

Updates to the Alberta Drug Benefit List

Effective March 1, 2024



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Administered by Alberta Blue Cross
on behalf of Alberta Health.

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

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Special Authorization

The following drug product(s) will be considered for coverage by Special Authorization effective March 1, 2024 for patients covered under Alberta government-sponsored drug programs.

New Drug Product(s) Available by Special Authorization

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
EMPAVELI 54 MG / VIAL INJECTION	PEGCETACOPLAN	00002533294	BVM
ULTOMIRIS 10 MG / ML INJECTION	RAVULIZUMAB	00002491559	APG
ULTOMIRIS (1100 MG / 11 ML) 100 MG / ML INJECTION	RAVULIZUMAB	00002533456	APG
ULTOMIRIS (300 MG / 3 ML) 100 MG / ML INJECTION	RAVULIZUMAB	00002533448	APG

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

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
FEBUXOSTAT 80 MG TABLET	FEBUXOSTAT	00002539837	SNS
SKYRIZI 600 MG / VIAL INJECTION	RISANKIZUMAB	00002532107	ABV
SKYRIZI 360 MG INJECTION CARTRIDGE	RISANKIZUMAB	00002532093	ABV
TARO-PERAMPANEL 2 MG TABLET	PERAMPANEL	00002522632	TAR
TARO-PERAMPANEL 4 MG TABLET	PERAMPANEL	00002522640	TAR
TARO-PERAMPANEL 6 MG TABLET	PERAMPANEL	00002522659	TAR
TARO-PERAMPANEL 8 MG TABLET	PERAMPANEL	00002522667	TAR
TARO-PERAMPANEL 10 MG TABLET	PERAMPANEL	00002522675	TAR
TARO-PERAMPANEL 12 MG TABLET	PERAMPANEL	00002522683	TAR
XOLAIR 75 MG / SYRINGE INJECTION	OMALIZUMAB	00002459787	NOV
XOLAIR 150 MG / SYRINGE INJECTION	OMALIZUMAB	00002459795	NOV

Drug Product(s) with Changes to Criteria for Coverage

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
TREMFYA ONE-PRESS 100 MG / SYRINGE INJECTION	GUSELKUMAB	00002487314	JAI

Restricted Benefit(s)

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

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
TEVA-AMPHETAMINE XR (25 MG) 6.25 MG / 6.25 MG / 6.25 MG / 6.25 MG EXTENDED-RELEASE CAPSULE	AMPHETAMINE SULFATE/ AMPHETAMINE ASPARTATE/ DEXTROAMPHETAMINE SULFATE/ DEXTROAMPHETAMINE SACCHARATE	00002439271	TEV

Drug Product(s) with Changes to Benefit Status

The following drug product(s) previously covered as restricted benefits will now be covered as regular benefits effective March 1, 2024.

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
APO-RIVAROXABAN 10 MG TABLET	RIVAROXABAN	00002470497	APX
PMS-RIVAROXABAN 10 MG TABLET	RIVAROXABAN	00002512041	PMS
REDDY-RIVAROXABAN 10 MG TABLET	RIVAROXABAN	00002472414	DRL
RIVAROXABAN 10 MG TABLET	RIVAROXABAN	00002541475	SIV
SANDOZ RIVAROXABAN 10 MG TABLET	RIVAROXABAN	00002482223	SDZ
TARO-RIVAROXABAN 10 MG TABLET	RIVAROXABAN	00002483807	TAR
TEVA-RIVAROXABAN 10 MG TABLET	RIVAROXABAN	00002507196	TEV
XARELTO 10 MG TABLET	RIVAROXABAN	00002316986	BAI

The following drug product(s) previously covered through Step Therapy / Special Authorization will now be covered as regular benefits effective March 1, 2024.

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
APO-RIVAROXABAN 15 MG TABLET	RIVAROXABAN	00002470500	APX
APO-RIVAROXABAN 20 MG TABLET	RIVAROXABAN	00002470519	APX
PMS-RIVAROXABAN 15 MG TABLET	RIVAROXABAN	00002512068	PMS
PMS-RIVAROXABAN 20 MG TABLET	RIVAROXABAN	00002512076	PMS
REDDY-RIVAROXABAN 15 MG TABLET	RIVAROXABAN	00002472430	DRL
REDDY-RIVAROXABAN 20 MG TABLET	RIVAROXABAN	00002472422	DRL
RIVAROXABAN 15 MG TABLET	RIVAROXABAN	00002541483	SIV
RIVAROXABAN 20 MG TABLET	RIVAROXABAN	00002541491	SIV
SANDOZ RIVAROXABAN 15 MG TABLET	RIVAROXABAN	00002482231	SDZ
SANDOZ RIVAROXABAN 20 MG TABLET	RIVAROXABAN	00002482258	SDZ
TARO-RIVAROXABAN 15 MG TABLET	RIVAROXABAN	00002483815	TAR
TARO-RIVAROXABAN 20 MG TABLET	RIVAROXABAN	00002483823	TAR
TEVA-RIVAROXABAN 15 MG TABLET	RIVAROXABAN	00002507218	TEV

Drug Product(s) with Changes to Benefit Status, continued

The following drug product(s) previously covered through Step Therapy / Special Authorization will now be covered as regular benefits effective March 1, 2024.

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
TEVA-RIVAROXABAN 20 MG TABLET	RIVAROXABAN	00002507226	TEV
XARELTO 15 MG TABLET	RIVAROXABAN	00002378604	BAI
XARELTO 20 MG TABLET	RIVAROXABAN	00002378612	BAI

The following drug product(s) previously covered through Special Authorization will now be covered as regular benefits effective March 1, 2024.

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
APO-RIVAROXABAN 2.5 MG TABLET	RIVAROXABAN	00002541734	APX
PMS-RIVAROXABAN 2.5 MG TABLET	RIVAROXABAN	00002527537	PMS
REDDY-RIVAROXABAN 2.5 MG TABLET	RIVAROXABAN	00002524503	DRL
RIVAROXABAN 2.5 MG TABLET	RIVAROXABAN	00002541467	SIV
SANDOZ RIVAROXABAN 2.5 MG TABLET	RIVAROXABAN	00002537877	SDZ
TARO-RIVAROXABAN 2.5 MG TABLET	RIVAROXABAN	00002526786	TAR
XARELTO 2.5 MG TABLET	RIVAROXABAN	00002480808	BAI

Added Product(s)

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
ACCEL-ONDANSETRON ODT 4 MG ORAL DISINTEGRATING TABLET / FILM	ONDANSETRON	00002535319	ACP
ACCEL-ONDANSETRON ODT 8 MG ORAL DISINTEGRATING TABLET / FILM	ONDANSETRON	00002535327	ACP
APO-DAPAGLIFLOZIN-METFORMIN 5 MG / 850 MG TABLET	DAPAGLIFLOZIN/ METFORMIN HCL	00002536153	APX
APO-DAPAGLIFLOZIN-METFORMIN 5 MG / 1000 MG TABLET	DAPAGLIFLOZIN/ METFORMIN HCL	00002536161	APX
ATENOLOL 25 MG TABLET	ATENOLOL	00002541564	SIV
AURO-CEPHALEXIN 25 MG / ML ORAL SUSPENSION	CEPHALEXIN	00002497743	AUR
BIJUVA 1 MG / 100 MG CAPSULE	ESTRADIOL-17B/ PROGESTERONE	00002505223	KTI
JAMP CEPHALEXIN 25 MG / ML ORAL SUSPENSION	CEPHALEXIN	00002528436	JPC
JAMP CEPHALEXIN 50 MG / ML ORAL SUSPENSION	CEPHALEXIN	00002528444	JPC
JAMP ESCITALOPRAM 10 MG TABLET	ESCITALOPRAM	00002508893	JPC
JAMP ESCITALOPRAM 20 MG TABLET	ESCITALOPRAM	00002508907	JPC
JAMP QUINAPRIL 10 MG TABLET	QUINAPRIL	00002517450	JPC

Added Product(s), continued

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
JAMP QUINAPRIL 20 MG TABLET	QUINAPRIL	00002517469	JPC
JAMP QUINAPRIL 40 MG TABLET	QUINAPRIL	00002517477	JPC
JAMP TOPIRAMATE 200 MG TABLET	TOPIRAMATE	00002345277	JPC
M-CITALOPRAM 10 MG TABLET	CITALOPRAM HYDROBROMIDE	00002532123	MTR
MINT-ATORVASTATIN 80 MG TABLET	ATORVASTATIN CALCIUM	00002479532	MPI
MINT-CANDESARTAN 32 MG TABLET	CANDESARTAN CILEXETIL	00002476932	MPI
NRA-MIRTAZAPINE 30 MG TABLET	MIRTAZAPINE	00002534932	NRA
PRZ-AMOXICILLIN 250 MG CAPSULE	AMOXICILLIN TRIHYDRATE	00002532042	PCI
PRZ-AMOXICILLIN 500 MG CAPSULE	AMOXICILLIN TRIHYDRATE	00002532050	PCI
PRZ-DOXYCYCLINE 100 MG TABLET	DOXYCYCLINE HYCLATE	00002536250	PCI
PRZ-METFORMIN 1000 MG TABLET	METFORMIN HCL	00002534673	PCI
TEVA-APIXABAN 2.5 MG TABLET	APIXABAN	00002484994	TEV
TEVA-APIXABAN 5 MG TABLET	APIXABAN	00002485001	TEV
TEVA-SALBUTAMOL HFA 100 MCG / DOSE INHALATION METERED DOSE AEROSOL	SALBUTAMOL	00002326450	TEV

New Established Interchangeable (IC) Grouping(s)

The following IC Grouping(s) have been established and LCA pricing will be applied effective April 1, 2024.

<u>Generic Description</u>	<u>Strength / Form</u>	<u>New LCA Price</u>
CEPHALEXIN	25 MG / ML ORAL SUSPENSION	0.1535
CEPHALEXIN	50 MG / ML ORAL SUSPENSION	0.2573
PERAMPANEL	2 MG TABLET	7.7902
PERAMPANEL	4 MG TABLET	7.7902
PERAMPANEL	6 MG TABLET	7.7902
PERAMPANEL	8 MG TABLET	7.7902
PERAMPANEL	10 MG TABLET	7.7902
PERAMPANEL	12 MG TABLET	7.7902

Least Cost Alternative (LCA) Price Change(s)

The following established IC Grouping(s) are affected and a revised LCA price has been established. Groupings affected by a price decrease, will be effective April 1, 2024. Please review the online [Interactive Drug Benefit List](#) for further information.

<u>Generic Description</u>	<u>Strength / Form</u>	<u>New LCA Price</u>
DAPAGLIFLOZIN/ METFORMIN HCL	5 MG / 850 MG TABLET	0.6432
DAPAGLIFLOZIN/ METFORMIN HCL	5 MG / 1000 MG TABLET	0.6432

Least Cost Alternative (LCA) Price Change(s), continued

<u>Generic Description</u>	<u>Strength / Form</u>	<u>New LCA Price</u>
DOXYCYCLINE HYCLATE	100 MG TABLET	0.4560
FENTANYL	12 MCG / HR TRANSDERMAL PATCH	3.3200
QUINAPRIL	10 MG TABLET	0.2321
QUINAPRIL	20 MG TABLET	0.2321
QUINAPRIL	40 MG TABLET	0.2321

Product(s) with a Price Change

The following product(s) had a Price Change. The previous higher price will be recognized until March 31, 2024. For products within an established IC Grouping, the LCA price may apply.

