Updates to the Alberta Drug Benefit List

Effective June 1, 2015

Alberta Government

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: http://www.health.alberta.ca/services/drug-benefit-list.html

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.

Copies of the *Alberta Drug Benefit List* are available from Pharmacy Services, Alberta Blue Cross at the address shown above.

Binder and contents: **$42.00** ($40.00 + $2.00 G.S.T.)
Contents only: **$36.75** ($35.00 + $1.75 G.S.T.)

A cheque or money order must accompany the request for copies.

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Special Authorization

The following drug product(s) will be considered for coverage by special authorization for patients covered under Alberta government-sponsored drug programs. Criteria for coverage of Alberta Human Services can be found in the June 1, 2015 Updates To the Alberta Human Services Drug Benefit Supplement.

New Drug Product(s) Available by Special Authorization

Trade Name / Strength / Form	Generic Description	DIN	MFR
ANORO ELLIPTA 62.5 MCG / DOSE (BASE) / 25 MCG / DOSE (BASE) INHALATION METERED INHALATION POWDER	UMECLIDINIUM BROMIDE/ VILANTEROL TRIFENATATE	00002418401	GSK
BREO ELLIPTA 100 MCG / DOSE / 25 MCG / DOSE (BASE) INHALATION METERED INHALATION POWDER	FLUTICASONE FUROATE/ VILANTEROL TRIFENATATE	00002408872	GSK

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

Trade Name / Strength / Form	Generic Description	DIN	MFR
JAMP-EZETIMIBE 10 MG TABLET	EZETIMIBE	00002423235	JPC
PIPERACILLIN AND TAZOBACTAM 2 G / VIAL (BASE) / 250 MG / VIAL (BASE) INJECTION	PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	00002401312	ALV
PIPERACILLIN AND TAZOBACTAM 3 G / VIAL (BASE) / 375 MG / VIAL (BASE) INJECTION	PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	00002401320	ALV
PIPERACILLIN AND TAZOBACTAM 4 G / VIAL (BASE) / 500 MG / VIAL (BASE) INJECTION	PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	00002401339	ALV

Drug Product(s) with Changes to Criteria for Coverage

Trade Name / Strength / Form	Generic Description	DIN	MFR
VICTRELIS 200 MG CAPSULE	BOCEPREVIR	00002370816	MFC
VICTRELIS TRIPLE (KIT) 200 MG / 200 MG / 80 MCG INJECTION SYRINGE/CAPSULE	BOCEPREVIR/ RIBAVIRIN/ PEGINTERFERON ALFA-2B	00002371448	MFC
VICTRELIS TRIPLE (KIT) 200 MG / 200 MG / 100 MCG INJECTION SYRINGE/CAPSULE	BOCEPREVIR/ RIBAVIRIN/ PEGINTERFERON ALFA-2B	00002371456	MFC
VICTRELIS TRIPLE (KIT) 200 MG / 200 MG / 120 MCG INJECTION SYRINGE/CAPSULE	BOCEPREVIR/ RIBAVIRIN/ PEGINTERFERON ALFA-2B	00002371464	MFC

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

Trade Name / Strength / Form	Generic Description	DIN	MFR
VICTRELIS TRIPLE (KIT) 200 MG / 200 MG / 150 MCG INJECTION SYRINGE/CAPSULE	BOCEPREVIR/ RIBAVIRIN/ PEGINTERFERON ALFA-2B	00002371472	MFC
XOLAIR 150 MG / VIAL INJECTION	OMALIZUMAB	00002260565	NOV

Added Product(s)

Trade Name / Strength / Form	Generic Description	DIN	MFR
APO-GLICLAZIDE MR 60 MG SUSTAINED-RELEASE TABLET	GLICLAZIDE	00002407124	APX
PRAMIPEXOLE 0.25 MG TABLET	PRAMIPEXOLE DIHYDROCHLORIDE	00002367602	SNS
PRAMIPEXOLE 1 MG TABLET	PRAMIPEXOLE DIHYDROCHLORIDE	00002367629	SNS

New Established Interchangeable (IC) Grouping(s)

The following IC Grouping(s) have been established and LCA pricing will be applied effective July 1, 2015.

Generic Description	Strength / Form	New LCA Price
GLICLAZIDE	60 MG ORAL SUSTAINED-RELEASE TABLET	0.2150

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 July 1, 2015.

