Updates to the Alberta Human Services Drug Benefit Supplement

Effective January 1, 2015

Alberta Human Services

Inquiries should be directed to:

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Website: http://www.employment.alberta.ca/FCH/2086.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* Publication 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 Alberta Human Services.

New Drug Product(s) Available by Special Authorization

Trade Name / Strength / Form	Generic Description	DIN	MFR
GALEXOS 150 MG CAPSULE	SIMEPREVIR SODIUM	00002416441	JAI

Drug Product(s) with Changes to Criteria for Coverage

Trade Name / Strength / Form	Generic Description	DIN	MFR
INCIVEK 375 MG TABLET	TELAPREVIR	00002371553	VER
PEGASYS RBV (KIT) 180 MCG / 200 MG INJECTION SYRINGE/ TABLET	PEGINTERFERON ALFA-2A/ RIBAVIRIN	00002253429	HLR
PEGETRON (KIT) 50 MCG / 200 MG INJECTION VIAL/ CAPSULE	PEGINTERFERON ALFA-2B/ RIBAVIRIN	00002246026	MFC
PEGETRON (KIT) 150 MCG / 200 MG INJECTION VIAL/ CAPSULE	PEGINTERFERON ALFA-2B/ RIBAVIRIN	00002246030	MFC
PEGETRON CLEARCLICK (KIT) 80 MCG / 200 MG INJECTION SYRINGE/ CAPSULE	PEGINTERFERON ALFA-2B/ RIBAVIRIN	00002254581	MFC
PEGETRON CLEARCLICK (KIT) 100 MCG / 200 MG INJECTION SYRINGE/ CAPSULE	PEGINTERFERON ALFA-2B/ RIBAVIRIN	00002254603	MFC
PEGETRON CLEARCLICK (KIT) 120 MCG / 200 MG INJECTION SYRINGE/ CAPSULE	PEGINTERFERON ALFA-2B/ RIBAVIRIN	00002254638	MFC
PEGETRON CLEARCLICK (KIT) 150 MG / 200 MG INJECTION SYRINGE/ CAPSULE	PEGINTERFERON ALFA-2B/ RIBAVIRIN	00002254646	MFC

PART 3

Special Authorization

PEGINTERFERON ALFA-2A/ RIBAVIRIN

Genotype 1 Chronic Hepatitis C:

"For the treatment of chronic hepatitis C genotype 1, in accordance with the boceprevir criteria, in patients who qualify for treatment with boceprevir."

"For the treatment of chronic hepatitis C genotype 1, in accordance with the simeprevir criteria, in patients who qualify for treatment with simeprevir."

(Refer to Section 3 of the Alberta Drug Benefit List for coverage of peginterferon alfa/ribavirin in combination with boceprevir or simeprevir for the treatment of Genotype 1 Chronic Hepatitis C.)

Chronic Hepatitis C (Genotypes 1- 6 and Patients With Advanced Fibrosis or Cirrhosis):

"For the treatment of chronic hepatitis C in adult patients with evidence of active liver disease.

Prior to initiation of Pegasys RBV therapy:

- To determine treatment duration and prognosis, HCV genotype testing is required for all patients.
- At least three (3) weeks before anticipated start date of therapy, please submit a Peginterferon Alfa-2a+Ribavirin/Peginterferon Alfa-2b+Ribavirin Special Authorization Request Form (ABC 30932) along with appropriate lab results to Alberta Blue Cross.

All Patients (with the Exception of Post-Liver Transplant Patients and Advanced Fibrosis or Cirrhosis Patients):

Prior to initiation of Pegasys RBV therapy:

- Genotype 1 patients and Genotype 2 or 3 patients with HIV co-infection must have a baseline serum sample stored for future viral load testing in the event that the week 12 HCV RNA test is positive.

Initial Alberta Blue Cross approval periods (for patients meeting criteria):

- Genotype 1 patients and Genotype 2 or 3 patients with HIV co-infection, may receive an initial approval for 14 weeks of coverage.
- Genotype 2 or 3 patients may receive initial and maximal approval for 24 weeks of coverage. These patients will not be eligible for continued approval.
- Genotype 4, 5 and 6 patients may receive initial and maximal approval for 48 weeks of coverage. These patients will not be eligible for continued approval.

At 12 weeks of treatment:

- HCV RNA testing is required for all Genotype 1 patients and Genotype 2 or 3 patients with HIV co-infection at the 12th week of treatment.
- If the HCV RNA test is positive, viral load testing is required on the previously stored baseline serum sample and the 12th week serum sample for evaluation of continued coverage.