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
APO-DOXY 100 MG TABLET	DOXYCYCLINE HYCLATE	00000874256	APX
APO-QUINAPRIL 10 MG TABLET	QUINAPRIL	00002248500	APX
APO-QUINAPRIL 20 MG TABLET	QUINAPRIL	00002248501	APX
APO-QUINAPRIL 40 MG TABLET	QUINAPRIL	00002248502	APX
AURO-DAPAGLIFLOZIN/METFORMIN 5 MG / 850 MG TABLET	DAPAGLIFLOZIN/ METFORMIN HCL	00002533073	AUR
AURO-DAPAGLIFLOZIN/METFORMIN 5 MG / 1000 MG TABLET	DAPAGLIFLOZIN/ METFORMIN HCL	00002533081	AUR
DOXYCYCLINE 100 MG TABLET	DOXYCYCLINE HYCLATE	00002351242	SNS
MINOCYCLINE 50 MG CAPSULE	MINOCYCLINE HCL	00002084090	AAP
MINOCYCLINE 100 MG CAPSULE	MINOCYCLINE HCL	00002084104	AAP
PMS-QUINAPRIL 10 MG TABLET	QUINAPRIL	00002340569	PMS
PMS-QUINAPRIL 20 MG TABLET	QUINAPRIL	00002340577	PMS
PMS-QUINAPRIL 40 MG TABLET	QUINAPRIL	00002340585	PMS
SANDOZ FENTANYL PATCH 12 MCG / HR TRANSDERMAL PATCH	FENTANYL	00002327112	SDZ
TEVA-CEPHALEXIN 125 25 MG / ML ORAL SUSPENSION	CEPHALEXIN	00000342106	TEV
TEVA-CEPHALEXIN 250 50 MG / ML ORAL SUSPENSION	CEPHALEXIN	00000342092	TEV
TEVA-DOXYCYCLINE 100 MG TABLET	DOXYCYCLINE HYCLATE	00002158574	TEV
TEVA-FENTANYL 12 MCG / HR TRANSDERMAL PATCH	FENTANYL	00002311925	TEV

PART 2

Drug Additions

ALBERTA DRUG BENEFIT LIST UPDATE

AMOXICILLIN TRIHYDRATE

250 MG (BASE) ORAL CAPSULE				
00002525348	AMOXICILLIN BP	SNS	\$	0.0672
00000628115	APO-AMOXI	APX	\$	0.0672
00002388073	AURO-AMOXICILLIN	AUR	\$	0.0672
00002433060	JAMP-AMOXICILLIN	JPC	\$	0.0672
00000406724	NOVAMOXIN	TEV	\$	0.0672
00002532042	PRZ-AMOXICILLIN	PCI	\$	0.0672
500 MG (BASE) ORAL CAPSULE				
00002477726	AG-AMOXICILLIN	AGP	\$	0.1308
00002401509	AMOXICILLIN	SIV	\$	0.1308
00002525356	AMOXICILLIN BP	SNS	\$	0.1308
00000628123	APO-AMOXI	APX	\$	0.1308
00002388081	AURO-AMOXICILLIN	AUR	\$	0.1308
00002433079	JAMP-AMOXICILLIN	JPC	\$	0.1308
00000406716	NOVAMOXIN	TEV	\$	0.1308
00002532050	PRZ-AMOXICILLIN	PCI	\$	0.1308

**AMPHETAMINE SULFATE/ AMPHETAMINE ASPARTATE/
 DEXTROAMPHETAMINE SULFATE/ DEXTROAMPHETAMINE
 SACCHARATE**

RESTRICTED BENEFIT

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

6.25 MG * 6.25 MG (BASE) * 6.25 MG * 6.25 MG ORAL EXTENDED-RELEASE CAPSULE				
00002445530	APO-AMPHETAMINE XR (25 MG)	APX	\$	0.8305
00002457334	SANDOZ AMPHETAMINE XR (25 MG)	SDZ	\$	0.8305
00002439271	TEVA-AMPHETAMINE XR (25 MG)	TEV	\$	0.8305

ALBERTA DRUG BENEFIT LIST UPDATE

APIXABAN

2.5 MG ORAL TABLET

00002487713	ACH-APIXABAN	AHI	\$	0.4084
00002530708	APIXABAN	SIV	\$	0.4084
00002487381	APO-APIXABAN	APX	\$	0.4084
00002486806	AURO-APIXABAN	AUR	\$	0.4084
00002528924	JAMP APIXABAN	JPC	\$	0.4084
00002529009	M-APIXABAN	MTR	\$	0.4084
00002492369	MAR-APIXABAN	MAR	\$	0.4084
00002495430	MINT-APIXABAN	MPI	\$	0.4084
00002492814	NAT-APIXABAN	NTP	\$	0.4084
00002526050	NRA-APIXABAN	NRA	\$	0.4084
00002489228	SANDOZ APIXABAN SDZ	SDZ	\$	0.4084
00002510464	TARO-APIXABAN	TAR	\$	0.4084
00002484994	TEVA-APIXABAN	TEV	\$	0.4084
00002377233	ELIQUIS	BMS	\$	1.6337

5 MG ORAL TABLET

00002487721	ACH-APIXABAN	AHI	\$	0.4084
00002530716	APIXABAN	SIV	\$	0.4084
00002487403	APO-APIXABAN	APX	\$	0.4084
00002486814	AURO-APIXABAN	AUR	\$	0.4084
00002528932	JAMP APIXABAN	JPC	\$	0.4084
00002529017	M-APIXABAN	MTR	\$	0.4084
00002492377	MAR-APIXABAN	MAR	\$	0.4084
00002495449	MINT-APIXABAN	MPI	\$	0.4084
00002492822	NAT-APIXABAN	NTP	\$	0.4084
00002526069	NRA-APIXABAN	NRA	\$	0.4084
00002489236	SANDOZ APIXABAN SDZ	SDZ	\$	0.4084
00002510472	TARO-APIXABAN	TAR	\$	0.4084
00002485001	TEVA-APIXABAN	TEV	\$	0.4084
00002397714	ELIQUIS	BMS	\$	1.6337

ATENOLOL

25 MG ORAL TABLET

00002541564	ATENOLOL	SIV	\$	0.0441
00002367556	JAMP-ATENOLOL	JPC	\$	0.0441
00002371979	MAR-ATENOLOL	MAR	\$	0.0441
00002368013	MINT-ATENOL	MPI	\$	0.0441
00002246581	PMS-ATENOLOL	PMS	\$	0.0441
00002373963	RAN-ATENOLOL	RAN	\$	0.0441
00002266660	TEVA-ATENOLOL	TEV	\$	0.0441

The DBL is not a prescribing or a diagnostic tool. Prescribers should refer to drug monographs and utilize professional judgment.

ALBERTA DRUG BENEFIT LIST UPDATE

ATORVASTATIN CALCIUM

80 MG (BASE)	ORAL TABLET			
00002457784	ACH-ATORVASTATIN	AHI	\$	0.2342
00002478188	AG-ATORVASTATIN	AGP	\$	0.2342
00002295318	APO-ATORVASTATIN	APX	\$	0.2342
00002348748	ATORVASTATIN	SNS	\$	0.2342
00002475057	ATORVASTATIN	RIV	\$	0.2342
00002411385	ATORVASTATIN-80	SIV	\$	0.2342
00002407280	AURO-ATORVASTATIN	AUR	\$	0.2342
00002504235	JAMP ATORVASTATIN CALCIUM	JPC	\$	0.2342
00002391082	JAMP-ATORVASTATIN	JPC	\$	0.2342
00002471191	M-ATORVASTATIN	MTR	\$	0.2342
00002454041	MAR-ATORVASTATIN	MAR	\$	0.2342
00002479532	MINT-ATORVASTATIN	MPI	\$	0.2342
00002392976	MYLAN-ATORVASTATIN	MYP	\$	0.2342
00002476541	NRA-ATORVASTATIN	NRA	\$	0.2342
00002477173	PMS-ATORVASTATIN	PMS	\$	0.2342
00002507269	PMSC-ATORVASTATIN	PMS	\$	0.2342
00002521598	PRZ-ATORVASTATIN	PCI	\$	0.2342
00002417960	REDDY-ATORVASTATIN	DRL	\$	0.2342
00002324970	SANDOZ ATORVASTATIN	SDZ	\$	0.2342
00002313758	TARO-ATORVASTATIN	SPG	\$	0.2342
00002310929	TEVA-ATORVASTATIN	TEV	\$	0.2342
00002243097	LIPITOR	BGP	\$	2.6598

CANDESARTAN CILEXETIL

32 MG	ORAL TABLET			
00002399105	APO-CANDESARTAN	APX	\$	0.2281
00002445816	AURO-CANDESARTAN	AUR	\$	0.2281
00002435845	CANDESARTAN	SNS	\$	0.2281
00002528266	CANDESARTAN	SIV	\$	0.2281
00002379295	CANDESARTAN CILEXETIL	AHI	\$	0.2281
00002386534	JAMP-CANDESARTAN	JPC	\$	0.2281
00002476932	MINT-CANDESARTAN	MPI	\$	0.2281
00002527030	NRA-CANDESARTAN	NRA	\$	0.2281
00002391228	PMS-CANDESARTAN	PMS	\$	0.2281
00002380714	RAN-CANDESARTAN	RAN	\$	0.2281
00002417340	SANDOZ CANDESARTAN	SDZ	\$	0.2281
00002366339	TEVA-CANDESARTAN	TEV	\$	0.2281
00002311658	ATACAND	AZC	\$	1.3488

CEPHALEXIN

25 MG / ML	ORAL SUSPENSION			
00002497743	AURO-CEPHALEXIN	AUR	\$	0.1535
00002528436	JAMP CEPHALEXIN	JPC	\$	0.1535
00000342106	TEVA-CEPHALEXIN 125	TEV	\$	0.1535
50 MG / ML	ORAL SUSPENSION			
00002528444	JAMP CEPHALEXIN	JPC	\$	0.2573
00000342092	TEVA-CEPHALEXIN 250	TEV	\$	0.2573

ALBERTA DRUG BENEFIT LIST UPDATE

CITALOPRAM HYDROBROMIDE

10 MG (BASE) ORAL TABLET				
00002387948	CITALOPRAM	SIV	\$	0.0796
00002430517	CITALOPRAM	JPC	\$	0.0796
00002445719	CITALOPRAM	SNS	\$	0.0796
00002532123	M-CITALOPRAM	MTR	\$	0.0796
00002371871	MAR-CITALOPRAM	MAR	\$	0.0796
00002429691	MINT-CITALOPRAM	MPI	\$	0.0796
00002409003	NATCO-CITALOPRAM	NTP	\$	0.0796
00002477637	NRA-CITALOPRAM	NRA	\$	0.0796
00002270609	PMS-CITALOPRAM	PMS	\$	0.0796
00002303256	RIVA-CITALOPRAM	RIV	\$	0.0796
00002312336	TEVA-CITALOPRAM	TEV	\$	0.0796