Please review the online Alberta Drug Benefit List at https://www.ab.bluecross.ca/dbl/idbl_main1.html for further information.

Generic Description	Strength / Form	New LCA Price
PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	2 G / VIAL (BASE) / 250 MG / VIAL (BASE) INJECTION	4.1727
PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	3 G / VIAL (BASE) / 375 MG / VIAL (BASE) INJECTION	6.2591
PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	4 G / VIAL (BASE) / 500 MG / VIAL (BASE) INJECTION	8.3458

Product(s) With A Price Change

The following product(s) had a Price Decrease. The previous higher price will be recognized until June 30, 2015. For products within an established IC Grouping, the LCA price may apply.

Trade Name / Strength / Form	Generic Description	DIN	MFR
PIPERACILLIN AND TAZOBACTAM 2 G / VIAL (BASE) / 250 MG / VIAL (BASE) INJECTION	PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	00002362619	STM
PIPERACILLIN SODIUM / TAZOBACTAM SODIUM 2 G / VIAL (BASE) / 250 MG / VIAL (BASE) INJECTION	PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	00002299623	SDZ
PIPERACILLIN AND TAZOBACTAM 3 G / VIAL (BASE) / 375 MG / VIAL (BASE) INJECTION	PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	00002362627	STM
PIPERACILLIN SODIUM / TAZOBACTAM SODIUM 3 G / VIAL (BASE) / 375 MG / VIAL (BASE) INJECTION	PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	00002299631	SDZ
PIPERACILLIN/TAZOBACTAM 3 G / VIAL (BASE) / 375 MG / VIAL (BASE) INJECTION	PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	00002370166	TEV
PIPERACILLIN AND TAZOBACTAM 4 G / VIAL (BASE) / 500 MG / VIAL (BASE) INJECTION	PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	00002362635	STM
PIPERACILLIN SODIUM/TAZOBACTAM SODIUM 4 G / VIAL (BASE) / 500 MG / VIAL (BASE) INJECTION	PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	00002299658	SDZ
PIPERACILLIN/TAZOBACTAM 4 G / VIAL (BASE) / 500 MG / VIAL (BASE) INJECTION	PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	00002370174	TEV
RAN-EZETIMIBE 10 MG TABLET	EZETIMIBE	00002419548	RAN

Discontinued Listing(s)

Notification of discontinuation has been received from the manufacturers. The Alberta government-sponsored drug programs previously covered the following drug product(s). Effective June 1, 2015, the listed product(s) will no longer be a benefit and will not be considered for coverage by special authorization. A transition period will be applied and, as of June 30, 2015 claims will no longer pay for these products. Please note, for products that were covered by Special Authorization, no transition period will be applied, and as of May 31, 2015, claims will no longer pay for these products.

Trade Name / Strength / Form	Generic Description	DIN	MFR
MINT-ALENDRONATE 10 MG TABLET	ALENDRONATE SODIUM	00002394863	MPI
MINT-METFORMIN 500 MG TABLET	METFORMIN HCL	00002388766	MPI

Discontinued Listing(s), continued

Trade Name / Strength / Form	Generic Description	DIN	MFR
MINT-METFORMIN 850 MG TABLET	METFORMIN HCL	00002388774	MPI
MYLAN-CAPTOPRIL 12.5 MG TABLET	CAPTOPRIL	00002163551	MYP
MYLAN-CAPTOPRIL 25 MG TABLET	CAPTOPRIL	00002163578	MYP
MYLAN-CAPTOPRIL 50 MG TABLET	CAPTOPRIL	00002163586	MYP
MYLAN-CAPTOPRIL 100 MG TABLET	CAPTOPRIL	00002163594	MYP
MYLAN-TICLOPIDINE 250 MG TABLET	TICLOPIDINE HCL	00002239744	MYP
PREMARIN 0.3 MG TABLET	CONJUGATED ESTROGENS	00002043394	PFI
PREMARIN 0.625 MG TABLET	CONJUGATED ESTROGENS	00002043408	PFI
PREMARIN 1.25 MG TABLET	CONJUGATED ESTROGENS	00002043424	PFI
TAZOCIN 2 G / VIAL (BASE) / 250 MG / VIAL (BASE) INJECTION	PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	00002170817	PFI
TAZOCIN 3 G / VIAL (BASE) / 375 MG / VIAL (BASE) INJECTION	PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	00002170795	PFI
TAZOCIN 4 G / VIAL (BASE) / 500 MG / VIAL (BASE) INJECTION	PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	00002170809	PFI

Product(s) Removed from the ADBL as Price Policy Requirements Not Satisfied

The Alberta government-sponsored drug programs previously covered the following drug product(s). Effective June 1, 2015, the listed product(s) will no longer be a benefit and will not be considered for coverage by special authorization. A transition period will be applied and, as of June 30, 2015 claims will no longer pay for these products. Please note, for products that were covered by Special Authorization, no transition period will be applied, and as of May 31, 2015, claims will no longer pay for these products.

