

Updates to the Alberta Drug Benefit List

Effective December 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.

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 Restricted Benefit / Special Authorization	1
■ Drug Product(s) with Changes for Coverage.....	1
Added Product(s).....	2
Least Cost Alternative (LCA) Price Change(s).....	2
Product(s) with a Price Change	2
Discontinued Listing(s).....	3
Product(s) Removed from the Alberta Drug Benefit List.....	3
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 December 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>
ORLADEYO 150 MG CAPSULE	BEROTRALSTAT HYDROCHLORIDE	00002527693	BCR
AMVUTTRA 25 MG / SYRINGE INJECTION	VUTRISIRAN SODIUM	00002542420	ANT

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

The following drug product(s) will be considered for coverage by Restricted Benefit / Special Authorization effective December 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>
JAMP SUMATRIPTAN DF 50 MG TABLET	SUMATRIPTAN SUCCINATE	00002545306	JPC
JAMP SUMATRIPTAN DF 100 MG TABLET	SUMATRIPTAN SUCCINATE	00002545314	JPC

Drug Product(s) with Changes to Criteria for Coverage

The following drug product(s) will have changes to criteria for coverage by Special Authorization effective November 5, 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>
TRIKAFTA 50 MG / 25 MG / 37.5 MG / 75 MG TABLET	ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR/ IVACAFTOR	00002526670	VER
TRIKAFTA 80 MG / 40 MG / 60 MG / 59.5 MG GRANULE	ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR/ IVACAFTOR	00002542285	VER
TRIKAFTA 100 MG / 50 MG / 75 MG / 75 MG GRANULE	ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR/ IVACAFTOR	00002542277	VER
TRIKAFTA 100 MG / 50 MG / 75 MG / 150 MG TABLET	ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR/ IVACAFTOR	00002517140	VER

The following drug product(s) will have changes to criteria for coverage by Special Authorization effective December 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>
QULIPTA 10 MG TABLET	ATOGEPAANT	00002533979	ABV
QULIPTA 30 MG TABLET	ATOGEPAANT	00002533987	ABV
QULIPTA 60 MG TABLET	ATOGEPAANT	00002533995	ABV

Added Product(s)

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
MEZERA 1 G DELAYED-RELEASE TABLET	MESALAZINE	00002545012	AVP
MINT-LOSARTAN / HCTZ 100 MG /12.5 MG TABLET	LOSARTAN POTASSIUM/ HYDROCHLOROTHIAZIDE	00002389665	MPI
SLYND 4 MG TABLET	DROSPIRENONE	00002522802	DUI

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 January 1, 2025. Please review the online [Interactive Drug Benefit List](#) for further information.

<u>Generic Description</u>	<u>Strength / Form</u>	<u>New LCA Price</u>
FUSIDIC ACID	2 % TOPICAL CREAM	0.5676
RUFINAMIDE	200 MG TABLET	1.0083
RUFINAMIDE	400 MG TABLET	2.1970
TESTOSTERONE ENANTHATE	200 MG / ML INJECTION	7.1189

Product(s) with a Price Change

The following product(s) had a Price Change. The previous higher price will be recognized until December 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>
AURO-RUFINAMIDE 200 MG TABLET	RUFINAMIDE	00002545985	AUR
AURO-RUFINAMIDE 400 MG TABLET	RUFINAMIDE	00002545993	AUR
LOVASTATIN 20 MG TABLET	LOVASTATIN	00002220172	AAP
LOVASTATIN 40 MG TABLET	LOVASTATIN	00002220180	AAP
SULFATRIM 400 MG / 80 MG TABLET	SULFAMETHOXAZOLE/ TRIMETHOPRIM	00000445274	AAP
TARO-FUSIDIC ACID 2 % TOPICAL CREAM	FUSIDIC ACID	00002528096	TAR
TESTOSTERONE ENANTHATE USP 200 MG / ML INJECTION	TESTOSTERONE ENANTHATE	00002536315	TGT
TEVA-MEXILETINE 100 MG CAPSULE	MEXILETINE HCL	00002230359	TEV

Discontinued Listing(s)