DAPAGLIFLOZIN/ METFORMIN HCL

5 MG * 850 MG ORAL TABLET				
00002536153	APO-DAPAGLIFLOZIN-METFORMIN	APX	\$	0.6432
00002533073	AURO-DAPAGLIFLOZIN/METFORMIN	AUR	\$	0.6432
00002449935	XIGDUO	AZC	\$	1.2863
5 MG * 1,000 MG ORAL TABLET				
00002536161	APO-DAPAGLIFLOZIN-METFORMIN	APX	\$	0.6432
00002533081	AURO-DAPAGLIFLOZIN/METFORMIN	AUR	\$	0.6432
00002449943	XIGDUO	AZC	\$	1.2863

DOXYCYCLINE HYCLATE

100 MG (BASE) ORAL TABLET				
00000874256	APO-DOXY	APX	\$	0.4560
00002351242	DOXYCYCLINE	SNS	\$	0.4560
00002536250	PRZ-DOXYCYCLINE	PCI	\$	0.4560
00002158574	TEVA-DOXYCYCLINE	TEV	\$	0.4560

ALBERTA DRUG BENEFIT LIST UPDATE

ESCITALOPRAM

10 MG ORAL TABLET

00002434652	ACH-ESCITALOPRAM	AHI	\$	0.3109
00002295016	APO-ESCITALOPRAM	APX	\$	0.3109
00002397358	AURO-ESCITALOPRAM	AUR	\$	0.3109
00002429039	ESCITALOPRAM	SIV	\$	0.3109
00002430118	ESCITALOPRAM	SNS	\$	0.3109
00002508893	JAMP ESCITALOPRAM	JPC	\$	0.3109
00002429780	JAMP-ESCITALOPRAM	JPC	\$	0.3109
00002471418	M-ESCITALOPRAM	MTR	\$	0.3109
00002423480	MAR-ESCITALOPRAM	MAR	\$	0.3109
00002407418	MINT-ESCITALOPRAM	MPI	\$	0.3109
00002309467	MYLAN-ESCITALOPRAM	MYP	\$	0.3109
00002440296	NAT-ESCITALOPRAM	NTP	\$	0.3109
00002476851	NRA-ESCITALOPRAM	NRA	\$	0.3109
00002469243	PMS-ESCITALOPRAM	PMS	\$	0.3109
00002303949	PMSC-ESCITALOPRAM	PMS	\$	0.3109
00002385481	RAN-ESCITALOPRAM	RAN	\$	0.3109
00002364077	SANDOZ ESCITALOPRAM	SDZ	\$	0.3109
00002318180	TEVA-ESCITALOPRAM	TEV	\$	0.3109
00002263238	CIPRALEX	LBC	\$	1.9735

20 MG ORAL TABLET

00002434660	ACH-ESCITALOPRAM	AHI	\$	0.3310
00002295024	APO-ESCITALOPRAM	APX	\$	0.3310
00002397374	AURO-ESCITALOPRAM	AUR	\$	0.3310
00002429047	ESCITALOPRAM	SIV	\$	0.3310
00002430126	ESCITALOPRAM	SNS	\$	0.3310
00002508907	JAMP ESCITALOPRAM	JPC	\$	0.3310
00002429799	JAMP-ESCITALOPRAM	JPC	\$	0.3310
00002471426	M-ESCITALOPRAM	MTR	\$	0.3310
00002423502	MAR-ESCITALOPRAM	MAR	\$	0.3310
00002407434	MINT-ESCITALOPRAM	MPI	\$	0.3310
00002309475	MYLAN-ESCITALOPRAM	MYP	\$	0.3310
00002440318	NAT-ESCITALOPRAM	NTP	\$	0.3310
00002476878	NRA-ESCITALOPRAM	NRA	\$	0.3310
00002469251	PMS-ESCITALOPRAM	PMS	\$	0.3310
00002303965	PMSC-ESCITALOPRAM	PMS	\$	0.3310
00002385503	RAN-ESCITALOPRAM	RAN	\$	0.3310
00002364085	SANDOZ ESCITALOPRAM	SDZ	\$	0.3310
00002318202	TEVA-ESCITALOPRAM	TEV	\$	0.3310
00002263254	CIPRALEX	LBC	\$	2.1070

ESTRADIOL-17B/ PROGESTERONE

1 MG * 100 MG ORAL CAPSULE

00002505223	BIJUVA	KTI	\$	0.8962
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METFORMIN HCL

1,000 MG ORAL TABLET

00002534673	PRZ-METFORMIN	PCI	\$	0.0399
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MINOCYCLINE HCL

50 MG (BASE) ORAL CAPSULE

00002084090	MINOCYCLINE	AAP	\$	0.5616
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100 MG (BASE) ORAL CAPSULE

00002084104	MINOCYCLINE	AAP	\$	1.0836
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MIRTAZAPINE**30 MG ORAL TABLET**

00002286629	APO-MIRTAZAPINE	APX	\$	0.1950
00002411709	AURO-MIRTAZAPINE	AUR	\$	0.1950
00002370689	MIRTAZAPINE	SNS	\$	0.1950
00002496674	MIRTAZAPINE	SIV	\$	0.1950
00002256118	MYLAN-MIRTAZAPINE	MYP	\$	0.1950
00002534932	NRA-MIRTAZAPINE	NRA	\$	0.1950
00002248762	PMS-MIRTAZAPINE	PMS	\$	0.1950
00002250608	SANDOZ MIRTAZAPINE	SDZ	\$	0.1950
00002259354	TEVA-MIRTAZAPINE	TEV	\$	0.1950
00002243910	REMERON	ORC	\$	1.4662

ONDANSETRON**4 MG ORAL DISINTEGRATING TABLET/FILM**

00002535319	ACCEL-ONDANSETRON ODT	ACP	\$	2.5450
00002511282	AURO-ONDANSETRON ODT	AUR	\$	3.2720
00002514966	MAR-ONDANSETRON ODT	MAR	\$	3.2720
00002487330	MINT-ONDANSETRON ODT	MPI	\$	3.2720
00002481723	ONDANSETRON ODT	SDZ	\$	3.2720
00002519232	ONDANSETRON ODT	JPC	\$	3.2720
00002524279	ONDANSETRON ODT	SNS	\$	3.2720
00002389983	ONDISSOLVE ODF	TAK	\$	3.2720
00002519445	PMS-ONDANSETRON ODT	PMS	\$	3.2720
00002239372	ZOFTRAN ODT	SDZ	\$	14.7040

8 MG ORAL DISINTEGRATING TABLET/FILM

00002535327	ACCEL-ONDANSETRON ODT	ACP	\$	3.8840
00002511290	AURO-ONDANSETRON ODT	AUR	\$	4.9930
00002514974	MAR-ONDANSETRON ODT	MAR	\$	4.9930
00002487349	MINT-ONDANSETRON ODT	MPI	\$	4.9930
00002481731	ONDANSETRON ODT	SDZ	\$	4.9930
00002519240	ONDANSETRON ODT	JPC	\$	4.9930
00002524287	ONDANSETRON ODT	SNS	\$	4.9930
00002389991	ONDISSOLVE ODF	TAK	\$	4.9930
00002519453	PMS-ONDANSETRON ODT	PMS	\$	4.9930
00002239373	ZOFTRAN ODT	SDZ	\$	22.4370

QUINAPRIL**10 MG (BASE) ORAL TABLET**

00002248500	APO-QUINAPRIL	APX	\$	0.1945	\$	0.2321
00002517450	JAMP QUINAPRIL	JPC	\$	0.1945	\$	0.2321
00002340569	PMS-QUINAPRIL	PMS	\$	0.1945	\$	0.2321
00001947672	ACCUPRIL	PFI	\$	0.1945	\$	1.0131

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

20 MG (BASE) ORAL TABLET

00002248501	APO-QUINAPRIL	APX	\$	0.1945	\$	0.2321
00002517469	JAMP QUINAPRIL	JPC	\$	0.1945	\$	0.2321
00002340577	PMS-QUINAPRIL	PMS	\$	0.1945	\$	0.2321
00001947680	ACCUPRIL	PFI	\$	0.1945	\$	1.0131

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

40 MG (BASE) ORAL TABLET

00002248502	APO-QUINAPRIL	APX	\$	0.1945	\$	0.2321
00002517477	JAMP QUINAPRIL	JPC	\$	0.1945	\$	0.2321
00002340585	PMS-QUINAPRIL	PMS	\$	0.1945	\$	0.2321
00001947699	ACCUPRIL	PFI	\$	0.1945	\$	1.0131

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

ALBERTA DRUG BENEFIT LIST UPDATE

RIVAROXABAN

2.5 MG ORAL TABLET

00002541734	APO-RIVAROXABAN	APX	\$	0.3550
00002527537	PMS-RIVAROXABAN	PMS	\$	0.3550
00002524503	REDDY-RIVAROXABAN	DRL	\$	0.3550
00002541467	RIVAROXABAN	SIV	\$	0.3550
00002537877	SANDOZ RIVAROXABAN	SDZ	\$	0.3550
00002526786	TARO-RIVAROXABAN	TAR	\$	0.3550
00002480808	XARELTO	BAI	\$	1.4200

10 MG ORAL TABLET

00002470497	APO-RIVAROXABAN	APX	\$	0.7175
00002512041	PMS-RIVAROXABAN	PMS	\$	0.7175
00002472414	REDDY-RIVAROXABAN	DRL	\$	0.7175
00002541475	RIVAROXABAN	SIV	\$	0.7175
00002482223	SANDOZ RIVAROXABAN	SDZ	\$	0.7175
00002483807	TARO-RIVAROXABAN	TAR	\$	0.7175
00002507196	TEVA-RIVAROXABAN	TEV	\$	0.7175
00002316986	XARELTO	BAI	\$	2.8700

15 MG ORAL TABLET

00002470500	APO-RIVAROXABAN	APX	\$	0.7175
00002512068	PMS-RIVAROXABAN	PMS	\$	0.7175
00002472430	REDDY-RIVAROXABAN	DRL	\$	0.7175
00002541483	RIVAROXABAN	SIV	\$	0.7175
00002482231	SANDOZ RIVAROXABAN	SDZ	\$	0.7175
00002483815	TARO-RIVAROXABAN	TAR	\$	0.7175
00002507218	TEVA-RIVAROXABAN	TEV	\$	0.7175
00002378604	XARELTO	BAI	\$	2.8700

20 MG ORAL TABLET

00002470519	APO-RIVAROXABAN	APX	\$	0.7175
00002512076	PMS-RIVAROXABAN	PMS	\$	0.7175
00002472422	REDDY-RIVAROXABAN	DRL	\$	0.7175
00002541491	RIVAROXABAN	SIV	\$	0.7175
00002482258	SANDOZ RIVAROXABAN	SDZ	\$	0.7175
00002483823	TARO-RIVAROXABAN	TAR	\$	0.7175
00002507226	TEVA-RIVAROXABAN	TEV	\$	0.7175
00002378612	XARELTO	BAI	\$	2.8700