Renewal approval period (for patients meeting criteria):

- Genotype 1 patients and Genotype 2 or 3 patients with HIV co-infection who respond to therapy as measured by a negative HCV RNA status at 12 weeks, may be approved for an additional 34 weeks of coverage (i.e. total 48 weeks).
- Genotype 1 patients and Genotype 2 or 3 patients with HIV co-infection who achieve a reduction in viral load by at least 2 logs (100 fold) but do not possess negative HCV RNA status at week 12 may be approved for an additional 14 weeks of coverage. Patients should be retested for HCV RNA status at 24 weeks:
- Patients who respond to therapy, as measured by a negative HCV RNA status at 24 weeks, may be approved for an additional 20 weeks of coverage (i.e. total 48 weeks).

PEGINTERFERON ALFA-2A/ RIBAVIRIN

- Those who fail to demonstrate negative HCV RNA status at 24 weeks will not be eligible for continued approval.

Post-Liver Transplant Patients:

Initial Alberta Blue Cross approval periods (for patients meeting criteria):

- Genotype 1 and Genotype 2 or 3 patients may receive an initial approval for 26 weeks of coverage.
- Genotype 4, 5 and 6 patients may receive initial and maximal approval for 48 weeks of coverage. These patients will not be eligible for continued approval.

At 24 weeks of treatment:

- HCV RNA testing is required for all Genotype 1 and Genotype 2 or 3 patients at the 24th week of treatment.

Renewal approval period (for patients meeting criteria):

- Genotype 1 and Genotype 2 or 3 patients who respond to therapy as measured by a negative HCV RNA status at 24 weeks, may be approved for an additional 22 weeks of coverage (i.e. total 48 weeks).
- Those who fail to demonstrate negative HCV RNA status at 24 weeks will not be eligible for continued approval.

Advanced Fibrosis or Cirrhosis Patients:

Initial Alberta Blue Cross approval periods (for patients meeting criteria):

- Patients with advanced fibrosis or cirrhosis may receive approval for 48 weeks of coverage.

Consideration for therapy in ALL patients (including post-liver transplant patients) who have previously received therapy:

- Consideration for therapy in patients who have previously received therapy may be given for patients who meet at least one of the following criteria:
- Advanced fibrosis or cirrhosis.
- Patients who have relapsed following non-pegylated interferon/ribavarin combination therapy.
- Patients who have failed to respond to or relapsed following interferon monotherapy."

Confirmation of the diagnosis of chronic hepatitis C and presence of active liver disease is required. Information must include 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 peginterferon alfa-2a/ribavirin must be completed using the Peginterferon Alfa-2a+Ribavirin/Peginterferon Alfa-2b+Ribavirin Special Authorization Request Form (ABC 30932). In order to meet the requirements of provincial privacy legislation, the patient's signature must be affixed to each completed form.

180 MCG * 200 MG	INJECTION	SYRINGE/TABLET		
00002253429	PEGASYS RBV (KIT)		HLR	$ 395.8400

PEGINTERFERON ALFA-2B/ RIBAVIRIN

Genotype 1 Chronic Hepatitis C:

"For the treatment of chronic hepatitis C genotype 1, in accordance with the boceprevir criteria, in patients who qualify for treatment with boceprevir."

"For the treatment of chronic hepatitis C genotype 1, in accordance with the simeprevir criteria, in patients who qualify for treatment with simeprevir."

(Refer to Section 3 of the Alberta Drug Benefit List for coverage of peginterferon alfa/ribavirin in combination with boceprevir or simeprevir for the treatment of Genotype 1 Chronic Hepatitis C.)

Chronic Hepatitis C (Genotypes 1- 6 and Patients With Advanced Fibrosis or Cirrhosis):

"For the treatment of chronic hepatitis C in adult patients (greater than or equal to 18 years of age) with evidence of active liver disease.

Prior to initiation of Pegetron therapy:

- To determine treatment duration and prognosis, HCV genotype testing is required for all patients.
- At least three (3) weeks before anticipated start date of therapy, please submit a Peginterferon Alfa-2a+Ribavirin/Peginterferon Alfa-2b+Ribavirin Special Authorization Request Form (ABC 30932) along with appropriate lab results to Alberta Blue Cross.

