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NOVA SCOTIA

PharmacareNEWS

inside

Nova Scotia Formulary Updates

Expanded Coverage for Chronic Hepatitis C

Effective **May 1, 2017,** Pharmacare will expand coverage for certain direct-acting antivirals (DAAs) and list new DAAs for Chronic Hepatitis C. The complete list of DAAs and their criteria is below.

Effective May 1, 2017, Pharmacare will no longer approve new requests for coverage of ombitasvir/paritaprevir/ritonavir and dasabuvir (Holkira PAK). For patients whose coverage of this drug was approved before May 1, 2017, Pharmacare will continue coverage until their current Exception Status Drug approval expires.

New Products

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Daklinza (daclatasvir)	30 mg Tab	02444747	DNP	E(SF)	BRI
	60 mg Tab	02444755	DNP	E(SF)	BRI

Criteria	For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C who meet the following criteria:	
		Approval Period and Regimen
	Genotype 1b • With no cirrhosis or with compensated cirrhosis	24 weeks in combination with asunaprevir
	Genotype 3 • With no cirrhosis	12 weeks in combination with sofosbuvir
	Genotype 3 • With compensated cirrhosis or decompensated cirrhosis • Post-liver transplant with no cirrhosis or with compensated cirrhosis	12 weeks in combination with sofosbuvir and ribavirin

Expanded Coverage for Chronic Hepatitis C Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Daklinza	30 mg Tab	02444747	DNP	E(SF)	BRI
(daclatasvir)	60 mg Tab	02444755	DNP	E(SF)	BRI

Criteria

Patients must also meet all of the following criteria:

- Prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescribers with expertise in the treatment of hepatitis C infection).
- Lab-confirmed hepatitis C genotype 1b and 3
- Quantitative hepatitis C virus (HCV) RNA value within the last 6 months
- Fibrosis stage F2 or greater (Metavir scale or equivalent) or Fibrosis stage less than F2 (Metavir scale or equivalent) and at least one of the following:
    - Co-infected with HIV or hepatitis B virus
    - Post-organ transplant (liver and/or non-liver transplant)
    - Extra-hepatic manifestations
    - Chronic kidney disease stage 3, 4 or 5 as defined by the National Kidney Foundation Kidney Disease Outcomes Quality Initiative
    - Co-existent liver disease with diagnostic evidence of fatty liver disease (e.g., non-alcoholic steatohepatitis)
    - Patients with diabetes being treated with antihyperglycemic medications
    - Woman of childbearing age who is planning a pregnancy within the next 12 months

Clinical Notes:

1. Treatment-experienced is defined as a patient who has been previously treated with PegIFN/RBV regimens and who has **not** experienced an adequate response.
2. Acceptable methods for the measurement of fibrosis score include Fibrotest, liver biopsy, transient elastography (FibroScan®), serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.
3. Extra-hepatic manifestations include but are not limited to: symptomatic vasculitis associated with HCV-related mixed cryoglobulinaemia, HCV immune complex-related nephropathy and non-Hodgkin B cell lymphoma, porphyria cutanea tarda, lichen planus, and glomerulonephritis.
4. Chronic kidney disease stage 3, 4 or 5 includes patients with glomerular filtration rate (GFR) <60 mL/min/1.73m^2 for ≥ 3 months.
5. Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A) and decompensated cirrhosis as a CTP score of 7 or above (Class B or C).

Claim Notes:

- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the following PINs:
    - 00904231 (30mg Tab)
    - 00904232 (60mg Tab)
- Claims will be limited to a 28-day supply.