Trade Name / Strength / Form	Generic Description	DIN	MFR
PIPERACILLIN AND TAZOBACTAM 2 G / VIAL (BASE) / 250 MG / VIAL (BASE) INJECTION	PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	00002308444	APX
PIPERACILLIN AND TAZOBACTAM 3 G / VIAL (BASE) / 375 MG / VIAL (BASE) INJECTION	PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	00002308452	APX
PIPERACILLIN/TAZOBACTAM 3 G / VIAL (BASE) / 375 MG / VIAL (BASE) INJECTION	PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	00002391538	MYP
JAMP-PIP/TAZ 4 G / VIAL (BASE) / 500 MG / VIAL (BASE) INJECTION	PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	00002420430	JPC
PIPERACILLIN AND TAZOBACTAM 4 G / VIAL (BASE) / 500 MG / VIAL (BASE) INJECTION	PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	00002308460	APX

Product(s) Removed from the ADBL as Price Policy Requirements Not Satisfied, continued

Trade Name / Strength / Form	Generic Description	DIN	MFR
PIPERACILLIN/TAZOBACTAM 4 G / VIAL (BASE) / 500 MG / VIAL (BASE) INJECTION	PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	00002391546	MYP

PART 2

Drug Additions

GLICLAZIDE

60 MG ORAL SUSTAINED-RELEASE TABLET

00002407124	**APO-GLICLAZIDE MR**	**APX**	$	**0.2150**
00002356422	DIAMICRON MR	SEV	$	0.2529

PRAMIPEXOLE DIHYDROCHLORIDE

0.25 MG ORAL TABLET

00002376350	**MYLAN-PRAMIPEXOLE**	**MYP**	$	**0.2628**
00002309122	**PRAMIPEXOLE**	**SIV**	$	**0.2628**
00002297302	ACT PRAMIPEXOLE	APH	$	0.2709
00002292378	APO-PRAMIPEXOLE	APX	$	0.2709
00002290111	PMS-PRAMIPEXOLE	PMS	$	0.2709
00002367602	PRAMIPEXOLE	SNS	$	0.2709
00002315262	SANDOZ PRAMIPEXOLE	SDZ	$	0.2709
00002269309	TEVA-PRAMIPEXOLE	TEV	$	0.2709
00002237145	MIRAPEX	BOE	$	1.0836

1 MG ORAL TABLET

00002376377	**MYLAN-PRAMIPEXOLE**	**MYP**	$	**0.5257**
00002309149	**PRAMIPEXOLE**	**SIV**	$	**0.5257**
00002297329	ACT PRAMIPEXOLE	APH	$	0.5418
00002292394	APO-PRAMIPEXOLE	APX	$	0.5418
00002290146	PMS-PRAMIPEXOLE	PMS	$	0.5418
00002367629	PRAMIPEXOLE	SNS	$	0.5418
00002315289	SANDOZ PRAMIPEXOLE	SDZ	$	0.5418
00002269325	TEVA-PRAMIPEXOLE	TEV	$	0.5418
00002237146	MIRAPEX	BOE	$	2.1672

PART 3

Special Authorization

BOCEPREVIR

NOTICE: Merck Canada Inc. has made the decision to discontinue the sale and distribution of Victrelis (boceprevir) and Victrelis Triple (boceprevir/ribavirin/peginterferon alfa-2b) in Canada by March 31, 2016.

**The Special Authorization Criteria outlined below remain part of the Alberta Drug Benefit List. In order to enable patients to complete their course of treatment prior to March 31, 2016, it is imperative that the below timelines are adhered to:

Patients must have already initiated four (4) weeks of treatment with peginterferon alfa/ribavirin PRIOR to the date of initiation of Victrelis or Victrelis Triple indicated below AND,

- Victrelis or Victrelis Triple must be initiated by May 1, 2015 for patients meeting criteria WITH compensated cirrhosis and/or WITH prior null response;
- Victrelis or Victrelis Triple must be initiated by August 1, 2015 for response guided therapy for previous treatment failures with NO cirrhosis, NOT prior null response;
- Victrelis or Victrelis Triple must be initiated by October 1, 2015 for response guided therapy for treatment naive patients with NO cirrhosis, NOT prior null response.

