

# Updates to the Alberta Drug Benefit List

Effective August 1, 2024



Inquiries should be directed to:

**Pharmacy Services**

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

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

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

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

Administered by Alberta Blue Cross  
on behalf of Alberta Health.

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

## Table of Contents

---

Special Authorization .....	1
■ New Drug Product(s) Available by Special Authorization.....	1
■ Additional Brand(s) and/or Strength(s) of Drug Product(s) Available by Special Authorization....	1
■ Drug Product(s) with Changes to Criteria for Coverage.....	1
Restricted Benefit(s).....	1
■ Additional Brand(s) and/or Strength(s) of Drug Product(s) Available by Restricted Benefit.....	2
Added Product(s).....	2
New Established Interchangeable (IC) Grouping(s).....	3
Least Cost Alternative (LCA) Price Change(s).....	3
Product(s) with a Price Change .....	4
Discontinued Listing(s).....	4
Part 2 Drug Additions.....	2-1
Part 3 Special Authorization.....	3-1

## Special Authorization

---

The following drug product(s) will be considered for coverage by Special Authorization effective August 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>
BRINEURA 30 MG / ML INJECTION	CERLIPONASE ALFA	00002484013	BMI
CAMZYOS 2.5 MG CAPSULE	MAVACAMTEN	00002532549	BMS
CAMZYOS 5 MG CAPSULE	MAVACAMTEN	00002532557	BMS
CAMZYOS 10 MG CAPSULE	MAVACAMTEN	00002532565	BMS
CAMZYOS 15 MG CAPSULE	MAVACAMTEN	00002532573	BMS
OXLUMO 94.5 MG / VIAL INJECTION	LUMASIRAN SODIUM	00002525755	ANT
VASCEPA 1 G CAPSULE	ICOSAPENT ETHYL	00002495244	HLS

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

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

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
RINVOQ 45 MG EXTENDED-RELEASE TABLET	UPADACITINIB	00002539721	ABV

### 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>
MAYZENT 0.25 MG TABLET	SIPONIMOD	00002496429	NOV
MAYZENT 2 MG TABLET	SIPONIMOD	00002496437	NOV
NUCALA 100 MG / SYRINGE INJECTION	MEPOLIZUMAB	00002492997	GSK
NUCALA (AUTOINJECTOR) 100 MG / SYRINGE INJECTION	MEPOLIZUMAB	00002492989	GSK
RINVOQ 15 MG EXTENDED-RELEASE TABLET	UPADACITINIB	00002495155	ABV
RINVOQ 30 MG EXTENDED-RELEASE TABLET	UPADACITINIB	00002520893	ABV

## Restricted Benefit(s)

---

The following drug product(s) will be considered for coverage via Restricted Benefit effective August 1, 2024 for patients covered under Alberta government-sponsored drug programs.

### 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>
LEFLUNOMIDE 10 MG TABLET	LEFLUNOMIDE	00002543575	SIV
LEFLUNOMIDE 20 MG TABLET	LEFLUNOMIDE	00002543583	SIV
SANDOZ LISDEXAMFETAMINE 20 MG CAPSULE	LISDEXAMFETAMINE DIMESYLATE	00002546256	SDZ
SANDOZ LISDEXAMFETAMINE 40 MG CAPSULE	LISDEXAMFETAMINE DIMESYLATE	00002546272	SDZ
SANDOZ LISDEXAMFETAMINE 50 MG CAPSULE	LISDEXAMFETAMINE DIMESYLATE	00002546280	SDZ
SANDOZ LISDEXAMFETAMINE 60 MG CAPSULE	LISDEXAMFETAMINE DIMESYLATE	00002546299	SDZ
TEVA-LISDEXAMFETAMINE 20 MG CAPSULE	LISDEXAMFETAMINE DIMESYLATE	00002545888	TEV
TEVA-LISDEXAMFETAMINE 30 MG CAPSULE	LISDEXAMFETAMINE DIMESYLATE	00002545896	TEV
TEVA-LISDEXAMFETAMINE 40 MG CAPSULE	LISDEXAMFETAMINE DIMESYLATE	00002545918	TEV
TEVA-LISDEXAMFETAMINE 50 MG CAPSULE	LISDEXAMFETAMINE DIMESYLATE	00002545926	TEV
TEVA-LISDEXAMFETAMINE 60 MG CAPSULE	LISDEXAMFETAMINE DIMESYLATE	00002545934	TEV

## Added Product(s)

---

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
AURO-NITROFURANTOIN 100 MG CAPSULE (MACROCRYSTALS / MONOHYDRATE)	NITROFURANTOIN	00002466392	AUR
BACLOFEN 10 MG TABLET	BACLOFEN	00002544660	SIV
BACLOFEN 20 MG TABLET	BACLOFEN	00002544679	SIV
GLYCOPYRROLATE 0.2 MG / ML INJECTION	GLYCOPYRROLATE	00002513749	JPC
METOCLOPRAMIDE OMEGA 5 MG / ML INJECTION	METOCLOPRAMIDE HCL	00002243563	OMG
NRA-OLANZAPINE 2.5 MG TABLET	OLANZAPINE	00002545586	NRA
NRA-OLANZAPINE 5 MG DISINTEGRATING TABLET	OLANZAPINE	00002536188	NRA
NRA-OLANZAPINE 5 MG TABLET	OLANZAPINE	00002545594	NRA
NRA-OLANZAPINE 7.5 MG TABLET	OLANZAPINE	00002545608	NRA
NRA-OLANZAPINE 10 MG DISINTEGRATING TABLET	OLANZAPINE	00002536196	NRA

## Added Product(s), continued

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
NRA-OLANZAPINE 10 MG TABLET	OLANZAPINE	00002545616	NRA
NRA-OLANZAPINE 15 MG TABLET	OLANZAPINE	00002545624	NRA
SUBOXONE 2 MG / 0.5 MG BUCCAL / SUBLINGUAL FILM	BUPRENORPHINE HCL/NALOXONE HYDROCHLORIDE DIHYDRATE	00002502313	IUK
SUBOXONE 8 MG / 2 MG BUCCAL / SUBLINGUAL FILM	BUPRENORPHINE HCL/NALOXONE HYDROCHLORIDE DIHYDRATE	00002502348	IUK
SUBOXONE 12 MG / 3 MG BUCCAL / SUBLINGUAL FILM	BUPRENORPHINE HCL/NALOXONE HYDROCHLORIDE DIHYDRATE	00002502356	IUK

## New Established Interchangeable (IC) Grouping(s)

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

<u>Generic Description</u>	<u>Strength / Form</u>	<u>New LCA Price</u>
LISDEXAMFETAMINE DIMESYLATE	20 MG CAPSULE	1.4161
LISDEXAMFETAMINE DIMESYLATE	30 MG CAPSULE	2.5406
LISDEXAMFETAMINE DIMESYLATE	40 MG CAPSULE	1.9715
LISDEXAMFETAMINE DIMESYLATE	50 MG CAPSULE	2.2491
LISDEXAMFETAMINE DIMESYLATE	60 MG CAPSULE	2.5268
NITROFURANTOIN	100 MG CAPSULE (MACROCRYSTALS / MONOHYDRATE)	0.3983

