA
NRA-LACOSAMIDE 150 MG TABLET	LACOSAMIDE	00002499584	NRA

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

Trade Name / Strength / Form	Generic Description	DIN	MFR
NRA-LACOSAMIDE 200 MG TABLET	LACOSAMIDE	00002499592	NRA
TARO-DEFERASIROX (TYPE J) 90 MG TABLET	DEFERASIROX	00002507315	TAR
TARO-DEFERASIROX (TYPE J) 180 MG TABLET	DEFERASIROX	00002507323	TAR
TARO-DEFERASIROX (TYPE J) 360 MG TABLET	DEFERASIROX	00002507331	TAR

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
ERELZI (SENSOREADY AUTO INJECTOR) 50 MG / SYRINGE INJECTION	ETANERCEPT	00002462850	SDZ
ERELZI 25 MG / SYRINGE INJECTION	ETANERCEPT	00002462877	SDZ
ERELZI 50 MG / SYRINGE INJECTION	ETANERCEPT	00002462869	SDZ
HUMIRA 20 MG / 0.2 ML INJECTION SYRINGE	ADALIMUMAB	00002474263	ABV
HUMIRA 40 MG / 0.8 ML INJECTION SYRINGE	ADALIMUMAB	00002258595	ABV
PROCYSBI 25 MG DELAYED-RELEASE CAPSULE	CYSTEAMINE BITARTRATE	00002464705	RAP
PROCYSBI 75 MG DELAYED-RELEASE CAPSULE	CYSTEAMINE BITARTRATE	00002464713	RAP
REVESTIVE 5 MG / VIAL INJECTION	TEDUGLUTIDE	00002445727	TAK

Added Product(s)

Trade Name / Strength / Form	Generic Description	DIN	MFR
AURO-BUSPIRONE 10 MG TABLET	BUSPIRONE HCL	00002500213	AUR
CREON MINIMICROSPHERES 35 UNIT CAPSULE	LIPASE/AMYLASE/PROTEASE	00002494639	BGP
JAMP PANTOPRAZOLE SODIUM 40 MG ENTERIC-COATED TAB	PANTOPRAZOLE SODIUM	00002392623	JPC
JAMP ROSUVASTATIN CALCIUM 5 MG TABLET	ROSUVASTATIN CALCIUM	00002498332	JPC

Added Product(s), continued

Trade Name / Strength / Form	Generic Description	DIN	MFR
JAMP ROSUVASTATIN CALCIUM 10 MG TABLET	ROSUVASTATIN CALCIUM	00002498340	JPC
JAMP ROSUVASTATIN CALCIUM 20 MG TABLET	ROSUVASTATIN CALCIUM	00002498359	JPC
JAMP ROSUVASTATIN CALCIUM 40 MG TABLET	ROSUVASTATIN CALCIUM	00002498367	JPC
NRA-LEVETIRACETAM 250 MG TABLET	LEVETIRACETAM	00002499193	NRA
NRA-LEVETIRACETAM 500 MG TABLET	LEVETIRACETAM	00002499207	NRA
NRA-LEVETIRACETAM 750 MG TABLET	LEVETIRACETAM	00002499215	NRA
NRA-PREGABALIN 25 MG CAPSULE	PREGABALIN	00002479117	NRA
NRA-PREGABALIN 50 MG CAPSULE	PREGABALIN	00002479125	NRA
NRA-PREGABALIN 75 MG CAPSULE	PREGABALIN	00002479133	NRA
NRA-PREGABALIN 150 MG CAPSULE	PREGABALIN	00002479168	NRA
NRA-QUETIAPINE 25 MG TABLET	QUETIAPINE FUMARATE	00002486237	NRA
NRA-RAMIPRIL 2.5 MG CAPSULE	RAMIPRIL	00002486172	NRA
NRA-RAMIPRIL 5 MG CAPSULE	RAMIPRIL	00002486180	NRA
NRA-RAMIPRIL 10 MG CAPSULE	RAMIPRIL	00002486199	NRA
NRA-ROSUVASTATIN 5 MG TABLET	ROSUVASTATIN CALCIUM	00002477483	NRA
NRA-ROSUVASTATIN 10 MG TABLET	ROSUVASTATIN CALCIUM	00002477491	NRA
NRA-ROSUVASTATIN 20 MG TABLET	ROSUVASTATIN CALCIUM	00002477505	NRA
NRA-ROSUVASTATIN 40 MG TABLET	ROSUVASTATIN CALCIUM	00002477513	NRA
NRA-SERTRALINE 25 MG CAPSULE	SERTRALINE HCL	00002488434	NRA
NRA-SERTRALINE 50 MG CAPSULE	SERTRALINE HCL	00002488442	NRA
NRA-SERTRALINE 100 MG CAPSULE	SERTRALINE HCL	00002488450	NRA
OMEPRAZOLE MAGNESIUM 20 MG SUSTAINED-RELEASE TABLET	OMEPRAZOLE	00002504294	SNS
PMS-TELMISARTAN 40 MG TABLET	TELMISARTAN	00002499622	PMS
PMS-TELMISARTAN 80 MG TABLET	TELMISARTAN	00002499630	PMS
PRIVA-DUTASTERIDE 0.5 MG CAPSULE	DUTASTERIDE	00002490587	PMI
SANDOZ CIPROFLOXACIN / DEXAMETHASONE OTIC SUSPENSION	CIPROFLOXACIN HCL/ DEXAMETHASONE	00002506882	SDZ
TEVA-BETAMETHASONE / CALCIPOTRIOL TOPICAL OINTMENT	CALCIPOTRIOL MONOHYDRATE/ BETAMETHASONE DIPROPIONATE	00002427419	TEV
TRI-CIRA 28 TABLET	NORGESTIMATE/ ETHINYL ESTRADIOL/ NORGESTIMATE/ ETHINYL ESTRADIOL/ NORGESTIMATE/ ETHINYL ESTRADIOL	00002508095	APX

New Established Interchangeable (IC) Grouping(s)

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

Generic Description	Strength / Form	New LCA Price
CALCIPOTRIOL MONOHYDRATE/ BETAMETHASONE DIPROPIONATE	50 MCG / G / 0.5 MG / G TOPICAL OINTMENT	1.2545
NORGESTIMATE/ ETHINYL ESTRADIOL/ NORGESTIMATE/ ETHINYL ESTRADIOL/ NORGESTIMATE/ ETHINYL ESTRADIOL	0.18 MG / 0.025 MG / 0.215 MG / 0.025 MG / 0.25 MG / 0.025 MG ORAL TABLET	0.5139

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 June 1, 2021. Please review the online **Interactive Drug Benefit List** for further information.*

Generic Description	Strength / Form	New LCA Price
DICLOFENAC	50 MG RECTAL SUPPOSITORY	0.8545
NORFLOXACIN	400 MG TABLET	1.6400