All Patients (with the Exception of Post-Liver Transplant Patients and Advanced Fibrosis or Cirrhosis Patients):

Prior to initiation of Pegetron therapy:

- Genotype 1 patients and Genotype 2 or 3 patients with HIV co-infection must have a baseline serum sample stored for future viral load testing in the event that the week 12 HCV RNA test is positive.

Initial Alberta Blue Cross approval periods (for patients meeting criteria):

- Genotype 1 patients and Genotype 2 or 3 patients with HIV co-infection, may receive an initial approval for 14 weeks of coverage.
- Genotype 2 or 3 patients may receive initial and maximal approval for 24 weeks of coverage. These patients will not be eligible for continued approval.
- Genotype 4, 5 and 6 patients may receive initial and maximal approval for 48 weeks of coverage. These patients will not be eligible for continued approval.

At 12 weeks of treatment:

- HCV RNA testing is required for all Genotype 1 patients and Genotype 2 or 3 patients with HIV co-infection at the 12th week of treatment.
- If the HCV RNA test is positive, viral load testing is required on the previously stored baseline serum sample and the 12th week serum sample for evaluation of continued coverage.

Renewal approval period (for patients meeting criteria):

- Genotype 1 patients and Genotype 2 or 3 patients with HIV co-infection who respond to therapy as measured by a negative HCV RNA status at 12 weeks, may be approved for an additional 34 weeks of coverage (i.e. total 48 weeks).
- Genotype 1 patients and Genotype 2 or 3 patients with HIV co-infection who achieve a reduction in viral load by at least 2 logs (100 fold) but do not possess negative HCV RNA status at week 12 may be approved for an additional 14 weeks of coverage. Patients should be retested for HCV RNA status at 24 weeks:
- Patients who respond to therapy, as measured by a negative HCV RNA status at 24 weeks,

PEGINTERFERON ALFA-2B/ RIBAVIRIN

may be approved for an additional 20 weeks of coverage (i.e. total 48 weeks).
- Those who fail to demonstrate negative HCV RNA status at 24 weeks will not be eligible for continued approval.

Post-Liver Transplant Patients:

Initial Alberta Blue Cross approval periods (for patients meeting criteria):

- Genotype 1 and Genotype 2 or 3 patients may receive an initial approval for 26 weeks of coverage.
- Genotype 4, 5 and 6 patients may receive initial and maximal approval for 48 weeks of coverage. These patients will not be eligible for continued approval.

At 24 weeks of treatment:

- HCV RNA testing is required for all Genotype 1 and Genotype 2 or 3 patients at the 24th week of treatment.

Renewal approval period (for patients meeting criteria):

- Genotype 1 and Genotype 2 or 3 patients who respond to therapy as measured by a negative HCV RNA status at 24 weeks, may be approved for an additional 22 weeks of coverage (i.e. total 48 weeks).
- Those who fail to demonstrate negative HCV RNA status at 24 weeks will not be eligible for continued approval.

Advanced Fibrosis or Cirrhosis Patients:

Initial Alberta Blue Cross approval periods (for patients meeting criteria):

- Patients with advanced fibrosis or cirrhosis may receive approval for 48 weeks of coverage.

Consideration for therapy in ALL patients (including post-liver transplant patients) who have previously received therapy:

- Consideration for therapy in patients who have previously received therapy may be given for patients who meet at least one of the following criteria:
- Advanced fibrosis or cirrhosis.
- Patients who have relapsed following non-pegylated interferon/ribavarin combination therapy.
- Patients who have failed to respond to or relapsed following interferon monotherapy."

Confirmation of the diagnosis of chronic hepatitis C and presence of active liver disease is required. Information must include 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 peginterferon alfa-2b/ribavirin must be completed using the Peginterferon Alfa-2a+Ribavirin/Peginterferon Alfa-2b+Ribavirin Special Authorization Request Form (ABC 30932). In order to meet the requirements of provincial privacy legislation, the patient's signature must be affixed to each completed form.