Expanded Coverage for Chronic Hepatitis C Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Epclusa (sofosbuvir/velpatasvir)	400mg/100mg Tab	02456370	DNP	E (SF)	GIL

Criteria

- For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C who meet the following criteria:

	Approval Period and Regimen
Genotypes 1, 2, 3, 4, 5, 6 or mixed genotypes • With compensated cirrhosis • With no cirrhosis	12 weeks
Genotypes 1, 2, 3, 4, 5, 6 or mixed genotypes • With decompensated cirrhosis	12 weeks in combination with ribavirin

Patients must also meet all of the following criteria:

- Prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescribers with expertise in the treatment of hepatitis C infection).
- Lab-confirmed hepatitis C genotype 1, 2, 3, 4, 5, 6 or mixed genotypes
- Quantitative hepatitis C virus (HCV) RNA value within the last 6 months
- Fibrosis stage F2 or greater (Metavir scale or equivalent) or Fibrosis stage less than F2 (Metavir scale or equivalent) and at least one of the following:
    - Co-infected with HIV or hepatitis B virus
    - Post-organ transplant (liver and/or non-liver transplant)
    - Extra-hepatic manifestations
    - Chronic kidney disease stage 3, 4 or 5 as defined by the National Kidney Foundation Kidney Disease Outcomes Quality Initiative
    - Co-existent liver disease with diagnostic evidence of fatty liver disease (e.g., non-alcoholic steatohepatitis
    - Patients with diabetes receiving treatment with antihyperglycemic medications
    - Woman of childbearing age who is planning pregnancy within the next 12 months

Clinical Notes:

1. Treatment-experienced is defined as a patient who has been previously treated with PegIFN/RBV regimens, including regimens containing HCV protease inhibitors (for genotype 1), and who has **not** experienced an adequate response.
2. Acceptable methods for the measurement of fibrosis score include Fibrotest, liver biopsy, transient elastography (FibroScan®), serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.

Expanded Coverage for Chronic Hepatitis C Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Epclusa (sofosbuvir/velpatasvir)	400mg/100mg Tab	02456370	DNP	E (SF)	GIL
Criteria	3. Extra-hepatic manifestations include but are not limited to: symptomatic vasculitis associated with HCV-related mixed cryoglobulinaemia, HCV immune complex-related nephropathy and non-Hodgkin B cell lymphoma, porphyria cutanea tarda, lichen planus, and glomerulonephritis. 4. Chronic kidney disease stage 3, 4 or 5 includes patients with glomerular filtration rate (GFR) <60 mL/min/1.73m^2 for ≥ 3 months. 5. Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A) and decompensated cirrhosis as a CTP score of 7 or above (Class B or C). **Claim Notes:** • Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the following PINs: o 00904233 o 00904234 • Claims will be limited to a 28-day supply.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Sunvepra (asunaprevir)	100mg capsules	02452294	DNP	E(SF)	BRI
Criteria	• For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C who meet the following criteria: **Approval Period and Regimen** **Genotype 1b** • With no cirrhosis or with compensated cirrhosis — 24 weeks in combination with daclatasvir Patients must also meet all of the following criteria: • Prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescribers with expertise in the treatment of hepatitis C infection). • Lab-confirmed hepatitis C genotype 1b • Quantitative hepatitis C virus (HCV) RNA value within the last 6 months				

Expanded Coverage for Chronic Hepatitis C Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Sunvepra (asunaprevir)	100mg capsules	02452294	DNP	E(SF)	BRI

Criteria

- Fibrosis stage F2 or greater (Metavir scale or equivalent) or Fibrosis stage less than F2 (Metavir scale or equivalent) and at least one of the following:
  - Co-infected with HIV or hepatitis B virus
  - Post-organ transplant (liver and/or non-liver transplant)
  - Extra-hepatic manifestations
  - Chronic kidney disease stage 3, 4 or 5 as defined by the National Kidney Foundation Kidney Disease Outcomes Quality Initiative
  - Co-existent liver disease with diagnostic evidence of fatty liver disease (e.g., non-alcoholic steatohepatitis)
  - Patients with diabetes being treated with antihyperglycemic medications
  - Woman of childbearing age who is planning a pregnancy within the next 12 months

Clinical Notes:

1. Treatment-experienced is defined as a patient who has been previously treated with PegIFN/RBV regimens and who has **not** experienced an adequate response.
2. Acceptable methods for the measurement of fibrosis score include Fibrotest, liver biopsy, transient elastography (FibroScan®), serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.
3. Extra-hepatic manifestations include but are not limited to: symptomatic vasculitis associated with HCV-related mixed cryoglobulinaemia, HCV immune complex-related nephropathy and non-Hodgkin B cell lymphoma, porphyria cutanea tarda, lichen planus, and glomerulonephritis.
4. Chronic kidney disease stage 3, 4 or 5 includes patients with glomerular filtration rate (GFR) <60 mL/min/1.73m^2 for ≥ 3 months.
5. Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A).

Claim Notes:

- Claims will be limited to a 28-day supply.

Expanded Coverage for Chronic Hepatitis C Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Zepatier (elbasvir/grazoprevir)	50mg/100mg tablets	02451131	DNP	E(SF)	FRS

Criteria	For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C with no cirrhosis or with compensated cirrhosis who meet the following criteria:	
		Approval Period and Regimen
	Genotype 1 • Treatment-naïve • Treatment-experienced prior relapsers	12 weeks *(8 weeks may be considered in treatment-naïve genotype 1b patients without significant fibrosis or cirrhosis)*
	Genotype 1b • Treatment-experienced on-treatment virologic failures	12 weeks
	Genotype 1a • Treatment-experienced on-treatment virologic failures	16 weeks in combination with ribavirin
	Genotype 4 • Treatment-naïve • Treatment-experienced prior relapsers	12 weeks
	Genotype 4 • Treatment-experienced on-treatment virologic failures	16 weeks in combination with ribavirin

	Patients must also meet all of the following criteria:
	• Prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescribers with expertise in the treatment of hepatitis C infection).
	• Lab-confirmed hepatitis C genotype 1 or 4.
	• Quantitative hepatitis C virus (HCV) RNA value within the last 6 months.
	• Fibrosis stage F2 or greater (Metavir scale or equivalent) or Fibrosis stage less than F2 (Metavir scale or equivalent) and at least one of the following:
	  ○ Co-infected with HIV or hepatitis B virus
	  ○ Post-organ transplant (liver and/or non-liver transplant)
	  ○ Extra-hepatic manifestations
	  ○ Chronic kidney disease stage 3, 4 or 5 as defined by the National Kidney Foundation Kidney Disease Outcomes Quality Initiative	

Expanded Coverage for Chronic Hepatitis C Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Zepatier (elbasvir/grazoprevir)	50mg/100mg tablets	02451131	DNP	E(SF)	FRS

Criteria

- Co-existent liver disease with diagnostic evidence of fatty liver disease (e.g., non-alcoholic steatohepatitis)
- Patients with diabetes being treated with antihyperglycemic medications.
- Woman of childbearing age who is planning a pregnancy within the next 12 months

Clinical Notes:

1. Treatment-experienced is defined as a patient who has been previously treated with PegIFN/RBV regimens, including regimens containing HCV protease inhibitors (for genotype 1), and who has **not** experienced an adequate response.
2. "Treatment-experienced prior relapser" is defined as a patient who has undetectable HCV RNA at the end of previous PegIFN/RBV therapy, including regimens containing NS3/4A protease inhibitors (for genotype 1), but with a subsequent detectable HCV RNA during follow-up.
3. "Treatment-experienced on-treatment virologic failure" is defined as a patient who has been previously treated with PegIFN/RBV regimens, including regimens containing HCV protease inhibitors (for genotype 1), and who has **not** experienced adequate response, including a null response, partial response or virologic breakthrough or rebound.
4. Acceptable methods for the measurement of fibrosis score include Fibrotest, liver biopsy, transient elastography (FibroScan®), serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.
5. Extra-hepatic manifestations include but are not limited to: symptomatic vasculitis associated with HCV-related mixed cryoglobulinaemia, HCV immune complex-related nephropathy and non-Hodgkin B cell lymphoma, porphyria cutanea tarda, lichen planus, and glomerulonephritis.
6. Chronic kidney disease stage 3, 4 or 5 includes patients with glomerular filtration rate (GFR) <60 mL/min/1.73m^2 for ≥ 3 months.
7. Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A).