Notification of discontinuation has been received from the manufacturer(s). The Alberta government-sponsored drug programs previously covered the following drug product(s). Effective December 1, 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 January 1, 2025 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>
CYMBALTA 30 MG DELAYED-RELEASE CAPSULE	DULOXETINE HYDROCHLORIDE	00002301482	LIL
CYMBALTA 60 MG DELAYED-RELEASE CAPSULE	DULOXETINE HYDROCHLORIDE	00002301490	LIL
IMDUR 60 MG EXTENDED-RELEASE TABLET	ISOSORBIDE-5-MONONITRATE	00002126559	JUN
PROZAC 10 MG CAPSULE	FLUOXETINE HCL	00002018985	LIL
PROZAC 20 MG CAPSULE	FLUOXETINE HCL	00000636622	LIL
RIVA-RISEDRONATE 35 MG TABLET	RISEDRONATE SODIUM	00002341077	RUV
SANDOZ DIMETHYL FUMARATE 120 MG DELAYED-RELEASE CAPSULE	DIMETHYL FUMARATE	00002513781	SDZ
SANDOZ DIMETHYL FUMARATE 240 MG DELAYED-RELEASE CAPSULE	DIMETHYL FUMARATE	00002513803	SDZ
TARO-DIPYRIDAMOLE / ASA 200 MG / 25 MG CAPSULE	DIPYRIDAMOLE/ ASA	00002471051	TAR
VITAMIN A ACID 0.01 % TOPICAL GEL	TRETINOIN	00001926462	VCL

Product(s) Removed from the Alberta Drug Benefit List

The Alberta government-sponsored drug programs previously covered the following drug product(s). Effective December 1, 2024, the listed product(s) will no longer be a benefit. A transition period will be applied and as of January 1, 2025 claims will no longer pay.

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
ACT LOVASTATIN 20 MG TABLET	LOVASTATIN	00002248572	TEV
ACT LOVASTATIN 40 MG TABLET	LOVASTATIN	00002248573	TEV

PART 2

Drug Additions

ALBERTA DRUG BENEFIT LIST UPDATE

DROSPIRENONE

4 MG ORAL TABLET
 00002522802 SLYND DUI \$ 0.4521

FUSIDIC ACID

2% TOPICAL CREAM
 00002528096 TARO-FUSIDIC ACID TAR \$ 0.5676
 00000586668 FUCIDIN LEO \$ 0.7374

LOSARTAN POTASSIUM/ HYDROCHLOROTHIAZIDE

100 MG * 12.5 MG ORAL TABLET
 00002423650 AURO-LOSARTAN HCT AUR \$ 0.3082
 00002388979 LOSARTAN/HCT SIV \$ 0.3082
 00002427656 LOSARTAN/HCTZ SNS \$ 0.3082
 00002389665 MINT-LOSARTAN/HCTZ MPI \$ 0.3082
 00002392232 PMS-LOSARTAN-HCTZ PMS \$ 0.3082
 00002362449 SANDOZ LOSARTAN HCT SDZ \$ 0.3082
 00002297841 HYZAAR ORC \$ 1.4627

LOVASTATIN

20 MG ORAL TABLET
 00002220172 LOVASTATIN AAP \$ 0.1354 \$ 1.1931
MAC pricing will be applied based on the LCA Price for rosuvastatin calcium 1 x 10 mg tablet or the LCA Price of atorvastatin 1 x 20 mg tablet whichever is lower.

40 MG ORAL TABLET
 00002220180 LOVASTATIN AAP \$ 0.1354 \$ 2.1793
MAC pricing will be applied based on the LCA Price for rosuvastatin calcium 1 x 10 mg tablet or the LCA Price of atorvastatin 1 x 20 mg tablet whichever is lower.

SULFAMETHOXAZOLE/ TRIMETHOPRIM

400 MG * 80 MG ORAL TABLET
 00000445274 SULFATRIM AAP \$ 0.2184

ALBERTA DRUG BENEFIT LIST UPDATE

SUMATRIPTAN SUCCINATE

This product is a benefit for patients 18 to 64 years of age inclusive for the treatment of acute migraine attacks in patients where other standard therapy has failed. (Refer to Criteria for Special Authorization of Select Drug Products of the List for eligibility in patients 65 years of age and older; and Criteria for Special Authorization of Select Drug Products in the Alberta Human Services Drug Benefit Supplement for eligibility in Alberta Human Services clients.)