## 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 September 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>
METHADONE HCL	1 MG TABLET	0.1026
METHADONE HCL	5 MG TABLET	0.3417
METHADONE HCL	10 MG TABLET	0.5466
METHADONE HCL	25 MG TABLET	1.0157
METHOTREXATE SODIUM	10 MG / SYRINGE INJECTION	16.3020
METHOTREXATE SODIUM	12.5 MG / SYRINGE INJECTION	17.1600
TIOTROPIUM BROMIDE MONOHYDRATE	18 MCG INHALATION SOLUTION	1.0057

## Product(s) with a Price Change

The following product(s) had a Price Change. The previous higher price will be recognized until August 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-METHADONE 1 MG TABLET	METHADONE HCL	00002533642	APX
APO-METHADONE 5 MG TABLET	METHADONE HCL	00002533650	APX
APO-METHADONE 10 MG TABLET	METHADONE HCL	00002533669	APX
APO-METHADONE 25 MG TABLET	METHADONE HCL	00002533677	APX
JAMP-CHOLESTYRAMINE 4 G POWDER PACKET	CHOLESTYRAMINE RESIN	00002478595	JPC
LUPIN-TIOTROPIUM 18 MCG INHALATION CAPSULE	TIOTROPIUM BROMIDE MONOHYDRATE	00002537850	LPC
MYLAN-CILAZAPRIL 1 MG TABLET	CILAZAPRIL	00002283778	MYP
PMS-METHOTREXATE 10 MG / SYRINGE INJECTION	METHOTREXATE SODIUM	00002539608	PMS
PMS-METHOTREXATE 12.5 MG / SYRINGE INJECTION	METHOTREXATE SODIUM	00002539616	PMS
PMS-NITROFURANTOIN 100 MG CAPSULE (MACROCRYSTALS / MONOHYDRATE)	NITROFURANTOIN	00002455676	PMS
SPIRIVA 18 MCG INHALATION CAPSULE	TIOTROPIUM BROMIDE MONOHYDRATE	00002246793	BOE

## Discontinued Listing(s)

Notification of discontinuation has been received from the manufacturer(s). The Alberta government-sponsored drug programs previously covered the following drug product(s). Effective August 1, 2024, the listed product(s) will no longer be a benefit and where applicable, will not be considered for coverage by Special Authorization. A transition period will be applied and as of September 1, 2024 claims will no longer pay for these product(s).

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
ADLYXINE 0.1 MG / ML INJECTION	LIXISENATIDE	00002464284	SAV
ALBRIOZA 3 G / 1 G ORAL POWDER PACKET	SODIUM PHENYLBUTYRATE/ URSODOXICOLTAURINE	00002527707	AYX
CHLORDIAZEPOXIDE 10 MG CAPSULE	CHLORDIAZEPOXIDE HCL	00000522988	AAP
SANDOZ K 20 20 MEQ TABLET / SUSTAINED-RELEASE TABLET	POTASSIUM CHLORIDE (K+)	00002242261	SDZ

## **PART 2**

# Drug Additions



ALBERTA DRUG BENEFIT LIST UPDATE

**BACLOFEN**

10 MG ORAL TABLET

00002139332	APO-BACLOFEN	APX	\$	0.1595
00002287021	BACLOFEN	SNS	\$	0.1595
00002544660	BACLOFEN	SIV	\$	0.1595
00002088398	MYLAN-BACLOFEN	MYP	\$	0.1595
00002063735	PMS-BACLOFEN	PMS	\$	0.1595

20 MG ORAL TABLET

00002139391	APO-BACLOFEN	APX	\$	0.3104
00002287048	BACLOFEN	SNS	\$	0.3104
00002544679	BACLOFEN	SIV	\$	0.3104
00002088401	MYLAN-BACLOFEN	MYP	\$	0.3104
00002063743	PMS-BACLOFEN	PMS	\$	0.3104

**BUPRENORPHINE HCL/ NALOXONE HYDROCHLORIDE DIHYDRATE**

2 MG (BASE) \* 0.5 MG (BASE) BUCCAL/SUBLINGUAL FILM

00002502313	SUBOXONE	IUK	\$	2.6700
-------------	----------	-----	----	--------

4 MG \* 1 MG BUCCAL/SUBLINGUAL FILM

00002502321	SUBOXONE	IUK	\$	3.6889
-------------	----------	-----	----	--------

8 MG (BASE) \* 2 MG (BASE) BUCCAL/SUBLINGUAL FILM

00002502348	SUBOXONE	IUK	\$	4.7300
-------------	----------	-----	----	--------

12 MG (BASE) \* 3 MG (BASE) BUCCAL/SUBLINGUAL FILM

00002502356	SUBOXONE	IUK	\$	7.0950
-------------	----------	-----	----	--------

**CHOLESTYRAMINE RESIN**

4 G ORAL POWDER PACKET

00002478595	JAMP-CHOLESTYRAMINE	JPC	\$	0.9217
-------------	---------------------	-----	----	--------

**CILAZAPRIL**

1 MG ORAL TABLET

00002283778	MYLAN-CILAZAPRIL	MYP	\$ 0.1945	\$ 0.3426
-------------	------------------	-----	-----------	-----------

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

**GLYCOPYRROLATE**

0.2 MG / ML INJECTION

00002039508	GLYCOPYRROLATE	SDZ	\$	2.7825
00002382857	GLYCOPYRROLATE	OMG	\$	2.7825
00002513749	GLYCOPYRROLATE	JPC	\$	2.7825
00002532379	GLYCOPYRROLATE	JPC	\$	2.7825
00002473879	GLYCOPYRROLATE (0.2 MG/1 ML)	STM	\$	2.7825
00002473895	GLYCOPYRROLATE (0.4 MG/2 ML)	STM	\$	2.7825
00002473887	GLYCOPYRROLATE (4 MG/20 ML)	STM	\$	2.7825
00002382849	GLYCOPYRROLATE MULTIDOSE	OMG	\$	2.7825

ALBERTA DRUG BENEFIT LIST UPDATE

**LEFLUNOMIDE**

RESTRICTED BENEFIT - This product is a benefit for the treatment of rheumatoid arthritis when the initial prescription is prescribed by a Specialist in Rheumatology or Internal Medicine.