Product(s) with a Price Change

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

Trade Name / Strength / Form	Generic Description	DIN	MFR
APO-BUSPIRONE 10MG TABLET	BUSPIRONE HCL	00002211076	APX
APO-DEFERASIROX (TYPE J) 90 MG TABLET	DEFERASIROX	00002485265	APX
APO-DEFERASIROX (TYPE J) 180 MG TABLET	DEFERASIROX	00002485273	APX
APO-DEFERASIROX (TYPE J) 360 MG TABLET	DEFERASIROX	00002485281	APX
NORFLOXACIN 400 MG TABLET	NORFLOXACIN	00002229524	AAP
NOVO-BUSPIRONE 10 MG TABLET	BUSPIRONE HCL	00002231492	TEV
PMS-BUSPIRONE 10 MG TABLET	BUSPIRONE HCL	00002230942	PMS
PMS-DICLOFENAC 50 MG RECTAL SUPPOSITORY	DICLOFENAC SODIUM	00002231506	PMS
SALAGEN 5 MG TABLET	PILOCARPINE HCL	00002216345	AMD
SANDOZ DICLOFENAC 50 MG RECTAL SUPPOSITORY	DICLOFENAC SODIUM	00002261928	SDZ
TARO-CIPROFLOXACIN / DEXAMETHASONE 0.3 % / 0.1% OTIC SUSPENSION	CIPROFLOXACIN HCL/ DEXAMETHASONE	00002481901	TAR
TRI-JORDYNA 28 (28 DAY) 0.18 MG / 0.035 MG / 0.215 MG / 0.035 MG / 0.25 MG / 0.035 MG TABLET	NORGESTIMATE/ ETHINYL ESTRADIOL/ NORGESTIMATE/ ETHINYL ESTRADIOL/ NORGESTIMATE/ ETHINYL ESTRADIOL	00002486318	GLM

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 May 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 June 1, 2021 claims will no longer pay for these product(s).

Trade Name / Strength / Form	Generic Description	DIN	MFR
LOPRESOR SR 100 MG SUSTAINED-RELEASE TABLET	METOPROLOL TARTRATE	00000658855	NOV
SANDOZ METOPROLOL SR 100 MG SUSTAINED-RELEASE TABLET	METOPROLOL TARTRATE	00002303396	SDZ

Product(s) Removed from the Alberta Drug Benefit List

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

Trade Name / Strength / Form	Generic Description	DIN	MFR
ENBREL 50 MG / SYRINGE INJECTION	ETANERCEPT	00002274728	AMG

PART 2

Drug Additions

BUSPIRONE HCL

10 MG ORAL TABLET

00002211076	**APO-BUSPIRONE**	**APX**	$	**0.2713**
00002500213	**AURO-BUSPIRONE**	**AUR**	$	**0.2713**
00002231492	**NOVO-BUSPIRONE**	**TEV**	$	**0.2713**
00002230942	**PMS-BUSPIRONE**	**PMS**	$	**0.2713**

CALCIPOTRIOL MONOHYDRATE/ BETAMETHASONE DIPROPIONATE

50 MCG / G (BASE) * 0.5 MG / G (BASE) TOPICAL OINTMENT

00002427419	**TEVA-BETAMETHASONE/CALCIPOTRIOL**	**TEV**	$	**1.2545**
00002244126	DOVOBET	LEO	$	1.5923

CIPROFLOXACIN HCL/ DEXAMETHASONE

0.3 % * 0.1 % OTIC SUSPENSION

00002506882	**SANDOZ CIPROFLOXACIN/DEXAMETHASONE**	**SDZ**	$	**1.9227**
00002481901	**TARO-CIPROFLOXACIN/DEXAMETHASONE**	**TAR**	$	**1.9227**
00002252716	CIPRODEX	NOV	$	3.8720

DICLOFENAC SODIUM

50 MG RECTAL SUPPOSITORY

00002231506	**PMS-DICLOFENAC**	**PMS**	$	**0.8545**
00002261928	**SANDOZ DICLOFENAC**	**SDZ**	$	**0.8545**
00000632724	VOLTAREN	NOV	$	1.4750

DUTASTERIDE

0.5 MG ORAL CAPSULE

00002404206	**APO-DUTASTERIDE**	**APX**	$	**0.3027**
00002469308	**AURO-DUTASTERIDE**	**AUR**	$	**0.3027**
00002429012	**DUTASTERIDE**	**SIV**	$	**0.3027**
00002443058	**DUTASTERIDE**	**SNS**	$	**0.3027**
00002484870	**JAMP DUTASTERIDE**	**JPC**	$	**0.3027**
00002416298	**MED-DUTASTERIDE**	**GMP**	$	**0.3027**
00002428873	**MINT-DUTASTERIDE**	**MPI**	$	**0.3027**
00002393220	**PMS-DUTASTERIDE**	**PMS**	$	**0.3027**
00002490587	**PRIVA-DUTASTERIDE**	**PMI**	$	**0.3027**
00002424444	**SANDOZ DUTASTERIDE**	**SDZ**	$	**0.3027**
00002408287	**TEVA-DUTASTERIDE**	**TEV**	$	**0.3027**
00002247813	AVODART	GSK	$	1.7660

LEVETIRACETAM

250 MG ORAL TABLET

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

500 MG ORAL TABLET

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

750 MG ORAL TABLET

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

1,000 MG ORAL TABLET

00002462028	SANDOZ LEVETIRACETAM	SDZ	$	0.7221

LIPASE/ AMYLASE/ PROTEASE

35,000 UNIT * 35,700 UNIT * 2,240 UNIT ORAL CAPSULE (ENTERIC-COATED PELLET)

00002494639	CREON 35 MINIMICROSPHERES	BGP	$	0.9531

NORFLOXACIN

400 MG ORAL TABLET

00002229524	NORFLOXACIN	AAP	$	1.6400

NORGESTIMATE/ ETHINYL ESTRADIOL/ NORGESTIMATE/ ETHINYL ESTRADIOL/ NORGESTIMATE/ ETHINYL ESTRADIOL

0.18 MG * 0.035 MG * 0.215 MG * 0.035 MG * 0.25 MG * 0.035 MG ORAL TABLET

00002508095	**TRI-CIRA 28**	**APX**	$	**0.5139**
00002486318	**TRI-JORDYNA 28 (28 DAY)**	**GLM**	$	**0.5139**

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
00002504294	OMEPRAZOLE MAGNESIUM (SUSTAINED-RELEASE TABLET)	SNS	***$ 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
00002392623	JAMP PANTOPRAZOLE SODIUM	JPC	***$ 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
00002471825	NRA-PANTOPRAZOLE	NRA	***$ 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.

PERINDOPRIL ERBUMINE/ INDAPAMIDE HEMIHYDRATE

4 MG * 1.25 MG ORAL TABLET

00002297574	APO-PERINDOPRIL-INDAPAMIDE	APX	***$ 0.2503***	$	0.2556
00002470438	SANDOZ PERINDOPRIL/INDAPAMIDE	SDZ	***$ 0.2503***	$	0.2556
00002464020	TEVA-PERINDOPRIL/INDAPAMIDE	TEV	***$ 0.2503***	$	0.2556
00002246569	COVERSYL PLUS	SEV	***$ 0.2503***	$	1.0796

MAC pricing will be applied based on the LCA Price for Lisinopril/ Hydrochlorothiazide 1 x 20 mg/25 mg tablet.