No new patients will be approved to initiate Victrelis or Victrelis Triple therapy outside these timelines.

Initial Coverage Criteria

The Drug Products are for use in combination with peginterferon alfa/ribavirin, for the treatment of genotype 1 chronic hepatitis C (CHC), in adults (eighteen (18) years of age or older) with compensated liver disease, including cirrhosis, and evidence of active liver disease (i.e., detectable HCV RNA within six (6) months from request), who have either not received previous therapy with peginterferon alfa/ribavirin, or who have failed previous therapy with peginterferon alfa/ribavirin following prior null response, partial response or relapse as defined below.

Failure of previous therapy with peginterferon alfa/ribavirin is defined as any of the following:
- prior null response: less than two (2) logs (100 fold) reduction in HCV RNA after twelve (12) weeks of treatment.
- partial response: a decrease in HCV RNA viral load greater than or equal to two (2) logs (100 fold) by treatment week twelve (12), but failure to achieve a sustained virologic response (SVR).
- relapse: undetectable HCV RNA at the end of previous therapy, with subsequently detectable HCV RNA.

Coverage cannot be considered where any of the following are present:
- treatment of CHC other than genotype 1;
- treatment as monotherapy;
- patients with decompensated liver disease (Child Pugh score greater than six (6)), including a history of the presence of clinical ascites, bleeding varices or hepatic encephalopathy;
- patients who previously received treatment with an HCV NS3/4A protease inhibitor (e.g., retreatment);
- extensions beyond the stated durations (below).

Where a person is eligible for initial coverage the following dosing guidelines must be met:
1) Boceprevir must be given in combination with peginterferon alfa/ribavirin.
2) Boceprevir dosing is 800 mg three (3) times a day as response guided therapy described below.
3) Futility rule applies to all patients: Discontinue all therapy if HCV RNA is 100 IU/Ml or greater at boceprevir week eight (8) (treatment week twelve (12)), or if HCV RNA is detectable at boceprevir week twenty (20) (treatment week twenty-four (24)).

Initial approval period (for patients meeting criteria, with NO cirrhosis, NOT prior null response):
- All patients must receive four (4) weeks of treatment with peginterferon alfa/ribavirin prior to the initiation of boceprevir.
- All patients may receive an initial approval for ten (10) weeks of treatment coverage of

BOCEPREVIR

boceprevir 800 mg three (3) times daily (to be added to peginterferon alfa/ribavirin).
-Treatment week refers to week of treatment inclusive of four (4) week run-in period with peginterferon alfa/ribavirin

Initial approval period for patients meeting criteria WITH compensated cirrhosis and/or WITH prior null response:
- Coverage may be provided for boceprevir and peginterferon alfa and ribavirin for a total of forty-four (44) weeks of boceprevir and forty-eight (48) weeks of peginterferon alfa/ribavirin.

Renewal approval period (for patients with NO cirrhosis, NOT prior null response, meeting criteria):

At boceprevir week four (4) (treatment week eight (8)):
- HCV RNA testing is required for all patients at boceprevir week four (4) to determine if HCV RNA is detectable.

At boceprevir week eight (8) (treatment week twelve (12)):
- HCV RNA testing is required for all patients at boceprevir week eight (8).
- If HCV RNA is 100 IU/mL or greater then triple therapy should be discontinued.
- If HCV RNA is less than 100 IU/mL then triple therapy may be approved for an additional fourteen (14) weeks of coverage.

At boceprevir week twenty (20) (treatment week twenty-four (24)):
- HCV RNA testing is required for all patients boceprevir week twenty (20).
- If HCV RNA is detectable then triple therapy should be discontinued.
- If HCV RNA is undetectable then continue as per response guided therapy described below.