50 MG (BASE) ORAL TABLET				
00002268388	APO-SUMATRIPTAN	APX	\$	2.7732
00002545306	JAMP SUMATRIPTAN DF	JPC	\$	2.7732
00002268914	MYLAN-SUMATRIPTAN	MYP	\$	2.7732
00002256436	PMS-SUMATRIPTAN	PMS	\$	2.7732
00002286521	SUMATRIPTAN	SNS	\$	2.7732
00002546035	SUMATRIPTAN	SIV	\$	2.7732
00002385570	SUMATRIPTAN DF	SIV	\$	2.7732
00002286823	TEVA-SUMATRIPTAN DF	TEV	\$	2.7732
00002212153	IMITREX DF	GSK	\$	17.6485
100 MG (BASE) ORAL TABLET				
00002268396	APO-SUMATRIPTAN	APX	\$	3.0549
00002545314	JAMP SUMATRIPTAN DF	JPC	\$	3.0549
00002268922	MYLAN-SUMATRIPTAN	MYP	\$	3.0549
00002256444	PMS-SUMATRIPTAN	PMS	\$	3.0549
00002286548	SUMATRIPTAN	SNS	\$	3.0549
00002546043	SUMATRIPTAN	SIV	\$	3.0549
00002385589	SUMATRIPTAN DF	SIV	\$	3.0549
00002239367	TEVA-SUMATRIPTAN	TEV	\$	3.0549
00002286831	TEVA-SUMATRIPTAN DF	TEV	\$	3.0549
00002212161	IMITREX DF	GSK	\$	19.4417

TESTOSTERONE ENANTHATE

200 MG / ML INJECTION				
00002536315	TESTOSTERONE ENANTHATE INJECTION USP	TGT	\$	7.1189
00000029246	DELATESTRYL	VCL	\$	11.5741

PART 3

Special Authorization

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

ATOGEPAANT

"Special authorization coverage may be provided for the prevention of episodic or chronic migraine in adult patients (18 years of age or older) who at baseline are refractory or intolerant to at least TWO oral prophylactic migraine medications of different classes.

'Episodic migraine' is defined as experiencing headaches for less than 15 days per month for more than three months of which at least four days per month of this period are with migraine.

'Chronic migraine' is defined as experiencing headaches for at least 15 days per month for more than three months of which at least eight days per month of this period are with migraine.

'Refractory' is defined as lack of effect in reducing the frequency of migraine days.

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

Only one Drug Product of an anti-calcitonin gene related peptide or onabotulinumtoxinA for the prevention of migraine would be allowed for coverage at a time.

For coverage, the patient should be under the care of a physician who has appropriate experience in the management of patients with migraine headaches.

-Initial coverage may be approved for up to a maximum daily dose of 60 mg for a period of 6 months.

-For initial coverage, the baseline number of migraine days per month must be provided.

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

For continued coverage beyond 6 months the patient must meet the following criteria:

1) The patient must be assessed by the physician after the initial 6 months of therapy to determine response.

2) The physician must confirm in writing, that the patient is a 'responder' that meets the following criteria:

-Reduction of at least 50% in the average number of migraine days per month compared to baseline.

Following this assessment, continued coverage may be approved for up to a maximum daily dose of 60 mg for a period of 6 months. Ongoing coverage may be considered if the patient is re-assessed by the physician every 6 months, and is confirmed to be continuing to respond to therapy by maintaining a reduction of at least 50% in the average number of migraine days per month compared to baseline."

All requests for atogepant (including renewal requests) must be completed using the Atogepant/Eptinezumab/Fremanezumab/Galcanezumab for Migraine Prevention Special Authorization Request Form (ABC 60095).

10 MG ORAL TABLET

00002533979	QULIPTA	ABV	\$	18.4400
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30 MG ORAL TABLET

00002533987	QULIPTA	ABV	\$	18.4400
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60 MG ORAL TABLET

00002533995	QULIPTA	ABV	\$	18.4400
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ALBERTA DRUG BENEFIT LIST UPDATE
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

BEROTRALSTAT HYDROCHLORIDE

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

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

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

*Response to initial berotralstat treatment is defined as:

- at least a 50% reduction in the number of HAE attacks requiring use of an acute injectable treatment compared to the three month baseline number of attacks prior to initiation of berotralstat.

**Continued response is defined as:

- maintenance of a minimum improvement of a 50% reduction in the number of HAE attacks requiring use of an acute injectable treatment compared to the baseline number of attacks observed before initiating treatment with berotralstat.

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

Coverage may be approved for a dosage of 150 mg once daily. Patients will be limited to receiving a one-month supply per prescription at their pharmacy."