50 MCG * 200 MG INJECTION VIAL/CAPSULE			
00002246026	PEGETRON (KIT)	MFC	$ 770.3500
150 MCG * 200 MG INJECTION VIAL/CAPSULE			
00002246030	PEGETRON (KIT)	MFC	$ 851.2300
80 MCG * 200 MG INJECTION SYRINGE/CAPSULE			
00002254581	PEGETRON CLEARCLICK (KIT)	MFC	$ 770.3500
100 MCG * 200 MG INJECTION SYRINGE/CAPSULE			
00002254603	PEGETRON CLEARCLICK (KIT)	MFC	$ 770.3500

PEGINTERFERON ALFA-2B/ RIBAVIRIN

120 MCG * 200 MG INJECTION SYRINGE/CAPSULE			
00002254638	PEGETRON CLEARCLICK (KIT)	MFC	$ 851.2300
150 MCG * 200 MG INJECTION SYRINGE/CAPSULE			
00002254646	PEGETRON CLEARCLICK (KIT)	MFC	$ 851.2300

SIMEPREVIR SODIUM

"For use in combination with peginterferon alfa/ribavirin, for the treatment of genotype 1 chronic hepatitis C (CHC), in adults (18 years of age or older) with compensated liver disease and detectable levels of hepatitis C virus (HCV) RNA in the last six months, and a fibrosis stage of F2, F3, or F4 and; who have either not received previous therapy with peginterferon alfa/ribavirin or have failed previous therapy with peginterferon alfa/ribavirin following prior null response, partial response or relapse.

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

Coverage cannot be considered for:
- treatment of CHC other than genotype 1;
- treatment as monotherapy;
- patients with the NS3 Q80K polymorphism;
- patients with decompensated liver disease (Child Pugh score greater than 6), including a history of the presence of clinical ascites, bleeding varices or hepatic encephalopathy;
- patients who previously received a prior full therapeutic course with an HCV NS3/4A protease inhibitor (e.g., retreatment);
- extensions beyond the stated duration (as stated below).

The following dosing guidelines must be met:
1) Simeprevir must be given in combination with peginterferon alfa/ribavirin.
2) Simeprevir dosing is 150 mg once a day as response guided therapy described below.
3) Futility (stopping) rule applies to all patients: Discontinue all therapy if HCV RNA is greater than or equal to 25 IU/mL at week 4, or if HCV RNA is detectable at week 12 or 24.

Initial approval period (for patients meeting criteria):
- All patients may receive an initial approval for 6 weeks of treatment coverage (6 weeks of simeprevir in combination with peginterferon alfa/ribavirin).

Renewal approval periods (for patients meeting criteria):

At treatment week 4:
- HCV RNA testing is required for all patients at the 4th week of treatment to determine the length of treatment.
- If HCV RNA is greater than or equal to 25 IU/mL, triple therapy should be discontinued.
- If HCV RNA is undetectable or detectable but less than 25 IU/mL, an additional 6 weeks of simeprevir may be approved (for a total of 12 weeks) plus an additional 8 weeks of peginterferon alfa/ribavirin.

At treatment week 12:
- HCV RNA testing is required for all patients at the 12th week of treatment. If HCV RNA is detectable at week 12, discontinue peginterferon alfa/ribavirin (treatment with simeprevir is complete at week 12).

For treatment naive patients and prior relapsers:
- If HCV RNA was undetectable at week 4, and is undetectable at week 12, peginterferon alfa/ribavirin may be approved for an additional 10 weeks (total treatment is 24 weeks).
- If HCV RNA was detectable but less than 25 IU/mL at week 4, and is undetectable at week 12, peginterferon alfa/ribavirin may be approved for an additional 12 weeks.

For prior partial and null responders:
- If HCV RNA was undetectable or detectable but less than 25 IU/mL at week 4, and is undetectable at week 12, peginterferon alfa/ribavirin maybe approved for an additional 12

SIMEPREVIR SODIUM

weeks.

At treatment week 24:
- HCV RNA testing is required for all patients at the 24th week of treatment. If HCV RNA is detectable at week 24, discontinue peginterferon alfa/ribavirin treatment.

For treatment naive patients and prior relapsers:
- If HCV RNA was detectable but less than 25 IU/mL at week 4, and undetectable at weeks 12 and 24, peginterferon alfa/ribavirin may be approved for an additional 22 weeks (total 48 weeks).

For prior partial and null responders:
- If HCV RNA was undetectable or detectable but less than 25 IU/mL at week 4, and undetectable at weeks 12 and 24, peginterferon alfa/ribavirin may be approved for an additional 22 weeks (total 48 weeks)."

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 the patient?s fibrosis stage and confirmation of whether the patient has Q80K polymorphism for those patients with subtype 1a HCV. All requests for simeprevir + peginterferon alfa/ribavirin must be completed using the Simeprevir + Peginterferon Alfa/Ribavirin Special Authorization Request Form (ABC 60016). In order to meet the requirements of provincial privacy legislation, the patient's signature must be affixed to each completed form.