8 MG * 2.5 MG ORAL TABLET

00002453061	APO-PERINDOPRIL-INDAPAMIDE	APX	***$ 0.2503***	$	0.2859
00002470446	SANDOZ PERINDOPRIL/INDAPAMIDE HD	SDZ	***$ 0.2503***	$	0.2859
00002464039	TEVA-PERINDOPRIL/INDAPAMIDE	TEV	***$ 0.2503***	$	0.2859
00002321653	COVERSYL PLUS HD	SEV	***$ 0.2503***	$	1.2541

MAC pricing will be applied based on the LCA Price for Lisinopril/ Hydrochlorothiazide 1 x 20 mg/25 mg tablet.

PILOCARPINE HCL

5 MG ORAL TABLET

00002496119	**ACCEL-PILOCARPINE**	**ACP**	$	**1.1362**
00002216345	SALAGEN	AMD	$	1.1713

PREGABALIN

25 MG ORAL CAPSULE

00002479117	**NRA-PREGABALIN**	**NRA**	$	**0.1481**

50 MG ORAL CAPSULE

00002479125	**NRA-PREGABALIN**	**NRA**	$	**0.2324**

75 MG ORAL CAPSULE

00002479133	**NRA-PREGABALIN**	**NRA**	$	**0.3007**

150 MG ORAL CAPSULE

00002479168	**NRA-PREGABALIN**	**NRA**	$	**0.4145**

PROGESTERONE

"Due to the high prevalence of peanut allergies within the population, Alberta Health has chosen to highlight the fact that Teva-Progesterone 100 mg capsules contain peanut oil, while the Brand Name drug product Prometrium does not. Please note that the Expert Committee does not regularly review possible allergens within drug products listed in the Alberta Drug Benefit List (ADBL) and it remains the responsibility of the prescribing physician and dispensing pharmacist to review all patient allergies."

100 MG ORAL CAPSULE

00002439913	**TEVA-PROGESTERONE (PEANUT OIL)**	**TEV**	$	**0.3762**
00002166704	PROMETRIUM	MFC	$	1.1330

QUETIAPINE FUMARATE

25 MG (BASE) ORAL TABLET

00002316080	**ACT QUETIAPINE**	**APH**	$	**0.0494**
00002475979	**AG-QUETIAPINE**	**AGP**	$	**0.0494**
00002313901	**APO-QUETIAPINE**	**APX**	$	**0.0494**
00002390205	**AURO-QUETIAPINE**	**AUR**	$	**0.0494**
00002447193	**BIO-QUETIAPINE**	**BMD**	$	**0.0494**
00002330415	**JAMP-QUETIAPINE**	**JPC**	$	**0.0494**
00002399822	**MAR-QUETIAPINE**	**MAR**	$	**0.0494**
00002438003	**MINT-QUETIAPINE**	**MPI**	$	**0.0494**
00002439158	**NAT-QUETIAPINE**	**NTP**	$	**0.0494**
00002486237	**NRA-QUETIAPINE**	**NRA**	$	**0.0494**
00002296551	**PMS-QUETIAPINE**	**PMS**	$	**0.0494**
00002317893	**QUETIAPINE**	**SIV**	$	**0.0494**
00002353164	**QUETIAPINE**	**SNS**	$	**0.0494**
00002387794	**QUETIAPINE**	**AHI**	$	**0.0494**
00002397099	**RAN-QUETIAPINE**	**RAN**	$	**0.0494**
00002236951	SEROQUEL	AZC	$	0.5195

RAMIPRIL

2.5 MG ORAL CAPSULE/TABLET

00002477572	**AG-RAMIPRIL (CAPSULE)**	**AGP**	$	**0.0817**
00002251531	**APO-RAMIPRIL (CAPSULE)**	**APX**	$	**0.0817**
00002387395	**AURO-RAMIPRIL (CAPSULE)**	**AUR**	$	**0.0817**
00002331128	**JAMP-RAMIPRIL (CAPSULE)**	**JPC**	$	**0.0817**
00002420465	**MAR-RAMIPRIL (CAPSULE)**	**MAR**	$	**0.0817**
00002421305	**MINT-RAMIPRIL (CAPSULE)**	**MPI**	$	**0.0817**
00002486172	**NRA-RAMIPRIL**	**NRA**	$	**0.0817**
00002469065	**PHARMA-RAMIPRIL (CAPSULE)**	**PMS**	$	**0.0817**
00002287927	**RAMIPRIL (CAPSULE)**	**SIV**	$	**0.0817**
00002374846	**RAMIPRIL (CAPSULE)**	**SNS**	$	**0.0817**
00002310511	**RAN-RAMIPRIL (CAPSULE)**	**RAN**	$	**0.0817**
00002247945	**TEVA-RAMIPRIL (CAPSULE)**	**TEV**	$	**0.0817**
00002221837	ALTACE (CAPSULE)	VCL	$	0.8726

5 MG ORAL CAPSULE/TABLET

00002477580	**AG-RAMIPRIL (CAPSULE)**	**AGP**	$	**0.0817**
00002251574	**APO-RAMIPRIL (CAPSULE)**	**APX**	$	**0.0817**
00002387409	**AURO-RAMIPRIL (CAPSULE)**	**AUR**	$	**0.0817**
00002331136	**JAMP-RAMIPRIL (CAPSULE)**	**JPC**	$	**0.0817**
00002420473	**MAR-RAMIPRIL (CAPSULE)**	**MAR**	$	**0.0817**
00002421313	**MINT-RAMIPRIL (CAPSULE)**	**MPI**	$	**0.0817**
00002486180	**NRA-RAMIPRIL**	**NRA**	$	**0.0817**
00002469073	**PHARMA-RAMIPRIL (CAPSULE)**	**PMS**	$	**0.0817**
00002287935	**RAMIPRIL (CAPSULE)**	**SIV**	$	**0.0817**
00002374854	**RAMIPRIL (CAPSULE)**	**SNS**	$	**0.0817**
00002310538	**RAN-RAMIPRIL (CAPSULE)**	**RAN**	$	**0.0817**
00002247946	**TEVA-RAMIPRIL (CAPSULE)**	**TEV**	$	**0.0817**
00002221845	ALTACE (CAPSULE)	VCL	$	0.8954

RAMIPRIL

10 MG ORAL CAPSULE/TABLET

00002477599	**AG-RAMIPRIL (CAPSULE)**	**AGP**	$	**0.1034**
00002251582	**APO-RAMIPRIL (CAPSULE)**	**APX**	$	**0.1034**
00002387417	**AURO-RAMIPRIL (CAPSULE)**	**AUR**	$	**0.1034**
00002331144	**JAMP-RAMIPRIL (CAPSULE)**	**JPC**	$	**0.1034**
00002420481	**MAR-RAMIPRIL (CAPSULE)**	**MAR**	$	**0.1034**
00002421321	**MINT-RAMIPRIL (CAPSULE)**	**MPI**	$	**0.1034**
00002486199	**NRA-RAMIPRIL**	**NRA**	$	**0.1034**
00002469081	**PHARMA-RAMIPRIL (CAPSULE)**	**PMS**	$	**0.1034**
00002287943	**RAMIPRIL (CAPSULE)**	**SIV**	$	**0.1034**
00002374862	**RAMIPRIL (CAPSULE)**	**SNS**	$	**0.1034**
00002310546	**RAN-RAMIPRIL (CAPSULE)**	**RAN**	$	**0.1034**
00002247947	**TEVA-RAMIPRIL (CAPSULE)**	**TEV**	$	**0.1034**
00002221853	ALTACE (CAPSULE)	VCL	$	1.1501