Claim Notes:

- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the following PINs:
  - 00904237
  - 00904238
- Claims will be limited to a 28-day supply.

Expanded Coverage for Chronic Hepatitis C Continued…

Updates to Existing Criteria

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Harvoni (ledipasvir/sofosbuvir)	90mg/400mg tablet	02432226	DNP	E(SF)	GIL

Criteria

- For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C who meet the following criteria:

	Approval Period and Regimen
Genotype 1 • Treatment-naïve with no cirrhosis, pre-treatment hepatitis C virus (HCV) RNA level < 6 million IU/mL, and mono-HCV infected only	8 weeks or 12 weeks*
Genotype 1 • Treatment-naïve with no cirrhosis, pre-treatment HCV RNA level ≥ 6 million IU/mL • Treatment-naïve with compensated cirrhosis • Treatment-experienced with no cirrhosis • HCV/HIV-1 co-infected patients, no cirrhosis or with compensated cirrhosis	12 weeks
Genotype 1 • Treatment-experienced with compensated cirrhosis	24 weeks
Genotype 1 • Decompensated cirrhosis • Liver transplant recipients with no cirrhosis or with compensated cirrhosis	12 weeks in combination with ribavirin

*For this population cohort, evidence has shown that the SVR rates with 8-week and 12-week treatment regimens are similar. Treatment regimens of up to 12 weeks are recognized by Health Canada as an approved treatment option. Requests may be considered for 12-week coverage for patients with advanced liver fibrosis.

Patients must also meet all of the following criteria:

- Prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescribers with expertise in the treatment of hepatitis C infection).
- Lab-confirmed hepatitis C genotype 1
- Quantitative HCV RNA value within the last 6 months

Expanded Coverage for Chronic Hepatitis C Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Harvoni (ledipasvir/sofosbuvir)	90mg/400mg tablet	02432226	DNP	E(SF)	GIL

Criteria

- Fibrosis stage F2 or greater (Metavir scale or equivalent) or Fibrosis stage less than F2 (Metavir scale or equivalent) and at least one of the following:
  - Co-infected with HIV or hepatitis B virus
  - Post-organ transplant (liver and/or non-liver transplant)
  - Extra-hepatic manifestations
  - Chronic kidney disease stage 3, 4 or 5 as defined by the National Kidney Foundation Kidney Disease Outcomes Quality Initiative
  - Co-existent liver disease with diagnostic evidence of fatty liver disease (e.g., non-alcoholic steatohepatitis)
  - Patients with diabetes being treated with antihyperglycemic medications
  - Woman of childbearing age who is planning a pregnancy within the next 12 months

Clinical Notes:

1. Treatment-experienced is defined as a patient who has been previously treated with PegIFN/RBV regimens, including regimens containing HCV protease inhibitors, and who has **not** experienced an adequate response.
2. Acceptable methods for the measurement of fibrosis score include Fibrotest, liver biopsy, transient elastography (FibroScan®), serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.
3. Extra-hepatic manifestations include but are not limited to: symptomatic vasculitis associated with HCV-related mixed cryoglobulinaemia, HCV immune complex-related nephropathy and non-Hodgkin B cell lymphoma, porphyria cutanea tarda, lichen planus, and glomerulonephritis.
4. Chronic kidney disease stage 3, 4 or 5 includes patients with glomerular filtration rate (GFR) <60 mL/min/1.73m^2 for ≥ 3 months.
5. Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A) and decompensated cirrhosis as a CTP score of 7 or above (Class B or C).