SALBUTAMOL

100 MCG / DOSE INHALATION METERED DOSE AEROSOL

<input checked="" type="checkbox"/>	00002326450	TEVA-SALBUTAMOL HFA	TEV	\$	0.0250
	00002245669	APO-SALBUTAMOL HFA	APX	\$	0.0273
	00002419858	SALBUTAMOL HFA	SNS	\$	0.0273
	00002241497	VENTOLIN HFA	GSK	\$	0.0315

TOPIRAMATE

200 MG ORAL TABLET

00002395754	ACH-TOPIRAMATE	AHI	\$	0.6748
00002279649	APO-TOPIRAMATE	APX	\$	0.6748
00002345846	AURO-TOPIRAMATE	AUR	\$	0.6748
00002287781	GLN-TOPIRAMATE	GLM	\$	0.6748
00002345277	JAMP TOPIRAMATE	JPC	\$	0.6748
00002435624	JAMP-TOPIRAMATE	JPC	\$	0.6748
00002315661	MINT-TOPIRAMATE	MPI	\$	0.6748
00002263386	MYLAN-TOPIRAMATE	MYP	\$	0.6748
00002263017	PMS-TOPIRAMATE	PMS	\$	0.6748
00002248862	TEVA-TOPIRAMATE	TEV	\$	0.6748
00002356872	TOPIRAMATE	SNS	\$	0.6748
00002230896	TOPAMAX	JAI	\$	4.7515

PART 3

Special Authorization

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

FEBUXOSTAT

"For the treatment of symptomatic gout in patients with a documented hypersensitivity to allopurinol or documented hematological abnormalities.

Special authorization may be granted for 6 months."

Please note: Hypersensitivity to allopurinol is a rare condition that is characterized by a major skin manifestation, fever, multi-organ involvement, lymphadenopathy and hematological abnormalities (eosinophilia, atypical lymphocytes). Intolerance or lack of response to allopurinol will not be covered by this criteria.

All requests for febuxostat must be completed using the Febuxostat Special Authorization Request Form (ABC 60037).

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

80 MG ORAL TABLET

00002533243	AURO-FEBUXOSTAT	AUR	\$	0.3975
00002539837	FEBUXOSTAT	SNS	\$	0.3975
00002490870	JAMP-FEBUXOSTAT	JPC	\$	0.3975
00002473607	MAR-FEBUXOSTAT	MAR	\$	0.3975
00002466198	TEVA-FEBUXOSTAT	TEV	\$	0.3975

FENTANYL

"For the treatment of persistent, severe chronic pain in those patients who require continuous around-the-clock analgesia for an extended period of time in those patients who cannot swallow. Special authorization may be granted for 6 months."

"For the treatment of persistent, severe chronic pain in those patients who require continuous around-the-clock analgesia for an extended period of time in those patients who require opioid therapy at a total daily dose of at least 60 mg/day oral morphine equivalents. Patients must have tried and not been able to tolerate at least two discrete courses of therapy with two of the following agents: morphine, hydromorphone and oxycodone, if not contraindicated. Special authorization may be granted for 6 months."

Information is required regarding previous medications utilized and the patient's response to therapy. Also, information regarding the number of discrete (separate) courses of these medications is required. A discrete course is defined as a separate treatment course, which may involve more than 1 agent, used at one time to manage the patient's condition.

All requests for fentanyl must be completed using the Fentanyl Special Authorization Request Form (ABC 60005).

(Please note: The following fentanyl products are benefits not requiring special authorization for individuals approved by Alberta Health for Palliative Coverage. Refer to the Palliative Coverage Drug Benefit Supplement for additional information on this coverage.)

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

12 MCG/HR TRANSDERMAL PATCH

00002327112	SANDOZ FENTANYL PATCH	SDZ	\$	3.3200
00002311925	TEVA-FENTANYL	TEV	\$	3.3200

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

GUSELKUMAB

Plaque Psoriasis

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

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

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

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

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

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

Initial coverage may be approved for 12 weeks as follows:

- Two doses of 100 mg of guselkumab at weeks 0 and 4, followed by an initial maintenance dose at 12 weeks.
- Patients will be limited to receiving one 100 mg dose of guselkumab 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 the initial coverage period.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet all of the following criteria:

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

Following this assessment, continued coverage may be considered for one 100 mg dose of guselkumab every 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

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

All requests (including renewal requests) for guselkumab for Plaque Psoriasis must be

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

GUSELKUMAB

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

Psoriatic Arthritis

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

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

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

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

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

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

Initial coverage may be approved for four doses of 100 mg of guselkumab at weeks 0, 4, 12 and 20.

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

For continued coverage beyond four doses, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial 24 weeks 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 considered for one 100 mg dose of guselkumab every 8 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to

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

GUSELKUMAB

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

100 MG / SYR INJECTION SYRINGE

<input checked="" type="checkbox"/> 00002469758	TREMFYA	JAI	\$ 3059.7400
<input checked="" type="checkbox"/> 00002487314	TREMFYA ONE-PRESS	JAI	\$ 3059.7400

OMALIZUMAB

Asthma

"Special authorization coverage may be provided for adults and adolescents (12 years of age and above) with severe persistent asthma who are identified as having severe disease despite optimized standard therapy. Optimized standard therapy defined by a full trial of, and documented compliance with:

- high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent) for at least twelve (12) months; AND,
- long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms daily or 24 micrograms of formoterol fumarate daily) for at least twelve (12) months; AND,
- Therapeutic trial with systemic corticosteroids (at least 10mg per day prednisolone (or equivalent)) for at least 4 weeks in the previous twelve (12) months, unless contraindicated or not tolerated.

For coverage, the drug must be initiated and monitored by a respirologist or clinical immunologist or allergist and meet the following clinical criteria (Initial Coverage or Continued Coverage, as appropriate). Patients will be limited to receiving a one (1) month supply of omalizumab per prescription at their pharmacy.

INITIAL COVERAGE:

Special authorization requests must meet all of the following criteria for initial approval:

- 1) Confirmation of severe persistent asthma through recent clinical and physiologic review with exclusion of other obstructive airways processes contributing to symptoms of severe asthma (i.e. psychogenic dyspnea; cardiac dyspnea);
- 2) Must be a non-smoker;
- 3) Confirmation of IgE mediated allergy to a perennial allergen by clinical history and allergy skin testing;
- 4) Baseline IgE level greater than/equal to 30 IU/mL and less than/equal to 700 IU/mL;
- 5) A weight between 20kg and 150kg;
- 6) An Asthma Control Questionnaire (ACQ-5) of at least 1.25, on at least two occasions over the past 6 months in a stable state;
- 7) Must provide documentation:
 - Spirometry measurement of FEV1;
 - Asthma Quality of Life Questionnaire (AQLQ - Juniper) score;
 - Number of exacerbations of asthma within the previous twelve (12) month period that resulted in:
 - an emergency room visit or hospitalization;
 - physician visits resulting in oral corticosteroids or an increased dose of oral corticosteroids;
 - chronic use (greater than 50% of the year) of oral corticosteroids;
- 8) One (1) or more severe exacerbations of asthma requiring a hospital admission or Emergency Room visit within the previous year while on systemic corticosteroids; OR
 - One (1) or more severe exacerbations of asthma requiring a hospital admission or Emergency Room visit requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least three (3) days, or parenteral corticosteroids); OR
 - Three (3) or more severe exacerbations of asthma within the previous year which required a physician visit and resulted in courses (or chronic use greater than 50% of the year), or increased dose of systemic corticosteroids.

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

OMALIZUMAB

Initial coverage may be approved for twenty-eight (28) weeks of up to 375 mg administered every 2 weeks based on the recommended dose and dosage adjustment outlined in the Health Canada approved Product Monograph.

CONTINUED MAINTENANCE TREATMENT:

A patient must be assessed for response to initial coverage of omalizumab with a minimum of twenty-four (24) weeks of therapy with omalizumab, and this assessment must be submitted to Alberta Blue Cross no later than four (4) weeks from the date of assessment.

The assessment must be done by a respirologist or clinical immunologist or allergist or such other clinicians as the Minister may designate. If the following criteria are met, special authorization may be granted for a further twelve (12) month period. Continued coverage may be considered if the following criteria are met at the end of each additional twelve (12) month period:

1) Demonstrated that the patient has an Improvement in FEV1 greater than 12% (and for adults a minimum greater than 200 mL) from initiation of therapy; OR Unchanged FEV1 with a clinically meaningful Improvement in Asthma Quality of Life Questionnaire score from baseline (greater than/equal to 0.5 mean from baseline); AND
- a decrease in the ACQ-5 of at least 0.5; OR
- a ACQ-5 score of less than/equal to 1.

2) Patients must demonstrate at least a 25% reduction in the number of exacerbations, which required oral corticosteroids from the twelve (12) months prior to initiation of omalizumab that required systemic corticosteroids; OR
For patients that were on chronic (greater than 50% of the year) courses of oral corticosteroids in the twelve (12) months prior to initiation of omalizumab, tapering of oral corticosteroid use by at least 25% from baseline.

3) A reduction in the number of exacerbations that have led to a hospital admission or emergency room visits, compared to the twelve (12) months prior to the commencement of omalizumab."

All requests (including renewal requests) for omalizumab for Asthma must be completed using the Omalizumab for Asthma Special Authorization Request Form (ABC 60020).

75 MG / SYR INJECTION

00002459787 XOLAIR

NOV

\$ 281.2400

OMALIZUMAB

Asthma

"Special authorization coverage may be provided for adults and adolescents (12 years of age and above) with severe persistent asthma who are identified as having severe disease despite optimized standard therapy. Optimized standard therapy defined by a full trial of, and documented compliance with:

- high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent) for at least twelve (12) months; AND,
- long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms daily or 24 micrograms of formoterol fumarate daily) for at least twelve (12) months; AND,
- Therapeutic trial with systemic corticosteroids (at least 10mg per day prednisolone (or equivalent)) for at least 4 weeks in the previous twelve (12) months, unless contraindicated or not tolerated.

For coverage, the drug must be initiated and monitored by a respirologist or clinical immunologist or allergist and meet the following clinical criteria (Initial Coverage or Continued Coverage, as appropriate). Patients will be limited to receiving a one (1) month supply of omalizumab per prescription at their pharmacy.