ROSUVASTATIN CALCIUM

5 MG (BASE) ORAL TABLET

00002438917	**ACH-ROSUVASTATIN**	**AHI**	$	**0.1284**
00002477033	**AG-ROSUVASTATIN**	**AGP**	$	**0.1284**
00002337975	**APO-ROSUVASTATIN**	**APX**	$	**0.1284**
00002442574	**AURO-ROSUVASTATIN**	**AUR**	$	**0.1284**
00002498332	**JAMP ROSUVASTATIN CALCIUM**	**JPC**	$	**0.1284**
00002391252	**JAMP-ROSUVASTATIN**	**JPC**	$	**0.1284**
00002477483	**NRA-ROSUVASTATIN**	**NRA**	$	**0.1284**
00002378523	**PMS-ROSUVASTATIN**	**PMS**	$	**0.1284**
00002382644	**RAN-ROSUVASTATIN**	**RAN**	$	**0.1284**
00002405628	**ROSUVASTATIN**	**SNS**	$	**0.1284**
00002411628	**ROSUVASTATIN-5**	**SIV**	$	**0.1284**
00002338726	**SANDOZ ROSUVASTATIN**	**SDZ**	$	**0.1284**
00002354608	**TEVA-ROSUVASTATIN**	**TEV**	$	**0.1284**
00002265540	CRESTOR	AZC	$	1.3210

10 MG (BASE) ORAL TABLET

00002438925	**ACH-ROSUVASTATIN**	**AHI**	$	**0.1354**
00002477041	**AG-ROSUVASTATIN**	**AGP**	$	**0.1354**
00002337983	**APO-ROSUVASTATIN**	**APX**	$	**0.1354**
00002442582	**AURO-ROSUVASTATIN**	**AUR**	$	**0.1354**
00002498340	**JAMP ROSUVASTATIN CALCIUM**	**JPC**	$	**0.1354**
00002391260	**JAMP-ROSUVASTATIN**	**JPC**	$	**0.1354**
00002477491	**NRA-ROSUVASTATIN**	**NRA**	$	**0.1354**
00002378531	**PMS-ROSUVASTATIN**	**PMS**	$	**0.1354**
00002382652	**RAN-ROSUVASTATIN**	**RAN**	$	**0.1354**
00002405636	**ROSUVASTATIN**	**SNS**	$	**0.1354**
00002411636	**ROSUVASTATIN-10**	**SIV**	$	**0.1354**
00002338734	**SANDOZ ROSUVASTATIN**	**SDZ**	$	**0.1354**
00002354616	**TEVA-ROSUVASTATIN**	**TEV**	$	**0.1354**
00002247162	CRESTOR	AZC	$	1.3722

ROSUVASTATIN CALCIUM

20 MG (BASE) ORAL TABLET

00002438933	**ACH-ROSUVASTATIN**	**AHI**	$	**0.1692**
00002477068	**AG-ROSUVASTATIN**	**AGP**	$	**0.1692**
00002337991	**APO-ROSUVASTATIN**	**APX**	$	**0.1692**
00002442590	**AURO-ROSUVASTATIN**	**AUR**	$	**0.1692**
00002498359	**JAMP ROSUVASTATIN CALCIUM**	**JPC**	$	**0.1692**
00002391279	**JAMP-ROSUVASTATIN**	**JPC**	$	**0.1692**
00002477505	**NRA-ROSUVASTATIN**	**NRA**	$	**0.1692**
00002378558	**PMS-ROSUVASTATIN**	**PMS**	$	**0.1692**
00002382660	**RAN-ROSUVASTATIN**	**RAN**	$	**0.1692**
00002405644	**ROSUVASTATIN**	**SNS**	$	**0.1692**
00002411644	**ROSUVASTATIN-20**	**SIV**	$	**0.1692**
00002338742	**SANDOZ ROSUVASTATIN**	**SDZ**	$	**0.1692**
00002354624	**TEVA-ROSUVASTATIN**	**TEV**	$	**0.1692**
00002247163	CRESTOR	AZC	$	1.7152

40 MG (BASE) ORAL TABLET

00002438941	**ACH-ROSUVASTATIN**	**AHI**	$	**0.1990**
00002477076	**AG-ROSUVASTATIN**	**AGP**	$	**0.1990**
00002338009	**APO-ROSUVASTATIN**	**APX**	$	**0.1990**
00002442604	**AURO-ROSUVASTATIN**	**AUR**	$	**0.1990**
00002498367	**JAMP ROSUVASTATIN CALCIUM**	**JPC**	$	**0.1990**
00002391287	**JAMP-ROSUVASTATIN**	**JPC**	$	**0.1990**
00002477513	**NRA-ROSUVASTATIN**	**NRA**	$	**0.1990**
00002378566	**PMS-ROSUVASTATIN**	**PMS**	$	**0.1990**
00002382679	**RAN-ROSUVASTATIN**	**RAN**	$	**0.1990**
00002405652	**ROSUVASTATIN**	**SNS**	$	**0.1990**
00002411652	**ROSUVASTATIN-40**	**SIV**	$	**0.1990**
00002338750	**SANDOZ ROSUVASTATIN**	**SDZ**	$	**0.1990**
00002354632	**TEVA-ROSUVASTATIN**	**TEV**	$	**0.1990**
00002247164	CRESTOR	AZC	$	2.0076

SERTRALINE HCL

25 MG (BASE) ORAL CAPSULE

00002477882	**AG-SERTRALINE**	**AGP**	$	**0.1516**
00002238280	**APO-SERTRALINE**	**APX**	$	**0.1516**
00002390906	**AURO-SERTRALINE**	**AUR**	$	**0.1516**
00002357143	**JAMP-SERTRALINE**	**JPC**	$	**0.1516**
00002399415	**MAR-SERTRALINE**	**MAR**	$	**0.1516**
00002402378	**MINT-SERTRALINE**	**MPI**	$	**0.1516**
00002488434	**NRA-SERTRALINE**	**NRA**	$	**0.1516**
00002244838	**PMS-SERTRALINE**	**PMS**	$	**0.1516**
00002245159	**SANDOZ SERTRALINE**	**SDZ**	$	**0.1516**
00002353520	**SERTRALINE**	**SNS**	$	**0.1516**
00002386070	**SERTRALINE**	**SIV**	$	**0.1516**
00002469626	**SERTRALINE**	**JPC**	$	**0.1516**
00002240485	**TEVA-SERTRALINE**	**TEV**	$	**0.1516**
00002132702	ZOLOFT	UJC	$	0.8937

50 MG (BASE) ORAL CAPSULE

00002477890	**AG-SERTRALINE**	**AGP**	$	**0.3032**
00002238281	**APO-SERTRALINE**	**APX**	$	**0.3032**
00002390914	**AURO-SERTRALINE**	**AUR**	$	**0.3032**
00002357151	**JAMP-SERTRALINE**	**JPC**	$	**0.3032**
00002399423	**MAR-SERTRALINE**	**MAR**	$	**0.3032**
00002402394	**MINT-SERTRALINE**	**MPI**	$	**0.3032**
00002488442	**NRA-SERTRALINE**	**NRA**	$	**0.3032**
00002244839	**PMS-SERTRALINE**	**PMS**	$	**0.3032**
00002245160	**SANDOZ SERTRALINE**	**SDZ**	$	**0.3032**
00002353539	**SERTRALINE**	**SNS**	$	**0.3032**
00002386089	**SERTRALINE**	**SIV**	$	**0.3032**
00002469634	**SERTRALINE**	**JPC**	$	**0.3032**
00002240484	**TEVA-SERTRALINE**	**TEV**	$	**0.3032**
00001962817	ZOLOFT	UJC	$	1.7872