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

150 MG (BASE) ORAL CAPSULE

00002527693 ORLADEYO

BCR

\$ 850.0000

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

ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR/ IVACAFTOR

For the treatment of cystic fibrosis (CF) in patients age two (2) years and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to elexacaftor/tezacaftor/ivacaftor and ivacaftor based on clinical and/or in vitro data. Patients should be optimized with best supportive care for their CF at the time of initiation.

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

For patients 2 to 5 years of age:

1. Number of days treated with oral and/or IV antibiotics for pulmonary exacerbations in the previous 6 months or number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months, AND
2. BMI z-score

For patients 6 years and older:

1. Baseline spirometry measurement of FEV1 % predicted (within the last 3 months), AND
2. Number of days treated with oral and/or IV antibiotics for pulmonary exacerbations in the previous 6 months or number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months, AND
3. Number of CF-related hospitalizations in the previous 6 months, AND
4. Baseline Body Mass Index (BMI) or BMI z-score in children

This drug must be prescribed by a prescriber affiliated with one of the following Alberta Cystic Fibrosis Clinics:

- Cystic Fibrosis Clinic, Adult: Kaye Edmonton Clinic
- Cystic Fibrosis Services - Adult Outpatient: Foothills Medical Centre
- Cystic Fibrosis Clinic, Pediatric: Stollery Children's Hospital
- Pediatric Cystic Fibrosis Clinic: Alberta Children's Hospital

For coverage, dosing will be approved as follows:

Patients 2 to < 6 years weighing < 14 kg: One packet (containing elexacaftor 80 mg, tezacaftor 40 mg and ivacaftor 60 mg granules) in the morning and one packet (ivacaftor 59.5 mg granules) in the evening.

Patients 2 to < 6 years weighing > / = 14 kg: One packet (containing elexacaftor 100 mg, tezacaftor 50 mg and ivacaftor 75 mg granules) in the morning and one packet (ivacaftor 75 mg granules) in the evening.

Patients 6 to < 12 years weighing < 30 kg: Two tablets (each containing elexacaftor 50 mg, tezacaftor 25 mg and ivacaftor 37.5 mg) in the morning and one tablet (ivacaftor 75 mg) in the evening.

Patients 6 to < 12 years weighing > / = 30 kg: Two tablets (each containing elexacaftor 100 mg, tezacaftor 50 mg and ivacaftor 75 mg) in the morning and one tablet (ivacaftor 150 mg) in the evening.

Patients > / = 12 years: Two tablets (each containing elexacaftor 100 mg, tezacaftor 50 mg and ivacaftor 75 mg) in the morning and one tablet (ivacaftor 150 mg) in the evening.

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

Initial coverage may be approved for 12 months for patients 2-5 years of age and 6 months for patients 6 years of age and older.

Subsequent renewal of coverage may be approved for 12 months

For continued coverage beyond the initial approval period, patients must demonstrate a benefit in at least ONE of the following:

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

ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR/ IVACAFTOR

For patients 2 to 5 years of age:

1. A decrease in the total number of days for which the patient received treatment with oral and/or IV antibiotics for pulmonary exacerbations in the previous 6 months compared with the 6-month period prior to initiating treatment; or, a decrease in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months compared with the 6-month period prior to initiating treatment, OR
2. No decline in BMI z-score compared with the baseline BMI z-score assessment

For patients 6 years and older:

1. Documented improvement in % predicted FEV1 of at least 5% compared with the baseline measurement, OR
2. A decrease in the total number of days for which the patient received treatment with oral and/or IV antibiotics for pulmonary exacerbations in the previous 6 months compared with the 6-month period prior to initiating treatment; or, a decrease in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months compared with the 6-month period prior to initiating treatment, OR
3. Decreased number of CF-related hospitalizations in the previous 6 months compared with the 6-month period prior to initiating treatment, OR
4. No decline in BMI or BMI z-score compared with the baseline BMI or BMI z-score assessment

Ongoing coverage may be considered only if patients have maintained a benefit in at least ONE of the parameters noted above at the end of each 12-month period.

Coverage cannot be provided for elexacaftor/tezacaftor/ivacaftor and ivacaftor for the following:

1. When intended for use in combination with other CFTR modulators; OR
2. Patient is the previous recipient of a double lung transplant.