INITIAL COVERAGE:

Special authorization requests must meet all of the following criteria for initial approval:

- 1) Confirmation of severe persistent asthma through recent clinical and physiologic review with exclusion of other obstructive airways processes contributing to symptoms of severe asthma (i.e. psychogenic dyspnea; cardiac dyspnea);
- 2) Must be a non-smoker;
- 3) Confirmation of IgE mediated allergy to a perennial allergen by clinical history and allergy skin testing;
- 4) Baseline IgE level greater than/equal to 30 IU/mL and less than/equal to 700 IU/mL;
- 5) A weight between 20kg and 150kg;
- 6) An Asthma Control Questionnaire (ACQ-5) of at least 1.25, on at least two occasions over the past 6 months in a stable state;
- 7) Must provide documentation:
 - Spirometry measurement of FEV1;
 - Asthma Quality of Life Questionnaire (AQLQ - Juniper) score;
 - Number of exacerbations of asthma within the previous twelve (12) month period that resulted in:
 - an emergency room visit or hospitalization;
 - physician visits resulting in oral corticosteroids or an increased dose of oral corticosteroids;
 - chronic use (greater than 50% of the year) of oral corticosteroids;
- 8) One (1) or more severe exacerbations of asthma requiring a hospital admission or Emergency Room visit within the previous year while on systemic corticosteroids; OR
 - One (1) or more severe exacerbations of asthma requiring a hospital admission or Emergency Room visit requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least three (3) days, or parenteral corticosteroids); OR
 - Three (3) or more severe exacerbations of asthma within the previous year which required a physician visit and resulted in courses (or chronic use greater than 50% of the year), or increased dose of systemic corticosteroids.

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

OMALIZUMAB

Initial coverage may be approved for twenty-eight (28) weeks of up to 375 mg administered every 2 weeks based on the recommended dose and dosage adjustment outlined in the Health Canada approved Product Monograph.

CONTINUED MAINTENANCE TREATMENT:

A patient must be assessed for response to initial coverage of omalizumab with a minimum of twenty-four (24) weeks of therapy with omalizumab, and this assessment must be submitted to Alberta Blue Cross no later than four (4) weeks from the date of assessment.

The assessment must be done by a respirologist or clinical immunologist or allergist or such other clinicians as the Minister may designate. If the following criteria are met, special authorization may be granted for a further twelve (12) month period. Continued coverage may be considered if the following criteria are met at the end of each additional twelve (12) month period:

1) Demonstrated that the patient has an Improvement in FEV1 greater than 12% (and for adults a minimum greater than 200 mL) from initiation of therapy; OR Unchanged FEV1 with a clinically meaningful Improvement in Asthma Quality of Life Questionnaire score from baseline (greater than/equal to 0.5 mean from baseline); AND
- a decrease in the ACQ-5 of at least 0.5; OR
- a ACQ-5 score of less than/equal to 1.

2) Patients must demonstrate at least a 25% reduction in the number of exacerbations, which required oral corticosteroids from the twelve (12) months prior to initiation of omalizumab that required systemic corticosteroids; OR
For patients that were on chronic (greater than 50% of the year) courses of oral corticosteroids in the twelve (12) months prior to initiation of omalizumab, tapering of oral corticosteroid use by at least 25% from baseline.

3) A reduction in the number of exacerbations that have led to a hospital admission or emergency room visits, compared to the twelve (12) months prior to the commencement of omalizumab."

All requests (including renewal requests) for omalizumab for Asthma must be completed using the Omalizumab for Asthma Special Authorization Request Form (ABC 60020).

Chronic Idiopathic Urticaria

"For the treatment of adults and adolescents (12 years of age and above) with moderate to severe chronic idiopathic urticaria (CIU), defined as having a baseline Urticaria Activity Score over 7 days (UAS7) of greater than or equal to 16, who remain symptomatic (presence of hives and/or associated itching) despite optimum management with available oral therapies. Oral therapies should include a therapeutic trial with H1 antihistamines, unless contraindicated or not tolerated.

For coverage, the drug must be initiated and monitored by a Specialist in Dermatology, Clinical Immunology or Allergy.

Coverage may be approved for a period of 24 weeks at a maximum dose of 300 mg every 4 weeks.

Patients will be limited to receiving a one-month supply of omalizumab 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.

Continued coverage of a further 24-week treatment period may be considered if the patient has experienced:

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- complete symptom control (i.e., UAS7 of 0) for less than 12 consecutive weeks; OR
- partial symptom control, with a reduction in baseline UAS7 of greater than or equal to 9.5 points.

Treatment cessation should be considered for patients who experience complete symptom control for at least 12 consecutive weeks at the end of a 24-week treatment period.

In patients where treatment is discontinued due to temporary symptom control, treatment re-initiation should be considered should CIU symptoms reappear."

All requests (including renewal requests) for omalizumab for Chronic Idiopathic Urticaria must be completed using the Omalizumab for Chronic Idiopathic Urticaria Special Authorization Request Form (ABC 60056).

150 MG / VIAL INJECTION

<input checked="" type="checkbox"/> 00002459795	XOLAIR	NOV	\$	641.6000
<input checked="" type="checkbox"/> 00002260565	XOLAIR	NOV	\$	646.4400

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PEGCETACOPLAN

Eligibility Criteria for Pegcetacoplan Coverage

In order to maintain the integrity of the ADBL, and having regard to the financial and social implications of covering pegcetacoplan for the treatment of paroxysmal nocturnal hemoglobinuria (PNH), the following special authorization criteria must be satisfied.

In order to be eligible for pegcetacoplan coverage for the treatment of PNH, a patient must have submitted a completed Application and have satisfied all of the following requirements:

The patient must:

- 1) Be an adult patient diagnosed with PNH in accordance with the requirements specified in the Clinical Criteria for pegcetacoplan;
 - 2) Have Alberta government-sponsored drug coverage;
 - 3) Meet the Registration Requirements;
 - 4) Satisfy the Clinical Criteria for pegcetacoplan (initial or continued coverage, as appropriate);
- AND
- 5) Meet the criteria specified in Contraindications to Coverage and Discontinuance of Coverage.

There is no guarantee that any application, whether for initial or continued coverage, will be approved. Depending on the circumstances of each case, the Minister or the Minister's delegate may:

- approve an Application;
- approve an Application with conditions;
- deny an Application;
- discontinue an approved Application; OR
- defer an Application pending the provision of further supporting information.

The process for review and approval is explained in further detail below.

Registration Requirements

If the patient is a citizen or permanent resident of Canada, the patient must be continuously registered in the Alberta Health Care Insurance Plan for a minimum of one (1) year prior to an application for coverage unless:

- the patient has moved to Alberta from another province or territory in Canada (the "province of origin"), and immediately prior to moving to Alberta, was covered for pegcetacoplan in the province of origin by a provincial or territorial government sponsored drug plan, (or the province of origin provided equivalent coverage for pegcetacoplan as does Alberta) and the patient has been registered in the Alberta Health Care Insurance Plan (the patient must provide supporting documentation from the province of origin to prove prior coverage).

If the patient is not a citizen or permanent resident of Canada, the patient must be continuously registered in the Alberta Health Care Insurance Plan for a minimum of five (5) years prior to an application for coverage unless:

- the patient has moved to Alberta from another province or territory in Canada (the "province of origin"), and immediately prior to moving to Alberta, was covered for pegcetacoplan in the province of origin by a provincial or territorial government sponsored drug plan, (or the province of origin provided equivalent coverage for pegcetacoplan as does Alberta) and the patient has been registered in the Alberta Health Care Insurance Plan (the patient must provide supporting documentation from the province of origin to prove prior coverage).

The Minister reserves the right to modify or waive the Registration Requirements applicable to a given patient if the patient can establish to the satisfaction of the Minister that the patient has not moved to Alberta for the sole/primary purpose of obtaining coverage of pegcetacoplan.

Clinical Criteria

In addition to meeting Sections 1 and Sections 2 herein, to be considered for coverage of pegcetacoplan, a patient must be assessed by a Specialist in Hematology (i.e. a physician who holds specialty certification in Hematology from the Royal College of Physicians and Surgeons

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PEGCETACOPLAN

of Canada) and meet all of the following clinical criteria (initial or continued coverage, as appropriate).

a. Clinical Criteria - Initial Coverage

All of the following Clinical Criteria must be established on the basis of evidence to the satisfaction of the Minister or the Minister's delegate for initial coverage:

- 1) The patient must have a confirmed diagnosis of PNH with all of the following:
 - 1.1. Patients must have met the ADBL coverage criteria for C5 inhibitor treatment (e.g., eculizumab) before receiving C5 inhibitor treatment.
 - 1.2. Patients must either have persistent anemia with hemoglobin levels <10.5 g/dL despite an adequate trial (i.e., 6 months) of C5 inhibitor treatment and causes other than extravascular hemolysis have been excluded, or have intolerable adverse events from C5 inhibitor treatment.

b. Clinical Criteria - Continued Coverage

All of the following Clinical Criteria must be established on the basis of evidence to the satisfaction of the Minister or the Minister's delegate for continued coverage:

- 1) Patient eligibility must be reviewed six (6) months after commencing therapy and every six (6) months thereafter;

AND

2) Continued eligibility will be subject to the assessment of evidence, in accordance with the following monitoring requirements, which demonstrates:

- Clinical improvement in the patient, OR
- Stabilization of the patient's condition;

Monitoring requirements;

The patient's Specialist in Hematology must provide the following monitoring information every six (6) months:

- Lactate dehydrogenase (LDH);
- Full blood count and reticulocytes;
- Transfusion history for previous six months;
- Iron studies;
- Urea, electrolytes and eGFR;
- Recent clinical history; AND
- Any other information requested by the Minister, the Minister's delegate, or an Expert Advisor.

The patient's Specialist in Hematology must provide the following monitoring information every twelve (12) months:

- Confirmation that the patient has been immunized or reimmunized (meningococcal, pneumococcal 23-valent, pneumococcal 13-valent and Hib) according to current clinical guidelines for vaccine use;
- Progress reports on the clinical symptoms that formed the basis of initial eligibility;
- Quality of life, through clinical narrative;
- Granulocyte or monocyte clone size (by flow cytometry): AND
- Any other information requested by the Minister, the Minister's delegate, or an Expert Advisor.

c. Contraindications to Coverage

- Small clone size - granulocyte and monocyte clone sizes below 10%;
- Aplastic anaemia with two or more of the following: neutrophil count below $0.5 \times 10^9/L$, platelet count below $20 \times 10^9/L$, reticulocytes below $25 \times 10^9/L$, or severe bone marrow hypocellularity;
- Patients with a presence of another life threatening or severe disease where the long term prognosis is unlikely to be influenced by therapy (for example acute myeloid leukaemia or high-risk myelodysplastic syndrome); OR
- The presence of another medical condition that in the opinion of the Minister or Minister's delegate might reasonably be expected to compromise a response to therapy.

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d. Discontinuation of Coverage

Coverage may be discontinued where one or more of the following situations apply:

- The patient or the patient's Specialist in Hematology fails to comply adequately with treatment or measures, including monitoring requirements, taken to evaluate the effectiveness of the therapy;
- There is a failure to provide the Minister, the Minister's delegate, or an Expert Advisor with information as required or as requested;
- If in the opinion of the Minister or the Minister's delegate, therapy fails to relieve the symptoms of disease that originally resulted in the patient being approved by the Minister or the Minister's delegate;
- The patient has (or develops) a condition referred to in Contraindications to Coverage.

The patient's Specialist in Hematology will be advised if their patient is at risk of being withdrawn from treatment for failure to comply with the above requirements or other perceived "non-compliance" and given a reasonable period of time to respond prior to coverage being discontinued.