Response guided therapy:

For treatment naive patients with NO cirrhosis, NOT prior null response the following will apply:

- If HCV RNA is undetectable at boceprevir week four (4) (treatment week eight (8)) AND boceprevir week twenty (20) (treatment week twenty-four (24)), all treatment should be stopped at boceprevir week twenty-four (24) (treatment week twenty-eight (28)).
- If HCV RNA is detectable at boceprevir week four (4) (treatment week eight (8)) and undetectable at boceprevir week twenty (20) (treatment week twenty-four (24)), boceprevir should be stopped at boceprevir week twenty-four (24) (treatment week twenty-eight (28)), and coverage may be provided for peginterferon alfa/ribavirin to continue for a total of forty-eight (48) weeks of peginterferon alfa/ribavirin treatment.

For previous treatment failures with NO cirrhosis, NOT prior null response

- If HCV RNA is undetectable at boceprevir week four (4) (treatment week eight (8)) AND boceprevir week twenty (20) (treatment week twenty-four (24)), all treatment should be stopped at boceprevir week thirty-two (32) (treatment week thirty-six (36)). Coverage may be provided for boceprevir and peginterferon alfa/ribavirin to continue to boceprevir week thirty-two (32) (treatment week thirty-six (36)).
- If HCV RNA is detectable boceprevir week four (4) (at treatment week eight (8)) and undetectable at boceprevir week twenty (20) (treatment week twenty-four (24)), coverage may be provided for boceprevir to continue to boceprevir week thirty-two (32) (treatment week thirty-six (36)) and peginterferon alfa/ribavirin to continue to for a total of forty-eight (48) weeks of peginterferon alfa/ribavirin treatment.

Confirmation of the diagnosis of genotype 1 chronic hepatitis C and presence of active liver disease is required. Information must include confirmation of compensated liver disease and the patient's pre-treatment serum HCV RNA (by PCR) status. Information is also required regarding whether liver enzymes (ALT/AST) are elevated, or the results of liver biopsy, or the results of transient elastography. All requests for boceprevir + peginterferon alfa/ribavirin must be completed using the Boceprevir + Peginterferon Alfa/Ribavirin Special Authorization Request

BOCEPREVIR

Form (ABC 31424). In order to meet the requirements of provincial privacy legislation, the patient's signature must be affixed to each completed form.

200 MG ORAL CAPSULE

00002370816	VICTRELIS	MFC	$	12.5000

BOCEPREVIR/ RIBAVIRIN/ PEGINTERFERON ALFA-2B

NOTICE: Merck Canada Inc. has made the decision to discontinue the sale and distribution of Victrelis (boceprevir) and Victrelis Triple (boceprevir/ribavirin/peginterferon alfa-2b) in Canada by March 31, 2016.

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Patients must have already initiated four (4) weeks of treatment with peginterferon alfa/ribavirin PRIOR to the date of initiation of Victrelis or Victrelis Triple indicated below AND,

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- Victrelis or Victrelis Triple must be initiated by October 1, 2015 for response guided therapy for treatment naive patients with NO cirrhosis, NOT prior null response.

No new patients will be approved to initiate Victrelis or Victrelis Triple therapy outside these timelines.

Initial Coverage Criteria

The Drug Products are for use in combination with peginterferon alfa/ribavirin, for the treatment of genotype 1 chronic hepatitis C (CHC), in adults (eighteen (18) years of age or older) with compensated liver disease, including cirrhosis, and evidence of active liver disease (i.e., detectable HCV RNA within six (6) months from request), who have either not received previous therapy with peginterferon alfa/ribavirin, or who have failed previous therapy with peginterferon alfa/ribavirin following prior null response, partial response or relapse as defined below.

Failure of previous therapy with peginterferon alfa/ribavirin is defined as any of the following:
- prior null response: less than two (2) logs (100 fold) reduction in HCV RNA after twelve (12) weeks of treatment.
- partial response: a decrease in HCV RNA viral load greater than or equal to two (2) logs (100 fold) by treatment week twelve (12), but failure to achieve a sustained virologic response (SVR).
- relapse: undetectable HCV RNA at the end of previous therapy, with subsequently detectable HCV RNA.

Coverage cannot be considered where any of the following are present:
- treatment of CHC other than genotype 1;
- treatment as monotherapy;
- patients with decompensated liver disease (Child Pugh score greater than six (6)), including a history of the presence of clinical ascites, bleeding varices or hepatic encephalopathy;
- patients who previously received treatment with an HCV NS3/4A protease inhibitor (e.g., retreatment);
- extensions beyond the stated durations (below).