100 MG (BASE) ORAL CAPSULE

00002477904	**AG-SERTRALINE**	**AGP**	$	**0.3303**
00002238282	**APO-SERTRALINE**	**APX**	$	**0.3303**
00002390922	**AURO-SERTRALINE**	**AUR**	$	**0.3303**
00002357178	**JAMP-SERTRALINE**	**JPC**	$	**0.3303**
00002399431	**MAR-SERTRALINE**	**MAR**	$	**0.3303**
00002402408	**MINT-SERTRALINE**	**MPI**	$	**0.3303**
00002488450	**NRA-SERTRALINE**	**NRA**	$	**0.3303**
00002244840	**PMS-SERTRALINE**	**PMS**	$	**0.3303**
00002245161	**SANDOZ SERTRALINE**	**SDZ**	$	**0.3303**
00002353547	**SERTRALINE**	**SNS**	$	**0.3303**
00002386097	**SERTRALINE**	**SIV**	$	**0.3303**
00002469642	**SERTRALINE**	**JPC**	$	**0.3303**
00002240481	**TEVA-SERTRALINE**	**TEV**	$	**0.3303**
00001962779	ZOLOFT	UJC	$	1.9010

SODIUM POLYSTYRENE SULFONATE

ORAL POWDER

00000755338	**SOLYSTAT**	**PPH**	$	**0.0926**
00002026961	KAYEXALATE	SAV	$	0.1851

TELMISARTAN

40 MG ORAL TABLET

00002453568	**AURO-TELMISARTAN**	**AUR**	$	**0.2161**
00002386755	**JAMP TELMISARTAN**	**JPC**	$	**0.2161**
00002486369	**MINT-TELMISARTAN**	**MPI**	$	**0.2161**
00002499622	**PMS-TELMISARTAN**	**PMS**	$	**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**
00002499630	**PMS-TELMISARTAN**	**PMS**	$	**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

PART 3

Special Authorization

ADALIMUMAB

Polyarticular Juvenile Idiopathic Arthritis

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

"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

ADALIMUMAB

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).

20 MG / SYR INJECTION SYRINGE

☒ 00002505258	HYRIMOZ (20 MG/0.4 ML INJ SYR)	SDZ	$	235.6350
☒ 00002459310	AMGEVITA (20 MG/0.4 ML INJ SYR)	AMG	$	235.6400
☒ 00002474263	HUMIRA (20 MG/0.2 ML INJ SYR)	ABV	$	392.7250

Polyarticular Juvenile Idiopathic Arthritis

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

"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

ADALIMUMAB

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).

ADALIMUMAB

Ankylosing Spondylitis

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

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

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

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

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

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

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

Following this assessment, continued coverage may be approved for one 40 mg dose every other week for a period of 12 months. Ongoing coverage may be considered if the

ADALIMUMAB

patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

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

Hidradenitis Suppurativa

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

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

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

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

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

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

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

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

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

Following this assessment, continued coverage may be considered for one 40 mg dose of adalimumab every week for an additional period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12

ADALIMUMAB

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

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

Moderately to Severe Active Crohn's Disease

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

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

-Adalimumab must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross for adalimumab for coverage for the treatment of Moderately to Severely Active Crohn's Disease patients ('Specialist').
-Patients must be 18 years of age or older to be considered for coverage of adalimumab.
-Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
-Patients may be allowed to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy (both primary loss of response and secondary loss of response) or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
-Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
-Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

Moderately to Severely Active Crohn's Disease:

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

Refractory is defined as one or more of the following:
1) Serious adverse effects or reactions to the treatments specified below; OR
2) Contraindications (as defined in product monographs) to the treatments specified below; OR
3) Previous documented lack of effect at doses and for duration of all treatments

ADALIMUMAB

specified below:
a) mesalamine: minimum of 3 grams/day for a minimum of 6 weeks; AND refractory to, or dependent on, glucocorticoids: following at least one tapering dosing schedule of 40mg/day, tapering by 5 mg each week to 20 mg then tapering by 2.5mg each week to zero, or similar.

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

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

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

Coverage Criteria for Moderately to Severely Active Crohn's Disease

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

Induction Dosing for New Patients:

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

Maintenance Dosing:

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

Maintenance Dosing for New Patients after Completion of Induction Dosing:

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

Maintenance Dosing for Existing Patients:

ADALIMUMAB

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

Continued Coverage for Maintenance Dosing:

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

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

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

Plaque Psoriasis

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

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

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

ADALIMUMAB

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

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

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

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

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

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

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

Polyarticular Juvenile Idiopathic Arthritis

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

ADALIMUMAB

"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

ADALIMUMAB

maintained a response to therapy as indicated by maintenance of the ACR Pedi 30, 3) Data from all of the six variables comprising the ACR Pedi 30 and the CHAQ scores must be reported in each request.

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

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

Psoriatic Arthritis

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

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

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

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

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

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

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

ADALIMUMAB

were deemed unresponsive to therapy.
-Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

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

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

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

Rheumatoid Arthritis

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

"Special authorization coverage may be provided for use in combination with methotrexate for 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

ADALIMUMAB

-Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial). [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine];
AND
-Leflunomide (minimum 10 week trial at 20 mg daily).

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

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

40 MG / SYR INJECTION SYRINGE

☒	00002459299	AMGEVITA (40 MG/0.8 ML INJ SYR)	AMG	$	471.2700
☒	00002459302	AMGEVITA 40 MG/0.8 ML AUTOINJECTOR PEN	AMG	$	471.2700
☒	00002473100	HADLIMA (40 MG/0.8 ML INJ PEN)	SSB	$	471.2700
☒	00002473097	HADLIMA (40 MG/0.8 ML INJ SYR)	SSB	$	471.2700
☒	00002502402	HULIO (40 MG/0.8 ML INJ PEN)	BGP	$	471.2700
☒	00002502399	HULIO (40 MG/0.8 ML INJ SYR)	BGP	$	471.2700
☒	00002492156	HYRIMOZ (40 MG/0.8 ML INJ PEN)	SDZ	$	471.2700
☒	00002492164	HYRIMOZ (40 MG/0.8 ML INJ SYR)	SDZ	$	471.2700
☒	00002502674	IDACIO (40 MG/0.8 ML INJ PEN)	FKC	$	471.2700
☒	00002258595	HUMIRA (40 MG/0.8 ML INJ SYR)	ABV	$	785.4500

Ankylosing Spondylitis

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

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

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

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

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

-Initial coverage may be approved for 12 weeks as follows: An initial 40 mg dose, followed by additional 40 mg doses administered every two weeks for up to 12 weeks after the first dose.
-Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
-Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).