**10 MG ORAL TABLET**

<b>00002478862</b>	<b>ACCEL-LEFLUNOMIDE</b>	<b>ACP</b>	<b>\$ 2.0000</b>
00002256495	APO-LEFLUNOMIDE	APX	\$ 2.6433
00002351668	LEFLUNOMIDE	SNS	\$ 2.6433
00002543575	LEFLUNOMIDE	SIV	\$ 2.6433
00002283964	SANDOZ LEFLUNOMIDE	SDZ	\$ 2.6433
00002261251	TEVA-LEFLUNOMIDE	TEV	\$ 2.6433
00002241888	ARAVA	SAV	\$ 11.4440

**20 MG ORAL TABLET**

<b>00002478870</b>	<b>ACCEL-LEFLUNOMIDE</b>	<b>ACP</b>	<b>\$ 2.0000</b>
00002256509	APO-LEFLUNOMIDE	APX	\$ 2.6433
00002351676	LEFLUNOMIDE	SNS	\$ 2.6433
00002543583	LEFLUNOMIDE	SIV	\$ 2.6433
00002283972	SANDOZ LEFLUNOMIDE	SDZ	\$ 2.6433
00002261278	TEVA-LEFLUNOMIDE	TEV	\$ 2.6433
00002241889	ARAVA	SAV	\$ 11.4443

**LISDEXAMFETAMINE DIMESYLATE**

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

**20 MG ORAL CAPSULE**

<b>00002546256</b>	<b>SANDOZ LISDEXAMFETAMINE</b>	<b>SDZ</b>	<b>\$ 1.4161</b>
<b>00002545888</b>	<b>TEVA-LISDEXAMFETAMINE</b>	<b>TEV</b>	<b>\$ 1.4161</b>
00002347156	VYVANSE	TAK	\$ 2.8322

**30 MG ORAL CAPSULE**

<b>00002545896</b>	<b>TEVA-LISDEXAMFETAMINE</b>	<b>TEV</b>	<b>\$ 2.5406</b>
00002322951	VYVANSE	TAK	\$ 3.3875

**40 MG ORAL CAPSULE**

<b>00002546272</b>	<b>SANDOZ LISDEXAMFETAMINE</b>	<b>SDZ</b>	<b>\$ 1.9715</b>
<b>00002545918</b>	<b>TEVA-LISDEXAMFETAMINE</b>	<b>TEV</b>	<b>\$ 1.9715</b>
00002347164	VYVANSE	TAK	\$ 3.9429

**50 MG ORAL CAPSULE**

<b>00002546280</b>	<b>SANDOZ LISDEXAMFETAMINE</b>	<b>SDZ</b>	<b>\$ 2.2491</b>
<b>00002545926</b>	<b>TEVA-LISDEXAMFETAMINE</b>	<b>TEV</b>	<b>\$ 2.2491</b>
00002322978	VYVANSE	TAK	\$ 4.4982

**60 MG ORAL CAPSULE**

<b>00002546299</b>	<b>SANDOZ LISDEXAMFETAMINE</b>	<b>SDZ</b>	<b>\$ 2.5268</b>
<b>00002545934</b>	<b>TEVA-LISDEXAMFETAMINE</b>	<b>TEV</b>	<b>\$ 2.5268</b>
00002347172	VYVANSE	TAK	\$ 5.0535

**METHADONE HCL**

**1 MG ORAL TABLET**

<b>00002533642</b>	<b>APO-METHADONE</b>	<b>APX</b>	<b>\$ 0.1026</b>
00002247698	METADOL	PAL	\$ 0.1399

**5 MG ORAL TABLET**

<b>00002533650</b>	<b>APO-METHADONE</b>	<b>APX</b>	<b>\$ 0.3417</b>
00002247699	METADOL	PAL	\$ 0.4659

**10 MG ORAL TABLET**

<b>00002533669</b>	<b>APO-METHADONE</b>	<b>APX</b>	<b>\$ 0.5466</b>
00002247700	METADOL	PAL	\$ 0.7454

**25 MG ORAL TABLET**

<b>00002533677</b>	<b>APO-METHADONE</b>	<b>APX</b>	<b>\$ 1.0157</b>
00002247701	METADOL	PAL	\$ 1.3850

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

**METHOTREXATE SODIUM**

10 MG / SYR (BASE)	INJECTION SYRINGE			
☒ 00002422174	METHOTREXATE INJECTION BP	PMS	\$	7.0000
00002539608	PMS-METHOTREXATE	PMS	\$	16.3020
00002454831	METOJECT SUBCUTANEOUS	MDX	\$	22.2300
12.5 MG / SYR	INJECTION SYRINGE			
00002539616	PMS-METHOTREXATE	PMS	\$	17.1600
00002454750	METOJECT SUBCUTANEOUS	MDX	\$	23.4000

**METOCLOPRAMIDE HCL**

5 MG / ML	INJECTION			
00002185431	METOCLOPRAMIDE HYDROCHLORIDE	SDZ	\$	2.3748
00002537397	METOCLOPRAMIDE HYDROCHLORIDE	JPC	\$	2.3748
00002243563	METOCLOPRAMIDE OMEGA	OMG	\$	2.3748

**NITROFURANTOIN**

100 MG	ORAL CAPSULE (MACROCRYSTALS/MONOHYDRATE)			
00002466392	AURO-NITROFURANTOIN	AUR	\$	0.3983
00002455676	PMS-NITROFURANTOIN	PMS	\$	0.3983

**OLANZAPINE**

2.5 MG	ORAL TABLET			
00002487608	AG-OLANZAPINE FC	AGP	\$	0.1772
00002281791	APO-OLANZAPINE	APX	\$	0.1772
00002417243	JAMP OLANZAPINE FC	JPC	\$	0.1772
00002410141	MINT-OLANZAPINE	MPI	\$	0.1772
00002545586	NRA-OLANZAPINE	NRA	\$	0.1772
00002372819	OLANZAPINE	SNS	\$	0.1772
00002385864	OLANZAPINE	SIV	\$	0.1772
00002303116	PMS-OLANZAPINE	PMS	\$	0.1772
00002310341	SANDOZ OLANZAPINE	SDZ	\$	0.1772
00002276712	TEVA-OLANZAPINE	TEV	\$	0.1772
00002229250	ZYPREXA	LIL	\$	2.0236
5 MG	ORAL TABLET			
00002487616	AG-OLANZAPINE FC	AGP	\$	0.3544
00002281805	APO-OLANZAPINE	APX	\$	0.3544
00002417251	JAMP OLANZAPINE FC	JPC	\$	0.3544
00002410168	MINT-OLANZAPINE	MPI	\$	0.3544
00002545594	NRA-OLANZAPINE	NRA	\$	0.3544
00002372827	OLANZAPINE	SNS	\$	0.3544
00002385872	OLANZAPINE	SIV	\$	0.3544
00002303159	PMS-OLANZAPINE	PMS	\$	0.3544
00002310368	SANDOZ OLANZAPINE	SDZ	\$	0.3544
00002276720	TEVA-OLANZAPINE	TEV	\$	0.3544
00002229269	ZYPREXA	LIL	\$	3.9807
7.5 MG	ORAL TABLET			
00002281813	APO-OLANZAPINE	APX	\$	0.5316
00002417278	JAMP OLANZAPINE FC	JPC	\$	0.5316
00002410176	MINT-OLANZAPINE	MPI	\$	0.5316
00002545608	NRA-OLANZAPINE	NRA	\$	0.5316
00002372835	OLANZAPINE	SNS	\$	0.5316
00002385880	OLANZAPINE	SIV	\$	0.5316
00002303167	PMS-OLANZAPINE	PMS	\$	0.5316
00002310376	SANDOZ OLANZAPINE	SDZ	\$	0.5316
00002276739	TEVA-OLANZAPINE	TEV	\$	0.5316
00002229277	ZYPREXA	LIL	\$	5.9711