Process for Pegcetacoplan Coverage

For both initial and continued coverage the following documents (the Application) must be completed and submitted:

- An Eculizumab/Pegcetacoplan/ Ravulizumab for Paroxysmal Nocturnal Hemoglobinuria Special Authorization Request Form completed by the patient's Specialist in Hematology;
 - An Eculizumab/Pegcetacoplan/ Ravulizumab Consent Form completed by the patient, and the patient's Specialist in Hematology (for any initial coverage application);
- AND
- Any other documentation that may be required by the Minister or the Minister's delegate.

a. Expert Review

Once the Minister or the Minister's delegate has confirmed that the patient meets the Registration Requirement or granted a waiver of the Registration Requirement, the Application will be given to one or more Expert Advisors for review.

The Application, together with the recommendation or recommendations of the Expert Advisor(s), is then forwarded to the Minister or the Minister's delegate for a decision regarding coverage.

After the Minister or Minister's delegate has rendered a decision, the patient's Specialist in Hematology and the patient will be notified by letter of the Minister's decision.

Approval of Coverage

The Minister or the Minister's delegate's decision in respect of an Application will specify the effective date of pegcetacoplan coverage, if coverage is approved.

Initial coverage may be approved for a period of up to six (6) months as follows: One dose of pegcetacoplan (1080 mg) twice weekly. For patients switching to pegcetacoplan from a C5 inhibitor, for the first 4 weeks, one dose of pegcetacoplan (1080 mg) twice weekly in addition to the patient's current dose of C5 inhibitor. After 4 weeks, the patient must discontinue the C5 inhibitor while continuing on monotherapy with pegcetacoplan. The dosing regimen may be changed to 1080 mg every third day if the patient has a LDH level greater than 2 times the upper limit of normal (ULN) on twice weekly dosing.

Continued coverage may be approved for one dose of 1080 mg of pegcetacoplan administered twice weekly (or every third day if the patient has a LDH level greater than 2 times the ULN on twice weekly dosing) for a period of six (6) months.

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PEGCETACOPLAN

If a patient is approved for coverage, prescriptions for pegcetacoplan must be written by a Specialist in Hematology. To avoid wastage, prescription quantities are limited to a two week supply. Extended quantity and vacation supplies are not permitted. The Government is not responsible and will not pay for costs associated with wastage or improper storage of pegcetacoplan.

Approval of coverage is granted for a specific period, to a maximum of six (6) months. If continued treatment is necessary, it is the responsibility of the patient and the Specialist in Hematology to submit a new Application to re-apply for pegcetacoplan coverage, and receive a decision thereon, prior to the expiry date of the authorization period.

Coverage will not be approved when any complement inhibitors are to be used in combination except in the first 4 weeks of treatment with a C5 inhibitor. Patients may be permitted to switch back to their previously trialed C5 inhibitor.

Withdrawal

Therapy may be withdrawn at the request of the patient at any time. Notification of withdrawal from therapy must be made by the Specialist in Hematology or patient in writing.

Applications, withdrawal requests, and any other information to be provided must be sent to Clinical Drug Services, Alberta Blue Cross.

1,080 MG / VIAL INJECTION			
00002533294	EMPAVELI	BVM	\$ 4970.0000

PERAMPANEL

"For adjunctive therapy in patients with refractory partial-onset seizures or primary generalized tonic-clonic (PGTC) 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 are eligible for auto-renewal"

2 MG ORAL TABLET			
00002522632	TARO-PERAMPANEL	TAR	\$ 7.7902
00002404516	FYCOMPA	EIS	\$ 10.2697
4 MG ORAL TABLET			
00002522640	TARO-PERAMPANEL	TAR	\$ 7.7902
00002404524	FYCOMPA	EIS	\$ 10.2697
6 MG ORAL TABLET			
00002522659	TARO-PERAMPANEL	TAR	\$ 7.7902
00002404532	FYCOMPA	EIS	\$ 10.2697

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PERAMPANEL

8 MG ORAL TABLET

00002522667	TARO-PERAMPANEL	TAR	\$	7.7902
00002404540	FYCOMPA	EIS	\$	10.2697

10 MG ORAL TABLET

00002522675	TARO-PERAMPANEL	TAR	\$	7.7902
00002404559	FYCOMPA	EIS	\$	10.2697

12 MG ORAL TABLET

00002522683	TARO-PERAMPANEL	TAR	\$	7.7902
00002404567	FYCOMPA	EIS	\$	10.2697

RAVULIZUMAB

Atypical Hemolytic Uremic Syndrome

1. Eligibility Criteria for Ravulizumab Coverage

In order to maintain the integrity of the ADBL, and having regard to the financial and social implications of covering ravulizumab for the treatment of atypical hemolytic uremic syndrome (aHUS), the following special authorization criteria must be satisfied.

In order to be eligible for ravulizumab coverage for the treatment of aHUS, a patient must have submitted a completed Application and have satisfied all of the following requirements:

The patient must:

- 1) Be a patient one month of age and older diagnosed with aHUS in accordance with the requirements specified in the Clinical Criteria for ravulizumab;
 - 2) Have Alberta government-sponsored drug coverage;
 - 3) Meet the Registration Requirements;
 - 4) Satisfy the Clinical Criteria for ravulizumab (initial or continued coverage, as appropriate);
- AND
- 5) Meet the criteria specified in Contraindications to Coverage and Discontinuance of Coverage.

There is no guarantee that any application, whether for initial or continued coverage, will be approved. Depending on the circumstances of each case, the Minister or the Minister's delegate may:

- approve an Application;
- approve an Application with conditions;
- deny an Application;
- discontinue an approved Application; OR
- defer an Application pending the provision of further supporting information.

The process for review and approval is explained in further detail below.

2. Registration Requirements

If the patient is a citizen or permanent resident of Canada, the patient must be continuously registered in the Alberta Health Care Insurance Plan for a minimum of one (1) year prior to an application for coverage unless:

- the patient is less than one (1) year of age at the date of the application, then the patient's parent/guardian/legal representative must be registered continuously in the Alberta Health Care Insurance Plan for a minimum of one (1) year; OR
- the patient has moved to Alberta from another province or territory in Canada (the "province of origin"), and immediately prior to moving to Alberta, was covered for ravulizumab in the province of origin by a provincial or territorial government sponsored drug plan, (or the province of origin provided equivalent coverage for ravulizumab as does Alberta) and the patient has been registered in the Alberta Health Care Insurance Plan (the patient must provide supporting documentation from the province of origin to prove prior coverage).

If the patient is not a citizen or permanent resident of Canada, the patient must be continuously registered in the Alberta Health Care Insurance Plan for a minimum of five (5) years prior to an application for coverage unless:

- the patient is less than five years of age at the date of the application, then the patient's parent/guardian/legal representative must be registered continuously in the Alberta Health Care Insurance Plan for a minimum of five years; OR
- the patient has moved to Alberta from another province or territory in Canada (the "province of origin"), and immediately prior to moving to Alberta, was covered for ravulizumab in the province of origin by a provincial or territorial government sponsored drug plan, (or the province of origin provided equivalent coverage for ravulizumab as does Alberta) and the patient has been registered in the Alberta Health Care Insurance Plan (the patient must provide supporting documentation from the province of origin to prove prior coverage).

The Minister reserves the right to modify or waive the Registration Requirements applicable to a

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given patient if the patient or the patient's parent/guardian/legal representative can establish to the satisfaction of the Minister that the patient has not moved to Alberta for the sole/primary purpose of obtaining coverage of ravulizumab.

3. Clinical Criteria

Patients with insufficient initial response or who have failed treatment with eculizumab at the Health Canada-recommended dosage are not eligible for reimbursement of ravulizumab.

In addition to meeting Sections 1 and Sections 2 herein, to be considered for coverage of ravulizumab, a patient must be assessed by a Specialist in Hematology or Nephrology (i.e. a physician who holds specialty certification in Hematology or Nephrology from the Royal College of Physicians and Surgeons of Canada) and meet all of the following clinical criteria (initial or continued coverage, as appropriate).

a. Clinical Criteria - Initial Coverage

All of the following Clinical Criteria must be established on the basis of evidence to the satisfaction of the Minister or the Minister's delegate for initial coverage:

1. Confirmed diagnosis of aHUS at initial presentation, defined by presence of thrombotic microangiopathy (TMA):
 - A disintegrin and metalloproteinase with a thrombospondin type 1 motif, member 13 (ADAMTS-13) activity $\geq 10\%$ on blood samples taken prior to plasma exchange or plasma infusion (PE/PI); and
 - Shiga toxin producing Escherichia coli (STEC) test negative in patients with a history of bloody diarrhea in the preceding two weeks; and
 - TMA must be unexplained (not a secondary TMA).
2. Evidence of ongoing active TMA and progressing, defined by laboratory test abnormalities despite plasmapheresis, if appropriate. Patients must demonstrate:
 - Unexplained (not a secondary TMA) thrombocytopenia (platelet count $< 150 \times 10^9/L$); and hemolysis as indicated by the documentation of two of the following: schistocytes on the blood film; low or absent haptoglobin; or lactate dehydrogenase (LDH) above normal; OR
 - Tissue biopsy confirming TMA in patients who do not have evidence of platelet consumption and hemolysis.
3. Evidence of at least one of the following documented clinical features of active organ damage or impairment:
 - Kidney impairment, as demonstrated by one of the following:
 - a) A decline in estimated glomerular filtration rate (eGFR) of $> 20\%$ in a patient with pre-existing renal impairment; and/or
 - b) Serum creatinine (SCr) $>$ upper limit of normal (ULN) for age or GFR < 60 mL/min and renal function deteriorating despite prior PE/PI in patients who have no history of pre-existing renal impairment (i.e., who have no baseline eGFR measurement); or
 - c) SCr $>$ the age appropriate ULN in pediatric patients (as determined by or in consultation with a pediatric nephrologist)OR
 - Onset of neurological impairment related to TMA; or
 - Other TMA-related manifestations, such as cardiac ischemia, bowel ischemia, pancreatitis, or retinal vein occlusion.

AND

4. All patients must receive meningococcal immunization with a quadravalent vaccine (A, C, Y and W135) at least two (2) weeks prior to receiving the first dose of ravulizumab. Treating physicians will be required to submit confirmation of meningococcal immunizations in order for their patients to continue to be eligible for treatment with ravulizumab. Pneumococcal immunization with a 23-valent polysaccharide vaccine and a 13-valent conjugate vaccine, and a Haemophilus influenzae type b (Hib) vaccine must be given according to current clinical

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guidelines. All patients must be monitored and reimmunized according to current clinical guidelines for vaccine use.

For kidney transplant patients: Transplant patients with a documented history of aHUS (i.e., history of TMA [not a secondary TMA only] with ADAMTS 13 >10%) would be eligible for ravulizumab if they:

- Develop TMA immediately (within hours to 1 month) following a kidney transplant; or
- Previously lost a native or transplanted kidney due to the development of TMA; or
- Have a history of proven aHUS and require prophylaxis with ravulizumab at the time of a kidney transplant.

For all patients: Patients should not have a history of ravulizumab treatment failure* (i.e., treated with ravulizumab with a previous aHUS recurrence).