Where a person is eligible for initial coverage the following dosing guidelines must be met:
1) Boceprevir must be given in combination with peginterferon alfa/ribavirin.
2) Boceprevir dosing is 800 mg three (3) times a day as response guided therapy described below.
3) Futility rule applies to all patients: Discontinue all therapy if HCV RNA is 100 IU/Ml or greater at boceprevir week eight (8) (treatment week twelve (12)), or if HCV RNA is detectable at boceprevir week twenty (20) (treatment week twenty-four (24)).

Initial approval period (for patients meeting criteria, with NO cirrhosis, NOT prior null response):
- All patients must receive four (4) weeks of treatment with peginterferon alfa/ribavirin prior to the initiation of boceprevir.
- All patients may receive an initial approval for ten (10) weeks of treatment coverage of

BOCEPREVIR/ RIBAVIRIN/ PEGINTERFERON ALFA-2B

boceprevir 800 mg three (3) times daily (to be added to peginterferon alfa/ribavirin).
-Treatment week refers to week of treatment inclusive of four (4) week run-in period with peginterferon alfa/ribavirin

Initial approval period for patients meeting criteria WITH compensated cirrhosis and/or WITH prior null response:
- Coverage may be provided for boceprevir and peginterferon alfa and ribavirin for a total of forty-four (44) weeks of boceprevir and forty-eight (48) weeks of peginterferon alfa/ribavirin.

Renewal approval period (for patients with NO cirrhosis, NOT prior null response, meeting criteria):

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At boceprevir week eight (8) (treatment week twelve (12)):
- HCV RNA testing is required for all patients at boceprevir week eight (8).
- If HCV RNA is 100 IU/mL or greater then triple therapy should be discontinued.
- If HCV RNA is less than 100 IU/mL then triple therapy may be approved for an additional fourteen (14) weeks of coverage.

At boceprevir week twenty (20) (treatment week twenty-four (24)):
- HCV RNA testing is required for all patients boceprevir week twenty (20).
- If HCV RNA is detectable then triple therapy should be discontinued.
- If HCV RNA is undetectable then continue as per response guided therapy described below.

Response guided therapy:

For treatment naive patients with NO cirrhosis, NOT prior null response the following will apply:

- If HCV RNA is undetectable at boceprevir week four (4) (treatment week eight (8)) AND boceprevir week twenty (20) (treatment week twenty-four (24)), all treatment should be stopped at boceprevir week twenty-four (24) (treatment week twenty-eight (28)).
- If HCV RNA is detectable at boceprevir week four (4) (treatment week eight (8)) and undetectable at boceprevir week twenty (20) (treatment week twenty-four (24)), boceprevir should be stopped at boceprevir week twenty-four (24) (treatment week twenty-eight (28)), and coverage may be provided for peginterferon alfa/ribavirin to continue for a total of forty-eight (48) weeks of peginterferon alfa/ribavirin treatment.

For previous treatment failures with NO cirrhosis, NOT prior null response

- If HCV RNA is undetectable at boceprevir week four (4) (treatment week eight (8)) AND boceprevir week twenty (20) (treatment week twenty-four (24)), all treatment should be stopped at boceprevir week thirty-two (32) (treatment week thirty-six (36)). Coverage may be provided for boceprevir and peginterferon alfa/ribavirin to continue to boceprevir week thirty-two (32) (treatment week thirty-six (36)).
- If HCV RNA is detectable boceprevir week four (4) (at treatment week eight (8)) and undetectable at boceprevir week twenty (20) (treatment week twenty-four (24)), coverage may be provided for boceprevir to continue to boceprevir week thirty-two (32) (treatment week thirty-six (36)) and peginterferon alfa/ribavirin to continue to for a total of forty-eight (48) weeks of peginterferon alfa/ribavirin treatment.

Confirmation of the diagnosis of genotype 1 chronic hepatitis C and presence of active liver disease is required. Information must include confirmation of compensated liver disease and the patient's pre-treatment serum HCV RNA (by PCR) status. Information is also required regarding whether liver enzymes (ALT/AST) are elevated, or the results of liver biopsy, or the results of transient elastography. All requests for boceprevir + peginterferon alfa/ribavirin must be completed using the Boceprevir + Peginterferon Alfa/Ribavirin Special Authorization Request

BOCEPREVIR/ RIBAVIRIN/ PEGINTERFERON ALFA-2B

Form (ABC 31424). In order to meet the requirements of provincial privacy legislation, the patient's signature must be affixed to each completed form.