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

**OLANZAPINE**

<b>10 MG (BASE) ORAL TABLET</b>			
00002487632	AG-OLANZAPINE FC	AGP	\$ 0.7088
00002281821	APO-OLANZAPINE	APX	\$ 0.7088
00002417286	JAMP OLANZAPINE FC	JPC	\$ 0.7088
00002410184	MINT-OLANZAPINE	MPI	\$ 0.7088
00002545616	NRA-OLANZAPINE	NRA	\$ 0.7088
00002372843	OLANZAPINE	SNS	\$ 0.7088
00002385899	OLANZAPINE	SIV	\$ 0.7088
00002303175	PMS-OLANZAPINE	PMS	\$ 0.7088
00002310384	SANDOZ OLANZAPINE	SDZ	\$ 0.7088
00002276747	TEVA-OLANZAPINE	TEV	\$ 0.7088
00002229285	ZYPREXA	LIL	\$ 7.9618
<b>15 MG ORAL TABLET</b>			
00002281848	APO-OLANZAPINE	APX	\$ 1.0631
00002417294	JAMP OLANZAPINE FC	JPC	\$ 1.0631
00002410192	MINT-OLANZAPINE	MPI	\$ 1.0631
00002545624	NRA-OLANZAPINE	NRA	\$ 1.0631
00002372851	OLANZAPINE	SNS	\$ 1.0631
00002385902	OLANZAPINE	SIV	\$ 1.0631
00002303183	PMS-OLANZAPINE	PMS	\$ 1.0631
00002310392	SANDOZ OLANZAPINE	SDZ	\$ 1.0631
00002276755	TEVA-OLANZAPINE	TEV	\$ 1.0631
00002238850	ZYPREXA	LIL	\$ 12.1457
<b>5 MG ORAL DISINTEGRATING TABLET</b>			
00002360616	APO-OLANZAPINE ODT	APX	\$ 0.3574
00002448726	AURO-OLANZAPINE ODT	AUR	\$ 0.3574
00002406624	JAMP-OLANZAPINE ODT	JPC	\$ 0.3574
00002436965	MINT-OLANZAPINE ODT	MPI	\$ 0.3574
00002536188	NRA-OLANZAPINE	NRA	\$ 0.3574
00002343665	OLANZAPINE ODT	SIV	\$ 0.3574
00002352974	OLANZAPINE ODT	SNS	\$ 0.3574
00002303191	PMS-OLANZAPINE ODT	PMS	\$ 0.3574
00002327775	SANDOZ OLANZAPINE ODT	SDZ	\$ 0.3574
00002243086	ZYPREXA ZYDIS	LIL	\$ 3.9589
<b>10 MG (BASE) ORAL DISINTEGRATING TABLET</b>			
00002360624	APO-OLANZAPINE ODT	APX	\$ 0.7143
00002448734	AURO-OLANZAPINE ODT	AUR	\$ 0.7143
00002406632	JAMP-OLANZAPINE ODT	JPC	\$ 0.7143
00002436973	MINT-OLANZAPINE ODT	MPI	\$ 0.7143
00002536196	NRA-OLANZAPINE	NRA	\$ 0.7143
00002343673	OLANZAPINE ODT	SIV	\$ 0.7143
00002352982	OLANZAPINE ODT	SNS	\$ 0.7143
00002303205	PMS-OLANZAPINE ODT	PMS	\$ 0.7143
00002327783	SANDOZ OLANZAPINE ODT	SDZ	\$ 0.7143
00002243087	ZYPREXA ZYDIS	LIL	\$ 7.9107

**TIOTROPIUM BROMIDE MONOHYDRATE**

<b>18 MCG INHALATION CAPSULE</b>			
00002537850	LUPIN-TIOTROPIUM	LPC	\$ 1.0057
00002246793	SPIRIVA	BOE	\$ 1.0057

## **PART 3**

# Special Authorization

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

**CERLIPONASE ALFA**

"For the treatment of neuronal ceroid lipofuscinosis type 2 (CLN2) disease, also known as tripeptidyl peptidase 1 (TPP1) deficiency, in patients who meet all of the following criteria:

- 1) has a confirmed diagnosis of CLN2 disease based on TPP1 enzyme activity and CLN2 genotype analysis.
- 2) has a minimum score of greater than or equal to 1 in each of the motor and the language domains of the CLN2 Clinical Rating Scale
- 3) has an aggregated motor-language score of greater than or equal to 3 on the CLN2 Clinical Rating Scale

Coverage may be approved for a period of 6 months.

Ongoing coverage may be considered only if the following criteria are met at the end of each 6-month period:

Patients must be assessed every 24 weeks for changes in motor and language function using the CLN2 Clinical Rating Scale and must NOT have:

- a 2 point or greater reduction in the aggregate motor-language score of the CLN2 Clinical Rating Scale that is maintained over any two consecutive 24 week assessments, OR
- the aggregate motor-language score of the CLN2 Clinical Rating Scale reaches zero at two consecutive 24-week assessments.

Patients will be limited to receiving one dose (2 vials) of cerliponase alfa per prescription at their pharmacy."

All requests (including renewal requests) for cerlipobase alpha must be completed using the Cerliponase Alpha Special Authorization Request Form (ABC 60121).

**30 MG / ML INJECTION**

00002484013 BRINEURA BMI \$ 3020.0000

---

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

**ICOSAPENT ETHYL**

"Special authorization coverage may be provided to reduce the risk of cardiovascular events [CV] (CV death, non-fatal myocardial infarction, non-fatal stroke, coronary revascularization, or hospitalization for unstable angina) in statin-treated patients, age 45 years and older with established cardiovascular disease (secondary prevention) and elevated triglycerides (TGs), if the following criteria are met:

Patients must:

- be receiving a maximally tolerated statin dose, targeted to achieve a low-density lipoprotein cholesterol (LDL-C) < 2 mmol/L for a minimum of four weeks

AND

- have a LDL-C > 1.0 mmol/L and < 2.6 mmol/L at baseline

AND

- have a fasting TG level of  $\geq 1.7$  mmol/L and < 5.6 mmol/L at baseline.

LDL-C and fasting TG levels must be measured within the preceding three months before starting treatment with icosapent ethyl.

Special authorization may be granted for 12 months.

Renewal requests may be considered for patients who continue to be maintained on a maximally tolerated statin dose."