Claim Notes:

- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the following PINs:
  - 00904032
  - 00904033
- Claims will be limited to a 28-day supply.

Expanded Coverage for Chronic Hepatitis C Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Sovaldi (sofosbuvir)	400mg tablet	02418355	DNP	E(SF)	GIL

Criteria

- For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C who meet the following criteria:

	Approval Period and Regimen
Genotype 2 • With no cirrhosis or with compensated cirrhosis	12 weeks in combination with ribavirin (RBV)
Genotype 3 • With no cirrhosis or with compensated cirrhosis	24 weeks in combination with RBV
Genotype 3 • With no cirrhosis	12 weeks in combination with daclatasvir
Genotype 3 • With compensated cirrhosis or decompensated cirrhosis • Post-liver transplant with no cirrhosis or with compensated cirrhosis	12 weeks in combination with daclatasvir and ribavirin

Patients must also meet all of the following criteria:

- Prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescribers with expertise in the treatment of hepatitis C infection).
- Lab-confirmed hepatitis C genotype 2 or 3.
- Quantitative hepatitis C virus (HCV) RNA value within the last 6 months.
- Fibrosis stage F2 or greater (Metavir scale or equivalent) or Fibrosis stage less than F2 (Metavir scale or equivalent) and at least one of the following:
    - Co-infected with HIV or hepatitis B virus
    - Post-organ transplant (liver and/or non-liver transplant)
    - Extra-hepatic manifestations
    - Chronic kidney disease stage 3, 4 or 5 as defined by the National Kidney Foundation Kidney Disease Outcomes Quality Initiative
    - Co-existent liver disease with diagnostic evidence of fatty liver disease (e.g., non-alcoholic steatohepatitis)
    - Patients with diabetes being treated with antihyperglycemic medications.
    - Woman of childbearing age who is planning a pregnancy within the next 12 months.

Expanded Coverage for Chronic Hepatitis C Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Sovaldi (sofosbuvir)	400mg tablet	02418355	DNP	E(SF)	GIL
Criteria	**Clinical Notes:** 1. Treatment-experienced is defined as a patient who has been previously treated with PegIFN/RBV regimens and who has **not** experienced an adequate response. 2. Acceptable methods for the measurement of fibrosis score include Fibrotest, liver biopsy, transient elastography (FibroScan®), serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination. 3. Extra-hepatic manifestations include but are not limited to: symptomatic vasculitis associated with HCV-related mixed cryoglobulinaemia, HCV immune complex-related nephropathy and non-Hodgkin B cell lymphoma, porphyria cutanea tarda, lichen planus, and glomerulonephritis. 4. Chronic kidney disease stage 3, 4 or 5 includes patients with glomerular filtration rate (GFR) <60 mL/min/1.73m^2 for ≥ 3 months. 5. Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A) and decompensated cirrhosis as a CTP score of 7 or above (Class B or C). **Claim Notes:** • Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the following PINs: o 00904041 o 00904042 • Claims will be limited to a 28-day supply.				

New Exception Status Benefits

The following products were reviewed by the Canadian Drug Expert Committee (CDEC) and will be listed with the following criteria effective **May 1, 2017.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Fibristal (ulipristal acetate)	5mg Tab	02408163	DNP	E (F)	ALL
Criteria	For the treatment of moderate to severe signs and symptoms of uterine fibroids in adult women of reproductive age, who are eligible for surgery, under the following conditions: • the duration of treatment will not exceed three months, per patient, per lifetime; and • the patient is under the care of a physician experienced in the management of gynecological conditions such as uterine fibroids				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Entyvio (vedolizumab)	300mg Vials	02436841	DNP	E (SF)	TAK

Criteria

Crohn's Disease

For patients with moderate to severely active Crohn's disease and are:

- refractory or have contraindications to an adequate course of 5-aminosalicylic acid and corticosteroids and other immunosuppressive therapy.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- initial reimbursement is restricted to induction doses of 300mg at Weeks 0, 2 and 6.
- clinical response to be assessed prior to the administration of the fourth dose.