200 MG * 200 MG * 80 MCG INJECTION SYRINGE/CAPSULE			
00002371448	VICTRELIS TRIPLE (KIT)	MFC	$ 2652.5500
200 MG * 200 MG * 100 MCG INJECTION SYRINGE/CAPSULE			
00002371456	VICTRELIS TRIPLE (KIT)	MFC	$ 2652.5500
200 MG * 200 MG * 120 MCG INJECTION SYRINGE/CAPSULE			
00002371464	VICTRELIS TRIPLE (KIT)	MFC	$ 2726.0000
200 MG * 200 MG * 150 MCG INJECTION SYRINGE/CAPSULE			
00002371472	VICTRELIS TRIPLE (KIT)	MFC	$ 2726.0000

EZETIMIBE

"For the treatment of hypercholesterolemia in patients who are intolerant to statins or in whom a statin is contraindicated and who are at high cardiovascular risk*; or

For the treatment of hypercholesterolemia when used in combination with a statin in patients failing to achieve target LDL with a statin at maximum tolerable dose or maximum recommended dose as per respective product monograph and who are at high cardiovascular risk*:

* High cardiovascular risk is defined as possessing one of the following:
1) Pre-existing cardiovascular disease and/or cerebrovascular disease, or
2) Diabetes, or
3) Familial hypercholesterolemia, or
4) Greater than or equal to 20% risk as defined by the Framingham Risk Assessment Tool, or
5) Three or more of the following risk factors:
- Family history of premature cardiovascular disease
- Smoking
- Hypertension
- Obesity
- Glucose intolerance
- Renal disease.

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

All requests for ezetimibe must be completed using the Ezetimibe Special Authorization Request Form (ABC 30925).

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

10 MG ORAL TABLET				
00002425610	**ACH-EZETIMIBE**	**AHI**	$	**0.4549**
00002429659	**EZETIMIBE**	**SIV**	$	**0.4549**
00002378035	**MYLAN-EZETIMIBE**	**MYP**	$	**0.4549**
00002419548	**RAN-EZETIMIBE**	**RAN**	$	**0.4549**
00002414716	ACT EZETIMIBE	APH	$	0.4612
00002427826	APO-EZETIMIBE	APX	$	0.4612
00002431300	EZETIMIBE	SNS	$	0.4612
00002423235	JAMP-EZETIMIBE	JPC	$	0.4612
00002422662	MAR-EZETIMIBE	MAR	$	0.4612
00002416409	PMS-EZETIMIBE	PMS	$	0.4612
00002416778	SANDOZ EZETIMIBE	SDZ	$	0.4612
00002354101	TEVA-EZETIMIBE	TEV	$	0.4612
00002247521	EZETROL	MFC	$	1.8360

FLUTICASONE FUROATE/ VILANTEROL TRIFENATATE

"For long-term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema, and to reduce the frequency of exacerbations of COPD, in patients who meet the following criteria:
- Have moderate to severe COPD as defined by spirometry, AND
- Have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA]) OR who experience exacerbations more than once per year while on a long-acting bronchodilator."

Special authorization will be granted for six months.
This product is eligible for auto-renewal.

All requests for fluticasone furoate + vilanterol trifenatate must be completed using the Fluticasone Furoate + Vilanterol Trifenatate/Umeclidinium Bromide + Vilanterol Trifenatate Special Authorization Request Form (ABC 60025).

100 MCG / DOSE * 25 MCG / DOSE (BASE)	INHALATION	METERED INHALATION POWDER		
00002408872	BREO ELLIPTA	GSK	$	4.0000

OMALIZUMAB

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

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

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

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

1) Confirmation of severe persistent asthma through recent clinical and physiologic review with exclusion of other obstructive airways processes contributing to symptoms of severe asthma (i.e. psychogenic dyspnea; cardiac dyspnea);

2) Must be a non-smoker;

3) Confirmation of IgE mediated allergy to a perennial allergen by clinical history and allergy skin testing;

4) Baseline IgE level greater than/equal to 30 IU/mL and less than/equal to 700 IU/mL;

5) A weight between 20kg and 150kg;

6) An Asthma Control Questionnaire (ACQ-5) of at least 1.25, on at least two occasions over the past 6 months in a stable state;

7) Must provide documentation:
- Spirometry measurement of FEV1;
- Asthma Quality of Life Questionnaire (AQLQ - Juniper) score;
- Number of exacerbations of asthma within the previous twelve (12) month period that resulted in:
    - an emergency room visit or hospitalization;
    - physician visits resulting in oral corticosteroids or an increased dose of oral corticosteroids;
    - chronic use (greater than 50% of the year) of oral corticosteroids;

8) One (1) or more severe exacerbations of asthma requiring a hospital admission or Emergency Room visit within the previous year while on systemic corticosteroids; OR
- One (1) or more severe exacerbations of asthma requiring a hospital admission or Emergency Room visit requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least three (3) days, or parenteral corticosteroids); OR
- Three (3) or more severe exacerbations of asthma within the previous year which required a physician visit and resulted in courses (or chronic use greater than 50% of the year), or increased dose of systemic corticosteroids.