All requests (including renewal requests) for elexacaftor/tezacaftor/ivacaftor + ivacaftor must be completed using the Combination CFTR Modulators Special Authorization Request Form (ABC 60090).

50 MG * 25 MG * 37.5 MG * 75 MG ORAL TABLET

00002526670 TRIKAFTA

VER

\$ 280.0000

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

ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR/ IVACAFTOR

For the treatment of cystic fibrosis (CF) in patients age two (2) years and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to elexacaftor/tezacaftor/ivacaftor and ivacaftor based on clinical and/or in vitro data. Patients should be optimized with best supportive care for their CF at the time of initiation.

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

For patients 2 to 5 years of age:

1. Number of days treated with oral and/or IV antibiotics for pulmonary exacerbations in the previous 6 months or number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months, AND
2. BMI z-score

For patients 6 years and older:

1. Baseline spirometry measurement of FEV1 % predicted (within the last 3 months), AND
2. Number of days treated with oral and/or IV antibiotics for pulmonary exacerbations in the previous 6 months or number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months, AND
3. Number of CF-related hospitalizations in the previous 6 months, AND
4. Baseline Body Mass Index (BMI) or BMI z-score in children

This drug must be prescribed by a prescriber affiliated with one of the following Alberta Cystic Fibrosis Clinics:

- Cystic Fibrosis Clinic, Adult: Kaye Edmonton Clinic
- Cystic Fibrosis Services - Adult Outpatient: Foothills Medical Centre
- Cystic Fibrosis Clinic, Pediatric: Stollery Children's Hospital
- Pediatric Cystic Fibrosis Clinic: Alberta Children's Hospital

For coverage, dosing will be approved as follows:

Patients 2 to < 6 years weighing < 14 kg: One packet (containing elexacaftor 80 mg, tezacaftor 40 mg and ivacaftor 60 mg granules) in the morning and one packet (ivacaftor 59.5 mg granules) in the evening.

Patients 2 to < 6 years weighing > / = 14 kg: One packet (containing elexacaftor 100 mg, tezacaftor 50 mg and ivacaftor 75 mg granules) in the morning and one packet (ivacaftor 75 mg granules) in the evening.

Patients 6 to < 12 years weighing < 30 kg: Two tablets (each containing elexacaftor 50 mg, tezacaftor 25 mg and ivacaftor 37.5 mg) in the morning and one tablet (ivacaftor 75 mg) in the evening.

Patients 6 to < 12 years weighing > / = 30 kg: Two tablets (each containing elexacaftor 100 mg, tezacaftor 50 mg and ivacaftor 75 mg) in the morning and one tablet (ivacaftor 150 mg) in the evening.

Patients > / = 12 years: Two tablets (each containing elexacaftor 100 mg, tezacaftor 50 mg and ivacaftor 75 mg) in the morning and one tablet (ivacaftor 150 mg) in the evening.

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

Initial coverage may be approved for 12 months for patients 2-5 years of age and 6 months for patients 6 years of age and older.

Subsequent renewal of coverage may be approved for 12 months

For continued coverage beyond the initial approval period, patients must demonstrate a benefit in at least ONE of the following:

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

ELEXACAFITOR/ TEZACAFITOR/ IVACAFITOR/ IVACAFITOR

For patients 2 to 5 years of age:

1. A decrease in the total number of days for which the patient received treatment with oral and/or IV antibiotics for pulmonary exacerbations in the previous 6 months compared with the 6-month period prior to initiating treatment; or, a decrease in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months compared with the 6-month period prior to initiating treatment, OR
2. No decline in BMI z-score compared with the baseline BMI z-score assessment

For patients 6 years and older:

1. Documented improvement in % predicted FEV1 of at least 5% compared with the baseline measurement, OR
2. A decrease in the total number of days for which the patient received treatment with oral and/or IV antibiotics for pulmonary exacerbations in the previous 6 months compared with the 6-month period prior to initiating treatment; or, a decrease in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months compared with the 6-month period prior to initiating treatment, OR
3. Decreased number of CF-related hospitalizations in the previous 6 months compared with the 6-month period prior to initiating treatment, OR
4. No decline in BMI or BMI z-score compared with the baseline BMI or BMI z-score assessment

Ongoing coverage may be considered only if patients have maintained a benefit in at least ONE of the parameters noted above at the end of each 12-month period.