All requests (including renewal requests) for icosapent ethyl must be completed using the Icosapent Ethyl Special Authorization Request Form (ABC 60123).

**1 G ORAL CAPSULE**

00002495244 VASCEPA HLS \$ 2.4200

---

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

**LUMASIRAN SODIUM**

"Special authorization coverage may be provided for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels in pediatric and adult patients with:

- a genetically confirmed diagnosis of PH1, AND
- in patients where urinary oxalate can be measured, are unable to normalize urine oxalate excretion while staying compliant with standard of care therapy, including vitamin B6 for a duration of 3 to 6 months.

For coverage, this drug must be initiated by a Specialist in Nephrology, Endocrinology & Metabolism, or Medical Genetics & Genomics with experience in the diagnosis and management of PH1. Renewals may be completed by a Specialist in Pediatrics, Nephrology, Endocrinology & Metabolism, or Medical Genetics & Genomics.

For initial coverage, the following pre-treatment information must be provided:

- 24-hour urinary oxalate level of 1.5 times the upper limit of normal (ULN) or greater, in patients where a urinary oxalate can be measured, or
- Spot urine oxalate:creatinine ratio, in patients who are not continent, or
- Predialysis plasma oxalate level, in patients with end-stage kidney disease (ESKD) or those who are on dialysis.

For coverage, dosing will be approved as follows:

- For patients with body weight less than 10 kg: 6 mg/kg once monthly for three loading doses, then 3 mg/kg maintenance dose once monthly thereafter.
- For patients with body weight of 10 kg to less than 20 kg: 6 mg/kg once monthly for three loading doses, then 6 mg/kg maintenance dose every three months thereafter (with the first maintenance dose given 1 month after the last loading dose).
- For patients with body weight of 20 kg and above: 3 mg/kg once monthly for three loading doses, then 3 mg/kg maintenance dose every three months thereafter (with the first maintenance dose given 1 month after the last loading dose).

Coverage may be approved for 12 months.

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

For continued coverage, evidence of response must be provided. Response is defined as:

- a lowering of 24-hour urine oxalate to less than 1.5 times the ULN, for patients in whom urinary oxalate can be measured, or
- a 30% reduction in urine oxalate:creatinine ratio in non-continent patients, or
- a 15% reduction in plasma oxalate level in patients with ESKD or who are on dialysis.

Coverage cannot be renewed once the patient has received a liver transplant with or without a kidney transplant."

All requests (including renewal requests) for lumasiran must be completed using the Lumasiran Special Authorization Request Form (ABC 60119).

**94.5 MG / VIAL INJECTION**

00002525755

OXLUMO

ANT

\$ 96855.3300

---



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

**MAVACAMTEN**

"Special authorization coverage may be provided for adult patients (18 years of age or older) with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) of New York Heart Association (NYHA) class II to III who meet all of the following criteria:

-Patients must have documented left ventricular ejection fraction (LVEF)  $\geq$  55% at rest determined by echocardiography.

-Patients must have left ventricular (LV) wall thickness  $\geq$  15 mm (or  $\geq$  13 mm with a family history of hypertrophic cardiomyopathy).

-Patients must have left ventricular outflow tract (LVOT) peak gradient  $\geq$  50 mm Hg at rest, after Valsalva maneuver, or post exercise, as confirmed by echocardiography.

-Patients must be receiving beta-blocker or calcium channel blocker therapy and experience clinical deterioration in symptoms or echocardiography while receiving either of these treatments.

For coverage, the drug must be initiated in consultation with a Specialist in Cardiology.  
-Initial coverage may be approved for up to 5 mg daily for 12 weeks.

For renewal of coverage, the physician must document that patients must NOT have:  
-a LVEF  $\leq$  30%, NOR  
-received septal reduction therapy.

Continued coverage may be approved for up to 15 mg daily for a period of 12 months."

All requests (including renewal requests) for mavacamten must be completed using the Mavacamten Special Authorization Request Form (ABC 60122).

**2.5 MG ORAL CAPSULE**

00002532549 CAMZYOS BMS \$ 61.6000

**5 MG ORAL CAPSULE**

00002532557 CAMZYOS BMS \$ 61.6000

**10 MG ORAL CAPSULE**

00002532565 CAMZYOS BMS \$ 61.6000

**15 MG ORAL CAPSULE**

00002532573 CAMZYOS BMS \$ 61.6000

---

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

**MEPOLIZUMAB**

**Asthma**

"Special authorization coverage may be provided for add-on maintenance treatment of adult patients with severe eosinophilic asthma if the following clinical criteria and conditions are met:

Patient is inadequately controlled with high-dose inhaled corticosteroids (ICS) and one or more additional asthma controller(s) (e.g., a long-acting beta-agonist [LABA]).

AND

Patient has a blood eosinophil count of greater than or equal to 300 cells/mcL AND has experienced two or more clinically significant asthma exacerbations\* in the 12 months prior to treatment initiation with mepolizumab;

OR

Patient has a blood eosinophil count of greater than or equal to 150 cells/mcL AND is receiving daily maintenance treatment with oral corticosteroids (OCS).

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

Initial coverage may be approved for 12 months of 100 mg administered every 4 weeks.

-Patients will be limited to receiving a one-month supply of mepolizumab per prescription at their pharmacy.

-Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).

-Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.

-Coverage cannot be provided for mepolizumab when this medication is intended for use in combination with other biologics for the treatment of asthma.

If ALL the following criteria are met, special authorization may be approved for 100 mg administered every 4 weeks for a further 12-month period.

- 1) An improvement in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 when compared to pre-treatment baseline or an ACQ-5 score of less than or equal to 1; AND
- 2) Maintenance or reduction in the number of clinically significant exacerbations\* compared to the 12 months prior to initiation of treatment with mepolizumab; AND
- 3) For patients on daily maintenance therapy with OCS prior to initiating mepolizumab, a decrease in the OCS dose.

Continued coverage may be considered for 100 mg administered every 4 weeks if ALL of the following criteria are met at the end of each additional 12-month period:

- 1) The ACQ-5 score achieved during the first 12 months of therapy is at least maintained throughout treatment or the ACQ-5 score is less than or equal to 1; AND
- 2) Maintenance or reduction in the number of clinically significant exacerbations\* compared to the previous 12-month period; AND

3) For patients on daily maintenance therapy with OCS prior to initiating mepolizumab, the reduction in the OCS dose achieved after the first 12 months of therapy is at least maintained throughout treatment.

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

All requests (including renewal requests) for mepolizumab must be completed using the

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

**MEPOLIZUMAB**

Benralizumab/Mepolizumab Special Authorization Request Form (ABC 60061).