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

OMALIZUMAB

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

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

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

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

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

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

150 MG / VIAL	INJECTION			
00002260565	XOLAIR		NOV	$ 600.0000

PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM

For the treatment of:

1) "Second-line therapy of intra-abdominal sepsis where there are serious adverse events due to first-line therapy or documented failure of first-line therapy (e.g. ampicillin + gentamicin + metronidazole), as defined by clinical deterioration after 72 h of antibiotic therapy or lack of improvement after completion of antibiotic therapy or

2) Second-line therapy of severe polymicrobial skin and skin structure infections (e.g. limb threatening diabetic foot) or

3) Therapy of severe ventilator-associated pneumonia where Pseudomonas and Staphylococcus aureus coverage is needed, or

4) Therapy for infections involving multi-resistant Pseudomonas aeruginosa from pulmonary secretions in cystic fibrosis patients, lung transplant patients or patients with bronchiectasis , where there is documented susceptibility to piperacillin/tazobactam sodium, or

5) For use in other Health Canada approved indications, in consultation with a specialist in Infectious Diseases."

In order to comply with all of the above criteria, information is required regarding the type of infection and organisms involved. Also, where the criteria restrict coverage of the requested drug to non-first line therapy, information is required regarding previous first-line antibiotic therapy that has been utilized, the patient's response to therapy, and the first line agents the organism is resistant to or why other first-line therapies cannot be used in this patient. Also, where applicable, the specialist in Infectious Diseases that recommended this drug is required.

2 G / VIAL (BASE) * 250 MG / VIAL (BASE) INJECTION				
00002362619	**PIPERACILLIN AND TAZOBACTAM**	**STM**	$	**4.1727**
00002401312	**PIPERACILLIN AND TAZOBACTAM**	**ALV**	$	**4.1727**
00002299623	**PIPERACILLIN SODIUM/TAZOBACTAM SODIUM**	**SDZ**	$	**4.1727**
3 G / VIAL (BASE) * 375 MG / VIAL (BASE) INJECTION				
00002362627	**PIPERACILLIN AND TAZOBACTAM**	**STM**	$	**6.2591**
00002401320	**PIPERACILLIN AND TAZOBACTAM**	**ALV**	$	**6.2591**
00002299631	**PIPERACILLIN SODIUM/TAZOBACTAM SODIUM**	**SDZ**	$	**6.2591**
00002370166	**PIPERACILLIN/TAZOBACTAM**	**TEV**	$	**6.2591**
4 G / VIAL (BASE) * 500 MG / VIAL (BASE) INJECTION				
00002362635	**PIPERACILLIN AND TAZOBACTAM**	**STM**	$	**8.3458**
00002401339	**PIPERACILLIN AND TAZOBACTAM**	**ALV**	$	**8.3458**
00002299658	**PIPERACILLIN SODIUM/TAZOBACTAM SODIUM**	**SDZ**	$	**8.3458**
00002370174	**PIPERACILLIN/TAZOBACTAM**	**TEV**	$	**8.3458**

UMECLIDINIUM BROMIDE/ VILANTEROL TRIFENATATE

"For the long-term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema, in patients who meet the following criteria:
- Have moderate to severe COPD as defined by spirometry, AND
- Have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA]).

Special authorization will be granted for six months."
This product is eligible for auto-renewal.

All requests for umeclidinium bromide + vilanterol trifenatate must be completed using the Fluticasone Furoate + Vilanterol Trifenatate/Umeclidinium Bromide + Vilanterol Trifenatate Special Authorization Request Form (ABC 60025).

62.5 MCG / DOSE (BASE)	* 25 MCG / DOSE (BASE)	INHALATION	METERED INHALATION POWDER	
00002418401	ANORO ELLIPTA		GSK	$ 2.7000