Coverage cannot be provided for elexacaftor/tezacaftor/ivacaftor and ivacaftor for the following:

1. When intended for use in combination with other CFTR modulators; OR
2. Patient is the previous recipient of a double lung transplant.

All requests (including renewal requests) for elexacaftor/tezacaftor/ivacaftor + ivacaftor must be completed using the Combination CFTR Modulators Special Authorization Request Form (ABC 60090).

100 MG * 50 MG * 75 MG * 150 MG ORAL TABLET

00002517140 TRIKAFTA

VER

\$ 280.0000

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

ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR/ IVACAFTOR

For the treatment of cystic fibrosis (CF) in patients age two (2) years and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to elexacaftor/tezacaftor/ivacaftor and ivacaftor based on clinical and/or in vitro data. Patients should be optimized with best supportive care for their CF at the time of initiation.

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

For patients 2 to 5 years of age:

1. Number of days treated with oral and/or IV antibiotics for pulmonary exacerbations in the previous 6 months or number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months, AND
2. BMI z-score

For patients 6 years and older:

1. Baseline spirometry measurement of FEV1 % predicted (within the last 3 months), AND
2. Number of days treated with oral and/or IV antibiotics for pulmonary exacerbations in the previous 6 months or number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months, AND
3. Number of CF-related hospitalizations in the previous 6 months, AND
4. Baseline Body Mass Index (BMI) or BMI z-score in children

This drug must be prescribed by a prescriber affiliated with one of the following Alberta Cystic Fibrosis Clinics:

- Cystic Fibrosis Clinic, Adult: Kaye Edmonton Clinic
- Cystic Fibrosis Services - Adult Outpatient: Foothills Medical Centre
- Cystic Fibrosis Clinic, Pediatric: Stollery Children's Hospital
- Pediatric Cystic Fibrosis Clinic: Alberta Children's Hospital

For coverage, dosing will be approved as follows:

Patients 2 to < 6 years weighing < 14 kg: One packet (containing elexacaftor 80 mg, tezacaftor 40 mg and ivacaftor 60 mg granules) in the morning and one packet (ivacaftor 59.5 mg granules) in the evening.

Patients 2 to < 6 years weighing > / = 14 kg: One packet (containing elexacaftor 100 mg, tezacaftor 50 mg and ivacaftor 75 mg granules) in the morning and one packet (ivacaftor 75 mg granules) in the evening.

Patients 6 to < 12 years weighing < 30 kg: Two tablets (each containing elexacaftor 50 mg, tezacaftor 25 mg and ivacaftor 37.5 mg) in the morning and one tablet (ivacaftor 75 mg) in the evening.

Patients 6 to < 12 years weighing > / = 30 kg: Two tablets (each containing elexacaftor 100 mg, tezacaftor 50 mg and ivacaftor 75 mg) in the morning and one tablet (ivacaftor 150 mg) in the evening.

Patients > / = 12 years: Two tablets (each containing elexacaftor 100 mg, tezacaftor 50 mg and ivacaftor 75 mg) in the morning and one tablet (ivacaftor 150 mg) in the evening.

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

Initial coverage may be approved for 12 months for patients 2-5 years of age and 6 months for patients 6 years of age and older.

Subsequent renewal of coverage may be approved for 12 months

For continued coverage beyond the initial approval period, patients must demonstrate a benefit in at least ONE of the following:

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

ELEXACAFITOR/ TEZACAFITOR/ IVACAFITOR/ IVACAFITOR

For patients 2 to 5 years of age:

1. A decrease in the total number of days for which the patient received treatment with oral and/or IV antibiotics for pulmonary exacerbations in the previous 6 months compared with the 6-month period prior to initiating treatment; or, a decrease in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months compared with the 6-month period prior to initiating treatment, OR
2. No decline in BMI z-score compared with the baseline BMI z-score assessment

For patients 6 years and older:

1. Documented improvement in % predicted FEV1 of at least 5% compared with the baseline measurement, OR
2. A decrease in the total number of days for which the patient received treatment with oral and/or IV antibiotics for pulmonary exacerbations in the previous 6 months compared with the 6-month period prior to initiating treatment; or, a decrease in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months compared with the 6-month period prior to initiating treatment, OR
3. Decreased number of CF-related hospitalizations in the previous 6 months compared with the 6-month period prior to initiating treatment, OR
4. No decline in BMI or BMI z-score compared with the baseline BMI or BMI z-score assessment

Ongoing coverage may be considered only if patients have maintained a benefit in at least ONE of the parameters noted above at the end of each 12-month period.