150 MG (BASE)	**ORAL**	**CAPSULE**		
00002416441	GALEXOS		JAI	$ 434.5500

TELAPREVIR

NOTICE: Vertex Pharmaceuticals (Canada) Incorporated has made the decision to discontinue the sale and distribution of Incivek (telaprevir) in Canada as of January 1, 2015.

The Special Authorization Criteria outlined below remain part of the Alberta Drug Benefit List to enable patients who initiated therapy with Incivek prior to January 1, 2015 to complete their course of treatment. No new patients will be approved to initiate Incivek therapy at this time.

"For use in combination with peginterferon alfa/ribavirin, for the treatment of genotype 1 chronic hepatitis C (CHC), in adults (18 years of age or older) with compensated liver disease, including cirrhosis, and evidence of active liver disease (i.e., detectable HCV RNA within 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.

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

Coverage cannot be considered for:
- treatment of CHC other than genotype 1;
- treatment as monotherapy;
- patients with decompensated liver disease (Child Pugh score greater than 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 duration (maximum 12 weeks as stated below).

The following dosing guidelines must be met:
1) Telaprevir must be given in combination with peginterferon alfa/ribavirin.
2) Telaprevir dosing is 1125 mg two times a day as response guided therapy described below.
3) Futility rule applies to all patients: Discontinue all therapy if HCV RNA is greater than 1000 IU/mL at week 4 or 12, or if HCV RNA is detectable at week 24.

Initial approval period (for patients meeting criteria):

- All patients may receive an initial approval for 6 weeks of treatment coverage (6 weeks of telaprevir in combination with peginterferon alfa/ribavirin).

Renewal approval periods (for patients meeting criteria):

At treatment week 4:
- HCV RNA testing is required for all patients at the 4th week of treatment.
- If HCV RNA is greater than 1000 IU/mL, triple therapy should be discontinued.
- If HCV RNA is undetectable or detectable but 1000 IU/mL or less, an additional 6 weeks of telaprevir may be approved (total duration of 12 weeks approved) plus an additional 8 weeks of peginterferon alfa/ribavirin.

At treatment week 12:
- HCV RNA testing is required for all patients at the 12th week of treatment.

For all patients:
- If HCV RNA is greater than 1000 IU/mL, peginterferon alfa/ribavirin should be discontinued.

Patients without cirrhosis: For treatment naive and prior relapse patients:
- If HCV RNA was undetectable at week 4 and is undetectable at week 12, peginterferon

TELAPREVIR

alfa/ribavirin may be approved for an additional 10 weeks (total 24 weeks peginterferon alfa/ribavirin).
- If HCV RNA was detectable at week 4 (1000 IU/mL or less) and is undetectable or detectable but 1000 IU/mL or less at week 12, peginterferon alfa/ribavirin maybe approved for an additional 12 weeks.

For prior partial and null responders:
- Peginterferon alfa/ribavirin maybe approved for an additional 12 weeks.

Patients with cirrhosis: For treatment naive and prior relapse patients:
- If HCV RNA was undetectable or detectable but 1000 IU/mL or less at weeks 4 and 12, peginterferon alfa/ribavirin may be approved for an additional 12 weeks.

At treatment week 24:
- HCV RNA testing is required for all patients at the 24th week of treatment.

For all patients:
- If HCV RNA is detectable discontinue treatment.

Patients without cirrhosis: For treatment naive and prior relapse patients:
- If HCV RNA was detectable at week 4 (1000 IU/mL or less) and undetectable or detectable but 1000 IU/mL or less at week 12, and undetectable at week 24, peginterferon alfa/ribavirin may be approved for an additional 22 weeks (total 48 weeks peginterferon alfa/ribavirin).

For prior partial and null responders:
- If HCV RNA was undetectable at week 24, peginterferon alfa/ribavirin may be approved for an additional 22 weeks (total 48 weeks peginterferon alfa/ribavirin).

Patients with cirrhosis: For treatment naive and prior relapse patients:
- If HCV RNA was undetectable or detectable but 1000 IU/mL or less at weeks 4 and 12, and undetectable at week 24, peginterferon alfa/ribavirin may be approved for an additional 22 weeks (total 48 weeks peginterferon alfa/ribavirin)."

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 telaprevir + peginterferon alfa/ribavirin must be completed using the Telaprevir + Peginterferon Alfa/Ribavirin Special Authorization Request Form (ABC 31418). In order to meet the requirements of provincial privacy legislation, the patient's signature must be affixed to each completed form.

375 MG ORAL TABLET

00002371553	INCIVEK	VER	$	69.3810