**Chronic Rhinosinusitis with Nasal Polyps**

"Special authorization coverage may be provided for add-on maintenance treatment with intranasal corticosteroids for adult patients with severe chronic rhinosinusitis with nasal polyps (CRSwNP), if the following criteria are met:

- Patient is inadequately controlled with intranasal corticosteroids and is experiencing refractory symptoms despite use of intranasal corticosteroids for 3 months at maximally tolerated doses, AND;
- Has endoscopically- or computed tomography-documented bilateral nasal polyps, AND
- Has undergone at least 1 prior surgical intervention for nasal polyps or has a contraindication to surgery.

A baseline assessment sino-nasal outcome test (SNOT-22) or endoscopic nasal polyps score (NPS) must be submitted with the initial request.

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

Initial coverage may be approved for 12 months of 100 mg administered every 4 weeks.

- Patients will be limited to receiving a one-month supply of mepolizumab per prescription at their pharmacy.
- Coverage cannot be provided for mepolizumab when this medication is intended for use in combination with other biologics for the treatment of CRSwNP.

For continued coverage, the patient must meet the following criteria:

- There is a clinically meaningful response on the SNOT-22 or endoscopic NPS relative to their baseline score prior to treatment. This is defined as an 8.9-point or greater decrease from baseline on the SNOT-22 or a 1-point or greater decrease from baseline on the NPS.

Continued coverage may be considered for 100 mg administered every 4 weeks for 12 months."

All requests (including renewal requests) for mepolizumab for Chronic Rhinosinusitis with Nasal Polyps must be completed using the Mepolizumab for Chronic Rhinosinusitis with Nasal Polyps Special Authorization Request Form (ABC 60120).

**100 MG / SYR INJECTION SYRINGE**

<input checked="" type="checkbox"/> 00002492997	NUCALA	GSK	\$ 2114.7500
<input checked="" type="checkbox"/> 00002492989	NUCALA (AUTOINJECTOR)	GSK	\$ 2114.7500

---

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

**SIPONIMOD**

"Special authorization coverage may be provided for the treatment of adult patients with secondary progressive multiple sclerosis (SPMS) with active disease to delay the progression of physical disability.

**Coverage**

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request. To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

**Initial Coverage**

- 1) The registered MS Neurologist must confirm a history of relapsing-remitting multiple sclerosis (RRMS) and current active SPMS.
- 2) The patient must have an Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5 at treatment initiation.
- 3) The patient must have documented EDSS progression during the two years prior to initiating treatment with siponimod (increase by 1 point or more if EDSS is less than 6.0; increase by 0.5 points or more if EDSS 6.0 or more at screening).

Coverage will not be approved when any MS disease-modifying therapy (DMT) or other immunosuppressive therapy is to be used in combination with siponimod.

Initial coverage may be approved for a 5-day dose titration followed by maintenance dosing of up to 2 mg daily for a period of 6 months. Patients will be limited to receiving a one-month supply of siponimod per prescription at their pharmacy for the first 6 months of coverage.

**Continued Coverage**

For continued coverage beyond the initial coverage period, the following criteria must be met:

- 1) The patient must be assessed for response to siponimod by a registered MS Neurologist.
- 2) The registered MS Neurologist must confirm a diagnosis of active SPMS.
- 3) The registered MS Neurologist must provide a current updated EDSS score.

Coverage will not be renewed for patients who exhibit:

-progression to an EDSS score of 7.0 or above at any time during siponimod treatment.

Continued coverage may be approved for up to 2 mg daily for a period of 24 months. Patients may receive up to 100 days' supply of siponimod per prescription at their pharmacy."

All requests (including renewal requests) for siponimod must be completed using the Siponimod for SPMS Special Authorization Request Form (ABC 60092).

**0.25 MG ORAL TABLET**

00002496429	MAYZENT	NOV	\$	22.3285
-------------	---------	-----	----	---------

**2 MG ORAL TABLET**

00002496437	MAYZENT	NOV	\$	89.3150
-------------	---------	-----	----	---------

## UPADACITINIB

### Atopic Dermatitis

"Special authorization coverage may be provided for the treatment of moderate-to-severe atopic dermatitis in adolescents 12 years of age or older (weighing 40 kg or more), and adults who:

- Have an Investigator's Global Assessment (IGA) score  $\geq 3$  and an Eczema Area and Severity Index (EASI) score  $\geq 16$ ; AND
- Who are refractory or intolerant to:
  - topical prescription corticosteroid and/or topical calcineurin inhibitors (TCIs); AND
  - at least one conventional systemic immunomodulatory drug (steroid-sparing); AND
  - phototherapy (unless restricted by geographic location)

For coverage, this drug must be prescribed by a Specialist in Dermatology, Allergy, Clinical Immunology or Pediatrics.

- Initial coverage may be approved for 15 mg\* once daily for 20 weeks.
- Patients will be limited to receiving a one month supply of upadacitinib per prescription at their pharmacy.
- Upadacitinib is not to be used in combination with phototherapy or immunomodulating drugs.
- Patients will not be permitted to switch back to upadacitinib if they were deemed unresponsive to therapy.

\*For patients 18 to 64 years of age with an inadequate response to 15 mg, the dose may be adjusted to 30 mg once daily by making an additional special authorization request to Alberta Blue Cross for the increased dose.

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

- 1) The patient must be assessed by a Specialist in Dermatology, Allergy, Clinical Immunology or Pediatrics after the initial 16 to 20 weeks to determine response. The Specialist in Dermatology, Allergy, Clinical Immunology or Pediatrics must confirm that the patient is a 'responder' who meets the following criteria:
  - EASI-75 response (greater than or equal to 75% improvement from baseline).

Following this assessment, continued coverage may be approved as follows:

- For adolescents 12 to 17 years and for adults 65 years of age or older, coverage may be approved for 15 mg once daily.
- For adults 18 to 64 years of age, coverage may be approved for up to 30 mg once daily.

Special Authorization may be granted for 6 months.

Ongoing coverage may be considered if the patient is re-assessed by a Specialist in Dermatology, Allergy, Clinical Immunology or Pediatrics every 6 months and is confirmed to be continuing to respond to therapy by confirmation of maintenance of EASI-75.

Coverage cannot be provided for upadacitinib when intended for use in combination with a biologic agent or other Janus kinase (JAK) inhibitors."

All requests (including renewal requests) for upadacitinib for Atopic Dermatitis must be completed using the Abrocitinib/Dupilumab/Upadacitinib for Atopic Dermatitis Special Authorization Request Form (ABC 60099).

### Rheumatoid Arthritis

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

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

**UPADACITINIB**

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

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

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

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

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

- Initial coverage may be approved for 15 mg once daily for three months.
- Patients will be limited to receiving a one-month supply of upadacitinib per prescription at their pharmacy.
- Patients will not be permitted to switch back to upadacitinib if they were deemed unresponsive to therapy.

For continued coverage beyond three months, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial three months to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
  - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
  - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

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

Following this assessment, continued coverage may be approved for upadacitinib 15 mg once daily for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
  - confirmation of maintenance of ACR20, or
  - maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
- 3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

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

Coverage cannot be provided for upadacitinib when intended for use in combination with a biologic agent or other Janus kinase (JAK) inhibitors."