Coverage cannot be provided for elexacaftor/tezacaftor/ivacaftor and ivacaftor for the following:

1. When intended for use in combination with other CFTR modulators; OR
2. Patient is the previous recipient of a double lung transplant.

All requests (including renewal requests) for elexacaftor/tezacaftor/ivacaftor + ivacaftor must be completed using the Combination CFTR Modulators Special Authorization Request Form (ABC 60090).

80 MG * 40 MG * 60 MG * 59.5 MG ORAL GRANULE

00002542285 TRIKAFTA

VER

\$ 420.0000

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

ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR/ IVACAFTOR

For the treatment of cystic fibrosis (CF) in patients age two (2) years and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to elexacaftor/tezacaftor/ivacaftor and ivacaftor based on clinical and/or in vitro data. Patients should be optimized with best supportive care for their CF at the time of initiation.

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

For patients 2 to 5 years of age:

1. Number of days treated with oral and/or IV antibiotics for pulmonary exacerbations in the previous 6 months or number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months, AND
2. BMI z-score

For patients 6 years and older:

1. Baseline spirometry measurement of FEV1 % predicted (within the last 3 months), AND
2. Number of days treated with oral and/or IV antibiotics for pulmonary exacerbations in the previous 6 months or number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months, AND
3. Number of CF-related hospitalizations in the previous 6 months, AND
4. Baseline Body Mass Index (BMI) or BMI z-score in children

This drug must be prescribed by a prescriber affiliated with one of the following Alberta Cystic Fibrosis Clinics:

- Cystic Fibrosis Clinic, Adult: Kaye Edmonton Clinic
- Cystic Fibrosis Services - Adult Outpatient: Foothills Medical Centre
- Cystic Fibrosis Clinic, Pediatric: Stollery Children's Hospital
- Pediatric Cystic Fibrosis Clinic: Alberta Children's Hospital

For coverage, dosing will be approved as follows:

Patients 2 to < 6 years weighing < 14 kg: One packet (containing elexacaftor 80 mg, tezacaftor 40 mg and ivacaftor 60 mg granules) in the morning and one packet (ivacaftor 59.5 mg granules) in the evening.

Patients 2 to < 6 years weighing > / = 14 kg: One packet (containing elexacaftor 100 mg, tezacaftor 50 mg and ivacaftor 75 mg granules) in the morning and one packet (ivacaftor 75 mg granules) in the evening.

Patients 6 to < 12 years weighing < 30 kg: Two tablets (each containing elexacaftor 50 mg, tezacaftor 25 mg and ivacaftor 37.5 mg) in the morning and one tablet (ivacaftor 75 mg) in the evening.

Patients 6 to < 12 years weighing > / = 30 kg: Two tablets (each containing elexacaftor 100 mg, tezacaftor 50 mg and ivacaftor 75 mg) in the morning and one tablet (ivacaftor 150 mg) in the evening.

Patients > / = 12 years: Two tablets (each containing elexacaftor 100 mg, tezacaftor 50 mg and ivacaftor 75 mg) in the morning and one tablet (ivacaftor 150 mg) in the evening.

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

Initial coverage may be approved for 12 months for patients 2-5 years of age and 6 months for patients 6 years of age and older.

Subsequent renewal of coverage may be approved for 12 months

For continued coverage beyond the initial approval period, patients must demonstrate a benefit in at least ONE of the following:

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

ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR/ IVACAFTOR

For patients 2 to 5 years of age:

1. A decrease in the total number of days for which the patient received treatment with oral and/or IV antibiotics for pulmonary exacerbations in the previous 6 months compared with the 6-month period prior to initiating treatment; or, a decrease in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months compared with the 6-month period prior to initiating treatment, OR
2. No decline in BMI z-score compared with the baseline BMI z-score assessment

For patients 6 years and older:

1. Documented improvement in % predicted FEV1 of at least 5% compared with the baseline measurement, OR
2. A decrease in the total number of days for which the patient received treatment with oral and/or IV antibiotics for pulmonary exacerbations in the previous 6 months compared with the 6-month period prior to initiating treatment; or, a decrease in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months compared with the 6-month period prior to initiating treatment, OR
3. Decreased number of CF-related hospitalizations in the previous 6 months compared with the 6-month period prior to initiating treatment, OR
4. No decline in BMI or BMI z-score compared with the baseline BMI or BMI z-score assessment

Ongoing coverage may be considered only if patients have maintained a benefit in at least ONE of the parameters noted above at the end of each 12-month period.