ADALIMUMAB

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

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

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

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

Hidradenitis Suppurativa

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

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

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

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

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

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

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

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

ADALIMUMAB

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

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

Moderately to Severe Active Crohn's Disease

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

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

-Adalimumab must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross for adalimumab for coverage for the treatment of Moderately to Severely Active Crohn's Disease patients ('Specialist').
-Patients must be 18 years of age or older to be considered for coverage of adalimumab.
-Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
-Patients may be allowed to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy (both primary loss of response and secondary loss of response) or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
-Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
-Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

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

Moderately to Severely Active Crohn's Disease:

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

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

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

AND
b) Immunosuppressive therapy as follows:
-Azathioprine: minimum of 2 mg/kg/day for a minimum of 3 months; OR
-6-mercaptopurine: minimum of 1mg/kg/day for a minimum of 3 months; OR

ADALIMUMAB

-Methotrexate: minimum of 15mg/week for a minimum of 3 months.
OR
-Immunosuppressive therapy discontinued at less than 3 months due to serious adverse effects or reactions.

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

Coverage Criteria for Moderately to Severely Active Crohn's Disease

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

Induction Dosing for New Patients:

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

Maintenance Dosing:

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

Maintenance Dosing for New Patients after Completion of Induction Dosing:

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

Maintenance Dosing for Existing Patients:

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

Continued Coverage for Maintenance Dosing:

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

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

ADALIMUMAB

Patient's Baseline Score."

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

Plaque Psoriasis

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

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

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

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

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

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

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

ADALIMUMAB

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

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

Polyarticular Juvenile Idiopathic Arthritis

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

"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

ADALIMUMAB

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

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

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

Psoriatic Arthritis

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

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

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

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

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

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

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

For continued coverage beyond 8 weeks, the patient must meet the following criteria:
1) The patient must be assessed by an RA Specialist after 8 weeks, but no longer than 12 weeks after, treatment with this biologic agent to determine response.
2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following

ADALIMUMAB

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

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

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

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

Rheumatoid Arthritis

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

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

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

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

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

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

-Initial coverage may be approved for five doses as follows: An initial 40 mg dose, followed by additional 40 mg doses at 2, 4, 6 and 8 weeks after the first dose.
-Patients will be limited to receiving a one-month supply of adalimumab per prescription at their pharmacy.
-Patients will be permitted to switch from one biologic agent to another (with the exception of

ADALIMUMAB

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

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

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

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

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

Ulcerative Colitis

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

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

ADALIMUMAB

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

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

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

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

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

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

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

BENRALIZUMAB

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

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

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

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

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

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

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

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

30 MG / SYR INJECTION SYRINGE

☒	00002473232	FASENRA	AZC	$ 3876.9200
☒	00002496135	FASENRA (PEN)	AZC	$ 3876.9200

CYSTEAMINE BITARTRATE

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

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

Special authorization may be granted for 12 months."

This product is eligible for auto-renewal.

25 MG ORAL DELAYED-RELEASE CAPSULE

00002464705	PROCYSBI	RAP	$	10.3500

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

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

Special authorization may be granted for 12 months."

This product is eligible for auto-renewal.

75 MG ORAL DELAYED-RELEASE CAPSULE

00002464713	PROCYSBI	RAP	$	31.0500

DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE

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

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

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

Special authorization may be granted for 24 months.

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

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

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

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

DEFERASIROX

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

FIRST-LINE DRUG PRODUCT(S): DEFEROXAMINE

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

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

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

Special authorization may be granted for 24 months."

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

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

90 MG ORAL TABLET

00002485265	**APO-DEFERASIROX (TYPE J)**	**APX**	$	**5.2605**
00002507315	**TARO-DEFERASIROX (TYPE J)**	**TAR**	$	**5.2605**
00002452219	JADENU	NOV	$	10.5210

DEFERASIROX

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

FIRST-LINE DRUG PRODUCT(S): DEFEROXAMINE

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

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

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

Special authorization may be granted for 24 months."

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

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

180 MG ORAL TABLET

00002485273	**APO-DEFERASIROX (TYPE J)**	**APX**	$	**10.5220**
00002507323	**TARO-DEFERASIROX (TYPE J)**	**TAR**	$	**10.5220**
00002452227	JADENU	NOV	$	21.0440

DEFERASIROX

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

FIRST-LINE DRUG PRODUCT(S): DEFEROXAMINE

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

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

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

Special authorization may be granted for 24 months."

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

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

360 MG ORAL TABLET

00002485281	**APO-DEFERASIROX (TYPE J)**	**APX**	$	**21.0455**
00002507331	**TARO-DEFERASIROX (TYPE J)**	**TAR**	$	**21.0455**
00002452235	JADENU	NOV	$	42.0910

ETANERCEPT

25 MG / VIAL INJECTION

00002242903	ENBREL	AMG	$	200.7100

Plaque Psoriasis

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

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

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

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

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

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

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

-Initial coverage may be approved for up to 100 mg per week for 12 weeks.
-Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- 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

ETANERCEPT

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

Polyarticular Juvenile Idiopathic Arthritis

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

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

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

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

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

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

ETANERCEPT

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).

ETANERCEPT

25 MG / SYR INJECTION SYRINGE

00002462877	ERELZI	SDZ	$	120.5000

Ankylosing Spondylitis

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

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

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

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

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

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

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

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

Plaque Psoriasis

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

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

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

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

ETANERCEPT

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

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

ETANERCEPT

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

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

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

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

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

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

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

Psoriatic Arthritis

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

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

ETANERCEPT

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

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

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

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

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

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

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

Rheumatoid Arthritis

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

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

Special authorization coverage of this agent may be provided for use as monotherapy in adult

ETANERCEPT

patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

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

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

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

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

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

All requests (including renewal requests) for etanercept for Rheumatoid Arthritis must be completed using the
Abatacept/Adalimumab/Anakinra/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 Special Authorization requests for etanercept for patients weighing 63 kg or more will be assessed for coverage with an etanercept biosimilar. The originator drug, Enbrel, will be approved for new etanercept starts for pediatric patients with Polyarticular Juvenile Idiopathic Arthritis or Plaque Psoriasis weighing less than 63 kg.

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

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

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

ETANERCEPT

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

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

ETANERCEPT

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

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

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

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

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

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

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

Psoriatic Arthritis

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

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

ETANERCEPT

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

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

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

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

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

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

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

Rheumatoid Arthritis

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

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

Special authorization coverage of this agent may be provided for use as monotherapy in adult

ETANERCEPT

patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

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

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

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

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

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

All requests (including renewal requests) for etanercept for Rheumatoid Arthritis must be completed using the
Abatacept/Adalimumab/Anakinra/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

ETANERCEPT

- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

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

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

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

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

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

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

Plaque Psoriasis

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

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

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

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

Patients who have a contraindication to either cyclosporine or methotrexate will be required to 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

ETANERCEPT

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

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

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

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

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

- Coverage may be approved for 0.8 mg/kg/dose (maximum dose 50 mg) weekly for 12 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of abatacept) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the

ETANERCEPT

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

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

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

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

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

Psoriatic Arthritis

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

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

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

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.
'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").

ETANERCEPT

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

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

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

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

Rheumatoid Arthritis

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

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

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

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

ETANERCEPT

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

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

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

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

ETANERCEPT

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

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

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

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

Plaque Psoriasis

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

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

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

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

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

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

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

ETANERCEPT

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

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

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

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

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

For continued coverage of this agent beyond 12 weeks, the patient must meet the following criteria:
1) The patient must be assessed by a Pediatric Rheumatology Specialist after 12 weeks, but no longer than 16 weeks after, treatment with this biologic agent to determine response.