All requests (including renewal requests) for upadacitinib for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Baricitinib/Certolizumab/Etanercept/Golimumab/Infliximab

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

**UPADACITINIB**

mab/ Sarilumab/Tocilizumab/Tofacitinib/Upadacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

**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 15 mg once daily for three months.
- Patients will be limited to receiving a one-month supply of upadacitinib per prescription at their pharmacy.
- Patients will not be permitted to switch back to upadacitinib if they were deemed unresponsive to therapy.

For continued coverage beyond three months, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial 3 months to determine response.
  - 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
    - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
    - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
- It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for 15 mg once daily, for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

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

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

**UPADACITINIB**

on record will be rounded to the correct number of decimal places as indicated above.

Coverage cannot be provided for upadacitinib when intended for use in combination with a biologic agent or other Janus kinase (JAK) inhibitors."

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

**Ankylosing Spondylitis**

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

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND
- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND
- who are refractory or intolerant to treatment with 2 or more NSAIDs each taken for a minimum of 4 weeks at maximum tolerated or recommended doses AND
- who are refractory or intolerant to treatment with a biologic DMARD (bDMARD) indicated for Ankylosing Spondylitis for a minimum of 12 weeks at maximum tolerated or recommended doses.

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

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

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

- Initial coverage may be approved for 15 mg once daily for 12 weeks.
- Patients will be limited to receiving a one-month supply of upadacitinib per prescription at their pharmacy.
- Patients will not be permitted to switch back to upadacitinib if they were deemed unresponsive to therapy.

For continued coverage beyond 12 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial 3 months to determine response.
- 2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
  - Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
  - Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for 15 mg once daily for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above.

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

All requests (including renewal requests) for upadacitinib for Ankylosing Spondylitis must be completed using the



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

**UPADACITINIB**

Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab/Upadacitinib for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

**Moderately to Severely Active Crohn's Disease**

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

- Upadacitinib 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 upadacitinib.
- Patients will be limited to receiving a one-month supply of upadacitinib per prescription at their pharmacy.
- Patients will not be permitted to switch back to upadacitinib if they were deemed unresponsive to therapy.
- Patients will be permitted to switch from one agent to another if unresponsive to therapy, or due to serious adverse effects or contraindications.

Prior to initiation of upadacitinib therapy for New Patients:

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

Moderately to Severely Active Crohn's Disease:

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

Refractory is defined as one or more of the following:

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

AND

b) Immunosuppressive therapy as follows:

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

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.

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

**UPADACITINIB**

Induction Dosing for New Patients:

- Coverage for Induction Dosing may only be approved for New Patients (those who have never been treated with upadacitinib by any health care provider).
- 'Induction Dosing' means a 45 mg once daily dose of upadacitinib per New Patient for 12 weeks. As an interim measure, coverage will be provided for up to a 30 mg once daily dose (for adults 18 to 64 years of age) or a 15 mg once daily dose (for adults 65 years of age or older) of upadacitinib for an additional 4 weeks, to allow time to determine whether the New Patient meets coverage criteria for Maintenance Dosing below.
- New Patients are eligible to receive Induction Dosing only once, after which time the Maintenance Dosing for New Patients and Continued Coverage for Maintenance Dosing criteria will apply.

Maintenance Dosing:

'Maintenance Dosing' means up to a 30 mg once daily dose (for adults 18 to 64 years of age) or a 15 mg once daily dose (for adults 65 years of age or older) of upadacitinib 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 upadacitinib.

Maintenance Dosing for New Patients after Completion of Induction Dosing:

- The New Patient must be assessed by a Specialist after 12 weeks but no longer than 16 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 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 up to a 30 mg once daily dose (for adults 18 to 64 years of age) or a 15 mg once daily dose (for adults 65 years of age or older) of upadacitinib per patient 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 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.

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

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

## UPADACITINIB

### Ulcerative Colitis

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

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

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

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

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:

- i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
- ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

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

Initial coverage may be approved for an initial dose of 45 mg once daily for 8 weeks. As an interim measure, coverage will be provided for up to a 30 mg once daily dose (for adults 18 to 64 years of age) or a 15 mg once daily dose (for adults 65 years of age or older) of upadacitinib for an additional 4 weeks, to allow time to determine whether the New Patient meets coverage criteria for Maintenance Dosing below.

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

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

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

Following this assessment, continued coverage may be approved as follows for a period of 12 months.

- For adults 18 to 64 years of age, coverage may be approved for up to 30 mg once daily.
- For adults 65 years of age or older, coverage may be approved for 15 mg once daily.

Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by a Specialist in Gastroenterology to determine response;
- 2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
  - a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of upadacitinib therapy.

Coverage cannot be provided for upadacitinib when intended for use in combination with

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

**UPADACITINIB**

a biologic agent, other Janus kinase (JAK) inhibitors or a sphingosine 1-phosphate receptor modulator."

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

**15 MG ORAL EXTENDED-RELEASE TABLET**

00002495155 RINVOQ ABV \$ 51.6810

## UPADACITINIB

### Atopic Dermatitis

"Special authorization coverage may be provided for the treatment of moderate-to-severe atopic dermatitis in adolescents 12 years of age or older (weighing 40 kg or more), and adults who:

- Have an Investigator's Global Assessment (IGA) score  $\geq 3$  and an Eczema Area and Severity Index (EASI) score  $\geq 16$ ; AND
- Who are refractory or intolerant to:
  - topical prescription corticosteroid and/or topical calcineurin inhibitors (TCIs); AND
  - at least one conventional systemic immunomodulatory drug (steroid-sparing); AND
  - phototherapy (unless restricted by geographic location)

For coverage, this drug must be prescribed by a Specialist in Dermatology, Allergy, Clinical Immunology or Pediatrics.

- Initial coverage may be approved for 15 mg\* once daily for 20 weeks.
- Patients will be limited to receiving a one month supply of upadacitinib per prescription at their pharmacy.
- Upadacitinib is not to be used in combination with phototherapy or immunomodulating drugs.
- Patients will not be permitted to switch back to upadacitinib if they were deemed unresponsive to therapy.

\*For patients 18 to 64 years of age with an inadequate response to 15 mg, the dose may be adjusted to 30 mg once daily by making an additional special authorization request to Alberta Blue Cross for the increased dose.

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

- 1) The patient must be assessed by a Specialist in Dermatology, Allergy, Clinical Immunology or Pediatrics after the initial 16 to 20 weeks to determine response. The Specialist in Dermatology, Allergy, Clinical Immunology or Pediatrics must confirm that the patient is a 'responder' who meets the following criteria:
  - EASI-75 response (greater than or equal to 75% improvement from baseline).

Following this assessment, continued coverage may be approved as follows:

- For adolescents 12 to 17 years and for adults 65 years of age or older, coverage may be approved for 15 mg once daily.
- For adults 18 to 64 years of age, coverage may be approved for up to 30 mg once daily.