Coverage cannot be provided for elexacaftor/tezacaftor/ivacaftor and ivacaftor for the following:

1. When intended for use in combination with other CFTR modulators; OR
2. Patient is the previous recipient of a double lung transplant.

All requests (including renewal requests) for elexacaftor/tezacaftor/ivacaftor + ivacaftor must be completed using the Combination CFTR Modulators Special Authorization Request Form (ABC 60090).

100 MG * 50 MG * 75 MG * 75 MG ORAL GRANULE

00002542277

TRIKAFTA

VER

\$ 420.0000

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

RUFINAMIDE

"For the treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients who meet the following criteria:

- are currently taking two or more anti-epileptic drugs (AEDs) without optimal seizure control;
AND
- have failed or demonstrated intolerance to adequate trials of both lamotrigine AND topiramate;
AND
- therapy must be initiated by a Neurologist.

Special authorization may be granted for six months."

This product is eligible for auto-renewal.

200 MG ORAL TABLET

00002545985	AURO-RUFINAMIDE	AUR	\$	1.0083
00002369621	BANZEL	EIS	\$	1.6219

400 MG ORAL TABLET

00002545993	AURO-RUFINAMIDE	AUR	\$	2.1970
00002369648	BANZEL	EIS	\$	3.5340

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

SUMATRIPTAN SUCCINATE

(Refer to 28:32.28 of the Alberta Drug Benefit List for coverage of patients 18 to 64 years of age inclusive.)

"For the treatment of acute migraine attacks in patients 65 years of age and older where other standard therapy has failed."

"For the treatment of acute migraine attacks in patients 65 years of age and older who have been using sumatriptan prior to turning 65."

"Special authorization for both criteria may be granted for 24 months."

In order to comply with the first criteria, information is required regarding previous medications utilized and the patient's response to therapy.

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

All requests (including renewal requests) for sumatriptan must be completed using the Almotriptan/Naratriptan/Rizatriptan/Sumatriptan/Zolmitriptan Special Authorization Request Form (ABC 60124)

50 MG (BASE)	ORAL TABLET			
00002268388	APO-SUMATRIPTAN	APX	\$	2.7732
00002545306	JAMP SUMATRIPTAN DF	JPC	\$	2.7732
00002268914	MYLAN-SUMATRIPTAN	MYP	\$	2.7732
00002256436	PMS-SUMATRIPTAN	PMS	\$	2.7732
00002286521	SUMATRIPTAN	SNS	\$	2.7732
00002546035	SUMATRIPTAN	SIV	\$	2.7732
00002385570	SUMATRIPTAN DF	SIV	\$	2.7732
00002286823	TEVA-SUMATRIPTAN DF	TEV	\$	2.7732
00002212153	IMITREX DF	GSK	\$	17.6485
100 MG (BASE)	ORAL TABLET			
00002268396	APO-SUMATRIPTAN	APX	\$	3.0549
00002545314	JAMP SUMATRIPTAN DF	JPC	\$	3.0549
00002268922	MYLAN-SUMATRIPTAN	MYP	\$	3.0549
00002256444	PMS-SUMATRIPTAN	PMS	\$	3.0549
00002286548	SUMATRIPTAN	SNS	\$	3.0549
00002546043	SUMATRIPTAN	SIV	\$	3.0549
00002385589	SUMATRIPTAN DF	SIV	\$	3.0549
00002239367	TEVA-SUMATRIPTAN	TEV	\$	3.0549
00002286831	TEVA-SUMATRIPTAN DF	TEV	\$	3.0549
00002212161	IMITREX DF	GSK	\$	19.4417

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

VUTRISIRAN SODIUM

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

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

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

Initial coverage may be approved for 25 mg administered subcutaneously once every three months for a period of nine months.

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

For renewal of coverage, patients must show continued benefit from treatment with vutrisiran and must NOT be:

- permanently bedridden and dependent on assistance for basic activities of daily living, NOR
- receiving end-of-life care.

Continued coverage may be approved for 25 mg every three months for a period of six months.

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

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

25 MG / SYR INJECTION SYRINGE

00002542420

AMVUTTRA

ANT

\$ 143041.0000