*Treatment failure is defined as:

- Dialysis-dependent at six months, and failed to demonstrate resolution or stabilization of neurological or extra-renal complications if these were originally present; OR
- On dialysis for >= four of the previous six months while receiving ravulizumab and failed to demonstrate resolution or stabilization of neurological or extra-renal complications if these were originally present; OR
- Worsening of kidney function with a reduction in eGFR or increase in SrCr >=25% from baseline.

b. Clinical Criteria - Continued Coverage

All of the following Clinical Criteria must be established on the basis of evidence to the satisfaction of the Minister or the Minister's delegate for continued coverage:

- 1) Patient eligibility must be reviewed six (6) months after commencing therapy, twelve (12) months after commencing therapy, followed by every 12 months thereafter;

AND

- 2) Continued eligibility will be subject to the assessment of evidence, in accordance with the following monitoring requirements, which demonstrates:

- Clinical improvement in the patient, OR
- Stabilization of the patient's condition;

Monitoring requirements;

The patient's Specialist in Hematology or Nephrology must provide the following monitoring information six (6) months after commencing therapy and twelve (12) months after commencing therapy:

- Have documented treatment response defined as, hematological normalization (e.g., platelet count, LDH), stabilization of end organ damage (such as acute kidney injury and brain ischemia), transplant graft survival in susceptible individuals, and dialysis avoidance in patients who are pre- end-stage kidney disease (ESKD)

OR

- Have limited organ reserve* or high-risk genetic mutation such as Factor H deficiency.

*Limited organ reserve is defined as: significant cardiomyopathy, neurological, gastrointestinal or pulmonary impairment related to TMA; or Grade 4 or 5 chronic kidney disease (eGFR <30 mL/min).

AND

- Absence of treatment failure (as defined above).

The patient's Specialist in Hematology or Nephrology must provide the following monitoring information every twelve (12) months:

- Confirmation that the patient has been immunized or reimmunized (meningococcal, pneumococcal 23-valent, pneumococcal 13-valent and Hib) according to current clinical guidelines for vaccine use;
- Progress reports on the clinical symptoms that formed the basis of initial eligibility;
- Quality of life, through clinical narrative; AND
- Any other information requested by the Minister, the Minister's delegate, or an Expert Advisor.

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For subsequent renewals, ongoing coverage may be considered only if the patient is re-assessed every 12 months and meets ALL of the following criteria;

- Treatment response and no treatment failure (as defined above), AND
- The patient has limited organ reserve (as defined above) or high-risk genetic mutation.

A patient previously diagnosed with aHUS and who responded to treatment with ravulizumab and has not failed ravulizumab is eligible to restart ravulizumab if the patient redevelops a TMA related to aHUS and meets the following clinical conditions:

- Significant hemolysis as evidenced by presence of schistocytes on the blood film, or low or absent haptoglobin, or LDH above normal; AND EITHER
- Platelet consumption as measured by either $\geq 25\%$ decline from patient baseline or thrombocytopenia (platelet count $< 150 \times 10^9/L$); OR
- TMA-related organ impairment (e.g., unexplained rise in serum creatinine with onset of urine dipstick positive for hemoglobin) including on recent biopsy."

c. Contraindications to Coverage

- The presence of another medical condition that in the opinion of the Minister or Minister's delegate might reasonably be expected to compromise a response to therapy.

d. Discontinuation of Coverage

Coverage may be discontinued where one or more of the following situations apply:

- The patient or the patient's Specialist in Hematology or Nephrology fails to comply adequately with treatment or measures, including monitoring requirements, taken to evaluate the effectiveness of the therapy;
 - There is a failure to provide the Minister, the Minister's delegate, or an Expert Advisor with information as required or as requested;
 - If in the opinion of the Minister or the Minister's delegate, therapy fails to relieve the symptoms of disease that originally resulted in the patient being approved by the Minister or the Minister's delegate;
 - The patient has (or develops) a condition referred to in Contraindications to Coverage.
- The patient's Specialist in Hematology or Nephrology will be advised if their patient is at risk of being withdrawn from treatment for failure to comply with the above requirements or other perceived "non-compliance" and given a reasonable period of time to respond prior to coverage being discontinued.

4. Process for Ravulizumab Coverage

For both initial and continued coverage the following documents (the Application) must be completed and submitted:

- A Ravulizumab for Atypical Hemolytic Uremic Syndrome Special Authorization Request Form completed by the patient's Specialist in Hematology or Nephrology;
- An Eculizumab/Pegcetacoplan/Ravulizumab Consent Form completed by the patient, or a patient's parent/guardian/legal representative, and the patient's Specialist in Hematology or Nephrology (for any initial coverage application); AND
- Any other documentation that may be required by the Minister or the Minister's delegate.

a. Expert Review

Once the Minister or the Minister's delegate has confirmed that the patient meets the Registration Requirement or granted a waiver of the Registration Requirement, the Application will be given to one or more Expert Advisors for review.

The Application, together with the recommendation or recommendations of the Expert Advisor(s), is then forwarded to the Minister or the Minister's delegate for a decision regarding coverage.

After the Minister or Minister's delegate has rendered a decision, the patient's Specialist in Hematology or Nephrology and the patient or patient's parent/guardian/legal representative will be notified by letter of the Minister's decision.

RAVULIZUMAB

5. Approval of Coverage

The Minister or the Minister's delegate's decision in respect of an Application will specify the effective date of ravulizumab coverage, if coverage is approved.

Initial coverage may be approved for up to 600 mg every 4 weeks for patients weighing 5 kg to less than 20 kg, or up to 3,600 mg every 8 weeks for patients weighing 20 kg or greater for a period of 6 months.

Following this assessment, continued coverage may be approved for up to 600 mg every 4 weeks for patients weighing 5 kg to less than 20 kg, or up to 3,600 mg every 8 weeks for patients weighing 20 kg or greater for a period of 6 months and every 12 months thereafter.

If a patient is approved for coverage, prescriptions for ravulizumab must be written by a Specialist in Hematology or Nephrology. To avoid wastage, prescription quantities are limited to one dose per fill. Extended quantity and vacation supplies are not permitted. The Government is not responsible and will not pay for costs associated with wastage or improper storage of ravulizumab.

Approval of coverage is granted for a specific period, to a maximum of twelve (12) months. If continued treatment is necessary, it is the responsibility of the patient or patient's parent/guardian/legal representative and the Specialist in Hematology or Nephrology to submit a new Application to re-apply for ravulizumab coverage, and receive a decision thereon, prior to the expiry date of the authorization period.

Coverage will not be approved when any complement inhibitors are to be used in combination.

6. Withdrawal

Therapy may be withdrawn at the request of the patient or the patient's parent/guardian/legal representative at any time. Notification of withdrawal from therapy must be made by the Specialist in Hematology, Nephrology or patient in writing.

Applications, withdrawal requests, and any other information to be provided must be sent to Clinical Drug Services, Alberta Blue Cross

Paroxysmal Nocturnal Hemoglobinuria

1. Eligibility Criteria for Ravulizumab Coverage

In order to maintain the integrity of the ADBL, and having regard to the financial and social implications of covering ravulizumab for the treatment of paroxysmal nocturnal hemoglobinuria (PNH), the following special authorization criteria must be satisfied.

In order to be eligible for ravulizumab coverage for the treatment of PNH, a patient must have submitted a completed Application and have satisfied all of the following requirements:

The patient must:

- 1) Be an adult patient diagnosed with PNH in accordance with the requirements specified in the Clinical Criteria for ravulizumab;
 - 2) Have Alberta government-sponsored drug coverage;
 - 3) Meet the Registration Requirements;
 - 4) Satisfy the Clinical Criteria for ravulizumab (initial or continued coverage, as appropriate);
- AND
- 5) Meet the criteria specified in Contraindications to Coverage and Discontinuance of Coverage.

There is no guarantee that any application, whether for initial or continued coverage, will be approved. Depending on the circumstances of each case, the Minister or the Minister's delegate may:

- approve an Application;

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- approve an Application with conditions;
- deny an Application;
- discontinue an approved Application; OR
- defer an Application pending the provision of further supporting information.

The process for review and approval is explained in further detail below.

2. Registration Requirements

If the patient is a citizen or permanent resident of Canada, the patient must be continuously registered in the Alberta Health Care Insurance Plan for a minimum of one (1) year prior to an application for coverage unless:

- the patient has moved to Alberta from another province or territory in Canada (the "province of origin"), and immediately prior to moving to Alberta, was covered for ravulizumab in the province of origin by a provincial or territorial government sponsored drug plan, (or the province of origin provided equivalent coverage for ravulizumab as does Alberta) and the patient has been registered in the Alberta Health Care Insurance Plan (the patient must provide supporting documentation from the province of origin to prove prior coverage).

If the patient is not a citizen or permanent resident of Canada, the patient must be continuously registered in the Alberta Health Care Insurance Plan for a minimum of five (5) years prior to an application for coverage unless:

- the patient has moved to Alberta from another province or territory in Canada (the "province of origin"), and immediately prior to moving to Alberta, was covered for ravulizumab in the province of origin by a provincial or territorial government sponsored drug plan, (or the province of origin provided equivalent coverage for ravulizumab as does Alberta) and the patient has been registered in the Alberta Health Care Insurance Plan (the patient must provide supporting documentation from the province of origin to prove prior coverage).

The Minister reserves the right to modify or waive the Registration Requirements applicable to a given patient if the patient can establish to the satisfaction of the Minister that the patient has not moved to Alberta for the sole/primary purpose of obtaining coverage of ravulizumab.

3. Clinical Criteria

Patients with insufficient initial response or who have failed treatment with eculizumab at the Health Canada-recommended dosage are not eligible for reimbursement of ravulizumab.

In addition to meeting Sections 1 and Sections 2 herein, to be considered for coverage of ravulizumab, a patient must be assessed by a Specialist in Hematology (i.e. a physician who holds specialty certification in Hematology from the Royal College of Physicians and Surgeons of Canada) and meet all of the following clinical criteria (initial or continued coverage, as appropriate).

a. Clinical Criteria - Initial Coverage

All of the following Clinical Criteria must be established on the basis of evidence to the satisfaction of the Minister or the Minister's delegate for initial coverage:

- 1) The diagnosis of PNH must have been established by flow cytometry and/or a FLAER test. The proportion of circulating cells of each type which are GPI-deficient and hence of the PNH clone is quantitated by flow cytometry. Patients must have a:
 - PNH granulocyte or monocyte clone size equal to or greater than 10%, AND
 - Raised LDH (value at least 1.5 times the upper limit of normal for the reporting laboratory).

2) Patients with a granulocyte or monocyte clone size equal to or greater than 10% also require AT LEAST ONE of the following:

- Thrombosis: Evidence that the patient has had a thrombotic or embolic event which required the institution of therapeutic anticoagulant therapy;
- Transfusions: Evidence that the patient has been transfused with at least four (4) units of red blood cells in the last twelve (12) months;
- Anemia: Evidence that the patient has chronic or recurrent anemia where causes other than

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hemolysis have been excluded and demonstrated by more than one measure of less than or equal to 70g/L or by more than one measure of less than or equal to 100 g/L with concurrent symptoms of anemia;

- Pulmonary insufficiency: Evidence that the patient has debilitating shortness of breath and/or chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded;
- Renal insufficiency: Evidence that the patient has a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60mL/min/1.73m², where causes other than PNH have been excluded; OR
- Smooth muscle spasm: Evidence that the patient has recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded.