Special Authorization may be granted for 6 months.

Ongoing coverage may be considered if the patient is re-assessed by a Specialist in Dermatology, Allergy, Clinical Immunology or Pediatrics every 6 months and is confirmed to be continuing to respond to therapy by confirmation of maintenance of EASI-75.

Coverage cannot be provided for upadacitinib when intended for use in combination with a biologic agent or other Janus kinase (JAK) inhibitors."

All requests (including renewal requests) for upadacitinib for Atopic Dermatitis must be completed using the Abrocitinib/Dupilumab/Upadacitinib for Atopic Dermatitis Special Authorization Request Form (ABC 60099).

### Moderately to Severely Active Crohn's Disease

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

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

**UPADACITINIB**

- Upadacitinib 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 upadacitinib.
- Patients will be limited to receiving a one-month supply of upadacitinib per prescription at their pharmacy.
- Patients will not be permitted to switch back to upadacitinib if they were deemed unresponsive to therapy.
- Patients will be permitted to switch from one agent to another if unresponsive to therapy, or due to serious adverse effects or contraindications.

Prior to initiation of upadacitinib therapy for New Patients:

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

Moderately to Severely Active Crohn's Disease:

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

Refractory is defined as one or more of the following:

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

AND

b) Immunosuppressive therapy as follows:

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

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 upadacitinib by any health care provider).
- 'Induction Dosing' means a 45 mg once daily dose of upadacitinib per New Patient for 12 weeks. As an interim measure, coverage will be provided for up to a 30 mg once daily dose (for adults 18 to 64 years of age) or a 15 mg once daily dose (for adults 65 years of age or older) of upadacitinib for an additional 4 weeks, to allow time to determine whether the New Patient meets coverage criteria for Maintenance Dosing below.

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

**UPADACITINIB**

- New Patients are eligible to receive Induction Dosing only once, after which time the Maintenance Dosing for New Patients and Continued Coverage for Maintenance Dosing criteria will apply.

Maintenance Dosing:

'Maintenance Dosing' means up to a 30 mg once daily dose (for adults 18 to 64 years of age) or a 15 mg once daily dose (for adults 65 years of age or older) of upadacitinib 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 upadacitinib.

Maintenance Dosing for New Patients after Completion of Induction Dosing:

- The New Patient must be assessed by a Specialist after 12 weeks but no longer than 16 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 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 up to a 30 mg once daily dose (for adults 18 to 64 years of age) or a 15 mg once daily dose (for adults 65 years of age or older) of upadacitinib per patient 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 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.

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

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

**Ulcerative Colitis**

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

- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks; AND
- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid

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

**UPADACITINIB**

dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

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

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

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:

- i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
- ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

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

Initial coverage may be approved for an initial dose of 45 mg once daily for 8 weeks. As an interim measure, coverage will be provided for up to a 30 mg once daily dose (for adults 18 to 64 years of age) or a 15 mg once daily dose (for adults 65 years of age or older) of upadacitinib for an additional 4 weeks, to allow time to determine whether the New Patient meets coverage criteria for Maintenance Dosing below.

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

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

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

Following this assessment, continued coverage may be approved as follows for a period of 12 months.

- For adults 18 to 64 years of age, coverage may be approved for up to 30 mg once daily.
- For adults 65 years of age or older, coverage may be approved for 15 mg once daily.

Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by a Specialist in Gastroenterology to determine response;
- 2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
  - a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of upadacitinib therapy.

Coverage cannot be provided for upadacitinib when intended for use in combination with a biologic agent, other Janus kinase (JAK) inhibitors or a sphingosine 1-phosphate receptor modulator."

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

**30 MG ORAL EXTENDED-RELEASE TABLET**



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

**UPADACITINIB**

00002520893 RINVOQ ABV \$ 76.9600

## UPADACITINIB

### Moderately to Severely Active Crohn's Disease

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

- Upadacitinib 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 upadacitinib.
- Patients will be limited to receiving a one-month supply of upadacitinib per prescription at their pharmacy.
- Patients will not be permitted to switch back to upadacitinib if they were deemed unresponsive to therapy.
- Patients will be permitted to switch from one agent to another if unresponsive to therapy, or due to serious adverse effects or contraindications.

Prior to initiation of upadacitinib therapy for New Patients:

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

Moderately to Severely Active Crohn's Disease:

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

Refractory is defined as one or more of the following:

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

AND

b) Immunosuppressive therapy as follows:

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

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

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

**UPADACITINIB**

have never been treated with upadacitinib by any health care provider).

- 'Induction Dosing' means a 45 mg once daily dose of upadacitinib per New Patient for 12 weeks. As an interim measure, coverage will be provided for up to a 30 mg once daily dose (for adults 18 to 64 years of age) or a 15 mg once daily dose (for adults 65 years of age or older) of upadacitinib for an additional 4 weeks, to allow time to determine whether the New Patient meets coverage criteria for Maintenance Dosing below.

- New Patients are eligible to receive Induction Dosing only once, after which time the Maintenance Dosing for New Patients and Continued Coverage for Maintenance Dosing criteria will apply.

Maintenance Dosing:

'Maintenance Dosing' means up to a 30 mg once daily dose (for adults 18 to 64 years of age) or a 15 mg once daily dose (for adults 65 years of age or older) of upadacitinib 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 upadacitinib.

Maintenance Dosing for New Patients after Completion of Induction Dosing:

- The New Patient must be assessed by a Specialist after 12 weeks but no longer than 16 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 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 up to a 30 mg once daily dose (for adults 18 to 64 years of age) or a 15 mg once daily dose (for adults 65 years of age or older) of upadacitinib per patient 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 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.

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

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

**Ulcerative Colitis**

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

**UPADACITINIB**

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

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

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

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

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:

- i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
- ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

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

Initial coverage may be approved for an initial dose of 45 mg once daily for 8 weeks. As an interim measure, coverage will be provided for up to a 30 mg once daily dose (for adults 18 to 64 years of age) or a 15 mg once daily dose (for adults 65 years of age or older) of upadacitinib for an additional 4 weeks, to allow time to determine whether the New Patient meets coverage criteria for Maintenance Dosing below.

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

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

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

Following this assessment, continued coverage may be approved as follows for a period of 12 months.

- For adults 18 to 64 years of age, coverage may be approved for up to 30 mg once daily.
- For adults 65 years of age or older, coverage may be approved for 15 mg once daily.

Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by a Specialist in Gastroenterology to determine response;
- 2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
  - a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of upadacitinib therapy.

Coverage cannot be provided for upadacitinib when intended for use in combination with a biologic agent, other Janus kinase (JAK) inhibitors or a sphingosine 1-phosphate receptor modulator."

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

**UPADACITINIB**

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

**45 MG ORAL EXTENDED-RELEASE TABLET**

00002539721 RINVOQ

ABV

\$ 101.8100

---