ETANERCEPT

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

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

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

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

Psoriatic Arthritis

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

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

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

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

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

- Initial coverage may be approved for 50 mg per week for 8 weeks.
- Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial 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.

ETANERCEPT

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

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

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

Rheumatoid Arthritis

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

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

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

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

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

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

ETANERCEPT

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

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

All requests (including renewal requests) for etanercept for Rheumatoid Arthritis must be completed using the
Abatacept/Adalimumab/Anakinra/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

ETANERCEPT

therapy to determine response.
2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
- Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
- Reduction of the Spinal Pain VAS by 2 cm or more.

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

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

Plaque Psoriasis

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

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

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

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

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

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

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

-Initial coverage may be approved for up to 100 mg per week for 12 weeks.
-Patients will be limited to receiving a one-month supply of etanercept per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- 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:

ETANERCEPT

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

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

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

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

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

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

ETANERCEPT

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

ETANERCEPT

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

ETANERCEPT

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).

IRON ISOMALTOSIDE 1000

"For the treatment of iron deficiency anemia (IDA) in adult patients who have intolerance OR have an inadequate response to a trial of oral iron therapy, OR in whom oral iron therapy is contraindicated.

"Intolerance" is defined as the persistence of gastrointestinal side-effects despite having tried:
-an adequate trial of at least two different formulations of oral iron (e.g. iron salts, polysaccharide iron, heme iron), or
-taking oral iron with small amounts of food, or
-utilizing alternate day dosing regimen of oral iron, or
-oral iron has been titrated up from low-dose.

"Inadequate response" is defined as one or more of the following:
-Hemoglobin (Hb) continues to decline while on oral iron therapy (Hb <90 g/L), or
-Hb increases less than 10 g/L after three months of oral iron therapy.

Contraindications to oral iron therapy may include the following:
-Patients have clinical malabsorption (e.g. history of bariatric surgery, clinically active Inflammatory Bowel Disease (IBD), Celiac disease, Chronic Kidney Disease, short bowel syndrome), or
-Patients have chronic blood loss, in which the pace of iron loss exceed ability to replete from oral iron intake, or
-Patients have time-limited conditions (i.e. perioperative) where oral iron will not provide adequate Hb levels.

This Product must be administered in a setting where appropriate monitoring and management of hypersensitivity reactions can be provided.

Special authorization may be granted for 12 months.
Renewal requests may be considered if intravenous iron is required to maintain normal hemoglobin in patients for whom the underlying cause of iron deficiency anemia cannot be resolved (e.g. ongoing blood losses)."

All requests for iron isomaltoside 1000 must be completed using the Iron Isomaltoside 1000 Special Authorization Request Form (ABC 60085).

100 MG / ML (BASE)	INJECTION			
00002477777	MONOFERRIC	PFI	$	45.0000

LACOSAMIDE

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

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

Special authorization may be granted for six months.

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

Each of these products is eligible for auto-renewal.

50 MG ORAL TABLET

00002475332	**AURO-LACOSAMIDE**	**AUR**	$	**0.6313**
00002488388	**JAMP-LACOSAMIDE**	**JPC**	$	**0.6313**
00002487802	**MAR-LACOSAMIDE**	**MAR**	$	**0.6313**
00002490544	**MINT-LACOSAMIDE**	**MPI**	$	**0.6313**
00002499568	**NRA-LACOSAMIDE**	**NRA**	$	**0.6313**
00002478196	**PHARMA-LACOSAMIDE**	**PMS**	$	**0.6313**
00002474670	**SANDOZ LACOSAMIDE**	**SDZ**	$	**0.6313**
00002472902	**TEVA-LACOSAMIDE**	**TEV**	$	**0.6313**
00002357615	VIMPAT	UCB	$	2.4093

100 MG ORAL TABLET

00002475340	**AURO-LACOSAMIDE**	**AUR**	$	**0.8750**
00002488396	**JAMP-LACOSAMIDE**	**JPC**	$	**0.8750**
00002487810	**MAR-LACOSAMIDE**	**MAR**	$	**0.8750**
00002490552	**MINT-LACOSAMIDE**	**MPI**	$	**0.8750**
00002499576	**NRA-LACOSAMIDE**	**NRA**	$	**0.8750**
00002478218	**PHARMA-LACOSAMIDE**	**PMS**	$	**0.8750**
00002474689	**SANDOZ LACOSAMIDE**	**SDZ**	$	**0.8750**
00002472910	**TEVA-LACOSAMIDE**	**TEV**	$	**0.8750**
00002357623	VIMPAT	UCB	$	3.4477

150 MG ORAL TABLET

00002475359	**AURO-LACOSAMIDE**	**AUR**	$	**1.1763**
00002488418	**JAMP-LACOSAMIDE**	**JPC**	$	**1.1763**
00002487829	**MAR-LACOSAMIDE**	**MAR**	$	**1.1763**
00002490560	**MINT-LACOSAMIDE**	**MPI**	$	**1.1763**
00002499584	**NRA-LACOSAMIDE**	**NRA**	$	**1.1763**
00002478226	**PHARMA-LACOSAMIDE**	**PMS**	$	**1.1763**
00002474697	**SANDOZ LACOSAMIDE**	**SDZ**	$	**1.1763**
00002472929	**TEVA-LACOSAMIDE**	**TEV**	$	**1.1763**
00002357631	VIMPAT	UCB	$	4.4862

200 MG ORAL TABLET

00002475367	**AURO-LACOSAMIDE**	**AUR**	$	**1.4500**
00002488426	**JAMP-LACOSAMIDE**	**JPC**	$	**1.4500**
00002487837	**MAR-LACOSAMIDE**	**MAR**	$	**1.4500**
00002490579	**MINT-LACOSAMIDE**	**MPI**	$	**1.4500**
00002499592	**NRA-LACOSAMIDE**	**NRA**	$	**1.4500**
00002478234	**PHARMA-LACOSAMIDE**	**PMS**	$	**1.4500**
00002474700	**SANDOZ LACOSAMIDE**	**SDZ**	$	**1.4500**
00002472937	**TEVA-LACOSAMIDE**	**TEV**	$	**1.4500**
00002357658	VIMPAT	UCB	$	5.5247

LANADELUMAB

150 MG / ML INJECTION

☒	00002480948	TAKHZYRO	SHB	$ 10269.0000
☒	00002505614	TAKHZYRO (SYRINGE)	SHB	$ 10269.0000

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

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

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

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

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

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

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

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

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

00002144336	**CARNITOR**	**SGM**	$	**0.3809**
00002492105	**ODAN LEVOCARNITINE**	**ODN**	$	**0.3809**

MODAFINIL

"For the treatment of documented narcolepsy. This drug product must be prescribed by a specialist in Neurology or Psychiatry, or a sleep specialist affiliated with a recognized level 1 lab.

Special authorization may be granted for 6 months."

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

100 MG ORAL TABLET

00002285398	**APO-MODAFINIL**	**APX**	$	**0.3427**
00002430487	**AURO-MODAFINIL**	**AUR**	$	**0.3427**
00002503727	**JAMP MODAFINIL**	**JPC**	$	**0.3427**
00002432560	**MAR-MODAFINIL**	**MAR**	$	**0.3427**
00002420260	**TEVA-MODAFINIL**	**TEV**	$	**0.3427**
00002239665	ALERTEC	TMP	$	1.4700

PEGFILGRASTIM

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

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

Please note: Coverage cannot be considered for palliative patients.