AND

3) All patients must receive meningococcal immunization with a quadravalent vaccine (A, C, Y and W135) at least two (2) weeks prior to receiving the first dose of ravulizumab. Treating physicians will be required to submit confirmation of meningococcal immunizations in order for their patients to continue to be eligible for treatment with ravulizumab. Pneumococcal immunization with a 23-valent polysaccharide vaccine and a 13-valent conjugate vaccine, and a Haemophilus influenza type b (Hib) vaccine must be given according to current clinical guidelines. All patients must be monitored and reimmunized according to current clinical guidelines for vaccine use.

b. Clinical Criteria - Continued Coverage

All of the following Clinical Criteria must be established on the basis of evidence to the satisfaction of the Minister or the Minister's delegate for continued coverage:

- 1) Patient eligibility must be reviewed six (6) months after commencing therapy and every six (6) months thereafter;

AND

2) Continued eligibility will be subject to the assessment of evidence, in accordance with the following monitoring requirements, which demonstrates:

- Clinical improvement in the patient, OR
- Stabilization of the patient's condition;

Monitoring requirements;

The patient's Specialist in Hematology must provide the following monitoring information every six (6) months:

- Lactate dehydrogenase (LDH);
- Full blood count and reticulocytes;
- Transfusion history for previous six months;
- Iron studies;
- Urea, electrolytes and eGFR;
- Recent clinical history; AND
- Any other information requested by the Minister, the Minister's delegate, or an Expert Advisor.

The patient's Specialist in Hematology must provide the following monitoring information every twelve (12) months:

- Confirmation that the patient has been immunized or reimmunized (meningococcal, pneumococcal 23-valent, pneumococcal 13-valent and Hib) according to current clinical guidelines for vaccine use;
- Progress reports on the clinical symptoms that formed the basis of initial eligibility;
- Quality of life, through clinical narrative;
- Granulocyte or monocyte clone size (by flow cytometry): AND
- Any other information requested by the Minister, the Minister's delegate, or an Expert Advisor.

c. Contraindications to Coverage

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- Small clone size - granulocyte and monocyte clone sizes below 10%;
- Aplastic anaemia with two or more of the following: neutrophil count below $0.5 \times 10^9/L$, platelet count below $20 \times 10^9/L$, reticulocytes below $25 \times 10^9/L$, or severe bone marrow hypocellularity;
- Patients with a presence of another life threatening or severe disease where the long term prognosis is unlikely to be influenced by therapy (for example acute myeloid leukaemia or high-risk myelodysplastic syndrome); OR
- The presence of another medical condition that in the opinion of the Minister or Minister's delegate might reasonably be expected to compromise a response to therapy.

d. Discontinuation of Coverage

Coverage may be discontinued where one or more of the following situations apply:

- The patient or the patient's Specialist in Hematology fails to comply adequately with treatment or measures, including monitoring requirements, taken to evaluate the effectiveness of the therapy;
- There is a failure to provide the Minister, the Minister's delegate, or an Expert Advisor with information as required or as requested;
- If in the opinion of the Minister or the Minister's delegate, therapy fails to relieve the symptoms of disease that originally resulted in the patient being approved by the Minister or the Minister's delegate;
- The patient has (or develops) a condition referred to in Contraindications to Coverage.

The patient's Specialist in Hematology will be advised if their patient is at risk of being withdrawn from treatment for failure to comply with the above requirements or other perceived "non-compliance" and given a reasonable period of time to respond prior to coverage being discontinued.

4. Process for Ravulizumab Coverage

For both initial and continued coverage the following documents (the Application) must be completed and submitted:

- An Eculizumab/Pegcetacoplan/Ravulizumab for Paroxysmal Nocturnal Hemoglobinuria Special Authorization Request Form completed by the patient's Specialist in Hematology;
- An Eculizumab/ Pegcetacoplan/Ravulizumab Consent Form completed by the patient and the patient's Specialist in Hematology (for any initial coverage application); AND
- Any other documentation that may be required by the Minister or the Minister's delegate.

a. Expert Review

Once the Minister or the Minister's delegate has confirmed that the patient meets the Registration Requirement or granted a waiver of the Registration Requirement, the Application will be given to one or more Expert Advisors for review.

The Application, together with the recommendation or recommendations of the Expert Advisor(s), is then forwarded to the Minister or the Minister's delegate for a decision regarding coverage.

After the Minister or Minister's delegate has rendered a decision, the patient's Specialist in Hematology and the patient will be notified by letter of the Minister's decision.

5. Approval of Coverage

The Minister or the Minister's delegate's decision in respect of an Application will specify the effective date of ravulizumab coverage, if coverage is approved.

Initial coverage may be approved for a period of up to six (6) months as follows: One loading dose of ravulizumab followed a maintenance dose at week 2, then one maintenance dose every eight (8) weeks.

Doses are based on the patient's body weight. The loading dose is as follows: 2400 mg for

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patients weighing 40 kg to less than 60 kg, 2700 mg for patients weighing 60 kg to less than 100 kg, or 3000 mg for patients weighing 100 kg or more. Maintenance dosing is as follows: 3000 mg for patients weighing 40 kg to less than 60 kg, 3300 mg for patients weighing 60 kg to less than 100 kg, or 3600 mg for patients weighing 100 kg or more.

Continued coverage may be approved for one dose of ravulizumab administered every eight (8) weeks, for a period of six (6) months.

The ravulizumab dosing schedule is allowed to occasionally vary by plus/minus 7 days of the scheduled infusion day (except for the first maintenance dose) but the subsequent dose should be administered according to the original schedule.

If a patient is approved for coverage, prescriptions for ravulizumab must be written by a Specialist in Hematology. To avoid wastage, prescription quantities are limited to one dose per fill. Extended quantity and vacation supplies are not permitted. The Government is not responsible and will not pay for costs associated with wastage or improper storage of ravulizumab.

Approval of coverage is granted for a specific period, to a maximum of six (6) months. If continued treatment is necessary, it is the responsibility of the patient and the Specialist in Hematology to submit a new Application to re-apply for ravulizumab coverage, and receive a decision thereon, prior to the expiry date of the authorization period.

Coverage will not be approved when any complement inhibitors are to be used in combination. Patients will not be permitted to switch back to a previously trialed complement inhibitor.

6. Withdrawal

Therapy may be withdrawn at the request of the patient or the patient's guardian/legal representative at any time. Notification of withdrawal from therapy must be made by the Specialist in Hematology or patient in writing.

Applications, withdrawal requests, and any other information to be provided must be sent to Clinical Drug Services, Alberta Blue Cross.

10 MG / ML INJECTION

00002491559	ULTOMIRIS	APG	\$	242.7383
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100 MG / ML INJECTION

<input checked="" type="checkbox"/> 00002533456	ULTOMIRIS (1100 MG/11 ML)	APG	\$	2427.3818
<input checked="" type="checkbox"/> 00002533448	ULTOMIRIS (300 MG/3 ML)	APG	\$	2427.3833

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

RISANKIZUMAB

"Special authorization coverage may be approved for coverage of risankizumab 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:

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

Prior to initiation of risankizumab therapy for New Patients:

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

Moderately to Severely Active Crohn's Disease:

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

Refractory is defined as one or more of the following:

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

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

AND

b) Immunosuppressive therapy as follows:

- Azathioprine: minimum of 2 mg/kg/day for a minimum of 3 months; OR
- 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 3 months; OR
- Methotrexate: minimum of 15 mg/week for a minimum of 3 months.

OR

- Immunosuppressive therapy discontinued at less than 3 months due to serious adverse effects or reactions.

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

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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 risankizumab by any health care provider).
- 'Induction Dosing' means a maximum of one 600 mg dose of risankizumab IV per New Patient at 0, 4 and 8 weeks.
- New Patients are eligible to receive Induction Dosing only once, after which time the Maintenance Dosing for New Patients and Continued Coverage for Maintenance Dosing criteria will apply.
- As an interim measure, one 360 mg dose of risankizumab SC will be provided at week 12 to allow time to determine whether the New Patient meets coverage criteria for Maintenance Dosing below.

Maintenance Dosing:

'Maintenance Dosing' means one 360 mg dose of risankizumab SC per patient every 8 weeks for a period of 12 months to:

- New Patients following the completion of Induction Dosing; OR
- Existing Patients, who are patients that are being treated, or have previously been treated, with risankizumab.

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.

Maintenance Dosing for Existing Patients:

- The patient must be assessed by a Specialist annually within 8 weeks after the last dose of risankizumab SC was administered to the patient and prior to administration of the next dose, to obtain a Modified Harvey Bradshaw Index Score (Existing Patient's Baseline Score) for Moderately to Severely Active Crohn's; AND
- these measures must be provided to Alberta Blue Cross for assessment for continued coverage for maintenance dosing.

Continued Coverage for Maintenance Dosing:

- Continued coverage may be considered for one 360 mg dose of risankizumab SC per patient provided no more often than every 8 weeks for a period of 12 months, if the following criteria are met at the end of each 12 month period:
 - The New Patient or the Existing Patient must be assessed by a Specialist annually within 8 weeks after the last dose of risankizumab SC 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; AND
 - For New Patients: The Specialist must confirm that the patient has maintained a greater than or equal to 3 point decrease from the New Patient's Baseline Score for Moderately to Severely Active Crohn's; OR
 - For Existing Patients: The Specialist must confirm that the patient has maintained the Existing Patient's Baseline Score."

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

600 MG / VIAL INJECTION

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

RISANKIZUMAB

00002532107 SKYRIZI ABV \$ 4593.1400

ALBERTA DRUG BENEFIT LIST UPDATE
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RISANKIZUMAB

Coverage Criteria for Moderately to Severely Active Crohn's Disease

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- The Specialist must confirm the Modified Harvey Bradshaw Index score shows a decrease from the New Patient's Baseline Score of greater than or equal to 3 points for patients with Moderately to Severely Active Crohn's.

Maintenance Dosing for Existing Patients:

- The patient must be assessed by a Specialist annually within 8 weeks after the last dose of risankizumab SC was administered to the patient and prior to administration of the next dose, to obtain a Modified Harvey Bradshaw Index Score (Existing Patient's Baseline Score) for Moderately to Severely Active Crohn's; AND
- these measures must be provided to Alberta Blue Cross for assessment for continued coverage for maintenance dosing.

Continued Coverage for Maintenance Dosing:

-Continued coverage may be considered for one 360 mg dose of risankizumab SC per patient provided no more often than every 8 weeks for a period of 12 months, if the following criteria are met at the end of each 12 month period:

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360 MG INJECTION CARTRIDGE

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

RISANKIZUMAB

00002532093	SKYRIZI	ABV	\$ 4593.1400
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