6 MG / SYR INJECTION SYRINGE

☒ 00002506238	NYVEPRIA (0.6 ML SYRINGE)	PFI	$	1375.0000
☒ 00002484153	FULPHILA (0.6 ML SYRINGE)	BGP	$	1424.6300
☒ 00002474565	LAPELGA (0.6 ML SYRINGE)	APX	$	1424.6300
☒ 00002497395	ZIEXTENZO (0.6 ML SYRINGE)	SDZ	$	1424.6300

TAFAMIDIS MEGLUMINE

20 MG ORAL CAPSULE

00002495732	VYNDAQEL	PFI	$	133.5700

"For the treatment of cardiomyopathy due to transthyretin-mediated amyloidosis (ATTR-CM), wild-type or hereditary, to reduce cardiovascular mortality and cardiovascular-related hospitalization in adult patients who meet the following criteria:
- Documented wild-type ATTR-CM* OR documented hereditary ATTR-CM**
And
- New York Heart Association (NYHA) class I to III
And
- a history of heart failure, defined as at least one prior hospitalization for heart failure or clinical evidence of heart failure that required treatment with a diuretic
And
- have not received a heart or liver transplant
And
- do not have an implanted cardiac mechanical assist device (CMAD)
* Documented wild-type ATTR-CM consists of all of the following: absence of a variant TTR genotype; evidence of cardiac involvement by echocardiography with end diastolic interventricular septal wall thickness of greater than 12 mm; presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connective tissue sheath, or cardiac); and TTR precursor protein identification by immunohistochemistry, scintigraphy, or mass spectrometry.
** Documented hereditary ATTR-CM consists of all of the following: presence of a variant TTR genotype associated with cardiomyopathy and presenting with a cardiomyopathy phenotype; evidence of cardiac involvement by echocardiography with end diastolic interventricular septal wall thickness of greater than 12 mm; presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connective tissue sheath, or cardiac).
For coverage, this drug must be prescribed by a Specialist in Cardiology, Internal Medicine or Oncology.
Initial coverage may be approved up to 80 mg once daily for 6 months.
Patients will be limited to receiving a one-month supply of tafamidis per prescription at their pharmacy.
For renewal of coverage, patients must NOT have:
- progressed to NYHA class IV, NOR
- received a heart or liver transplant, NOR
- received an implanted CMAD
Continued coverage may be approved for up to 80 mg once daily for a period of 6 months.
Coverage cannot be provided for use in combination with other disease modifying treatments for ATTR including interfering ribonucleic acid drugs or transthyretin stabilizers."

All requests for tafamidis meglumine must be completed using the Tafamidis for ATTR-CM Special Authorization Request Form (ABC 60086).

TEDUGLUTIDE

"Special authorization coverage may be provided for the treatment of adult patients (18 years of age or older) with short bowel syndrome (SBS) if all of the following criteria are met:

- SBS is a result of major intestinal resection (e.g., due to injury, volvulus, vascular disease, cancer, Crohn's Disease), and

- Resection has resulted in dependency on parenteral nutrition (PN) for at least 12 months, and

- PN is required at least three times weekly to meet caloric, fluid or electrolyte needs due to ongoing malabsorption, and

- PN frequency and volume have been stable for at least one month.

For coverage, the drug must be initiated and monitored by a specialist in gastroenterology or an internal medicine specialist with an interest in gastroenterology on a case-by-case basis, in geographic areas where access to this specialty is not available ('Specialist').

Initial coverage may be approved for up to 24 weeks of 0.05 mg/kg/day administered subcutaneously once daily.

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

For continued coverage beyond 24 weeks, the patient must meet the following criteria:

1) The patient must be assessed by the Specialist between weeks 20 and 24, after initiation of therapy to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' as demonstrated by:
- at least a 20% reduction in weekly PN volume from baseline.

Following this assessment, continued coverage may be provided for 0.05 mg/kg/day administered subcutaneously once daily for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

1) The patient has been assessed by the Specialist to determine response;

2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:

- confirmation of maintenance of at least a 20% reduction in weekly PN volume from baseline."

5 MG / VIAL INJECTION

00002445727	REVESTIVE	TAK	$	904.0000

Adult Short Bowel Syndrome

"Special authorization coverage may be provided for the treatment of adult patients (18 years of age or older) with short bowel syndrome (SBS) if all of the following criteria are met:

- SBS is a result of major intestinal resection (e.g., due to injury, volvulus, vascular disease, cancer, Crohn's Disease), and

- Resection has resulted in dependency on parenteral nutrition (PN) for at least 12 months, and

- PN is required at least three times weekly to meet caloric, fluid or electrolyte needs due to ongoing malabsorption, and

- PN frequency and volume have been stable for at least one month.

For coverage, the drug must be initiated and monitored by a specialist in gastroenterology or an internal medicine specialist with an interest in gastroenterology on a case-by-case basis, in geographic areas where access to this specialty is not available ('Specialist').

TEDUGLUTIDE

Initial coverage may be approved for up to 24 weeks of 0.05 mg/kg/day administered subcutaneously once daily.

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

For continued coverage beyond 24 weeks, the patient must meet the following criteria:

1) The patient must be assessed by the Specialist between weeks 20 and 24, after initiation of therapy to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' as demonstrated by:
- at least a 20% reduction in weekly PN volume from baseline.

Following this assessment, continued coverage may be provided for 0.05 mg/kg/day administered subcutaneously once daily for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

1) The patient has been assessed by the Specialist to determine response;

2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:

- confirmation of maintenance of at least a 20% reduction in weekly PN volume from baseline."

Pediatric Short Bowel Syndrome

"Special authorization coverage may be provided for the treatment of pediatric patients (between 1 and 17 years of age) with short bowel syndrome (SBS) if all of the following criteria are met:
- Cumulative lifetime duration of parenteral support therapy must be at least 12 months, and
- Parenteral support must provide more than 30% of caloric and/or fluid/electrolyte needs, and
- Parenteral support requirements must be stable or there must have been no improvement in enteral feeding for at least the preceding three months.
For coverage, the drug must be initiated and monitored by a physician currently working within a specialized multi-disciplinary intestinal rehabilitation program ('Specialist').
Initial coverage may be approved for up to 24 weeks of 0.05 mg/kg/day administered subcutaneously once daily.
- Patients will be limited to receiving a four week supply of teduglutide per prescription at their pharmacy.
For continued coverage beyond 24 weeks, the patient must meet the following criteria:
1) The patient must be assessed by the Specialist between weeks 20 and 24, after initiation of therapy to determine response.
2) The Specialist must confirm in writing that the patient is a 'responder' as demonstrated by:
- at least a 20% reduction in parenteral support volume compared to the baseline volume.

Following this assessment, continued coverage may be provided for 0.05 mg/kg/day administered subcutaneously once daily for a period of 6 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 6-month period:

1) The patient has been assessed by the Specialist to determine a continued response to treatment.

Note: Discontinuation of treatment should be based on the prescribing physician's assessment of the patient's response and tolerance to treatment with teduglutide."