Ulcerative Colitis

For the treatment of adult patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:

- refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
- corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)

Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:

- a decrease in the partial Mayo score ≥ 2 from baseline, and
- a decrease in the rectal bleeding subscore ≥1.

Clinical Notes:

- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.
- Patients with severe disease do not require a trial of 5-ASA

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial Approval: 16 weeks.
- Renewal Approval: 1 year.

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Dificid (fidaxomicin)	200mg Tab	02387174	DNP	E (SFC)	FRS
Criteria	For the treatment of Clostridium Difficile Infection (CDI) where the patient: • has experienced a third or subsequent episode within 6 months of treatment with vancomyin for prior episode(s), with no previous trial of fidaxomicin; OR • has experienced treatment failure* with oral vancomycin for the current CDI episode; OR • has had a documented allergy (immune-mediated reaction) to oral vancomycin; OR • has experienced a severe adverse reaction or intolerance** to oral vancomycin treatment that resulted in the discontinuation of vancomycin therapy. **Re-treatment criteria:** • Re-treatment with fidaxomicin will only be considered for an early relapse occurring within 30 days of the completion of the most recent fidaxomicin course. • Relapse/recurrence occurring beyond 30 days after the completion of the most recent fidaxomicin course will require a trial with vancomycin, unless there is a documented allergy, severe adverse reaction or intolerance to prior oral vancomycin use. **Clinical Notes:** • *Treatment failure is defined as 7 days of vancomycin therapy without acceptable clinical improvement. • **Details of severe adverse reaction or intolerance must be provided and should be clinically related to oral administration of vancomycin. **Claim Note:** • Requests will be approved for 200mg twice a day for 10 days.				

The following products were reviewed by the pCODR Expert Review Committee (pERC) and will be listed with the following criteria effective **May 1, 2017.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Zydelig (idelalisib)	100mg Tab 150mg Tab	02438798 02438801	DNP	E (SFC)	GIL
Criteria	• In combination with rituximab for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL). Treatment should continue until unacceptable toxicity or disease progression				

Criteria Update

The following criteria updates will be effective **May 1, 2017.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Buprenorphine/ naloxone (Brand and Generics)	2mg/0.5mg SL Tab 8mg/2mg SL Tab	Various Various	DN DN	E (SF) E (SF)	VAR VAR
Criteria	• For the treatment of opioid use disorder.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Sabril (vigabatrin)	0.5g Sachet 500mg Tablet	02068036 02065819	DNP DNP	E (SF) E (SF)	LBK LBK
Criteria	• For the treatment of epilepsy in those patients who respond inadequately to alternative treatment combinations, or in whom other drug combinations have not been tolerated, and in whom the potential benefits conferred by its use outweigh the risk of ophthalmologic abnormalities. • For the management of infantile spasms.				

Change in Benefit Status

Effective **April 15, 2017,** the following products were moved to full benefit status and will no longer require special authorization.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Jamp-Vancomycin	125mg Cap	02407744	DNPM	SFC	JPC
Vancomycin HCl	125mg Cap	02377470	DNPM	SFC	FKB
Vancocin	125mg Cap	00800430	DNPM	SFC	MRS

Effective **April 15, 2017,** the following products were moved to non-benefit status and will no longer be covered under the Nova Scotia Pharmacare Programs.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Jamp-Vancomycin	250mg Cap	02407752	**Not Insured**	JPC
Vancomycin HCl	250mg Cap	02377489	**Not Insured**	FKB
Vancocin	250mg Cap	00788716	**Not Insured**	MRS

New Products

The following products are new strengths added to the Nova Scotia Formulary, effective **April 15, 2017**. The benefit status within the Nova Scotia Pharmacare Programs is indicated and any existing criteria will apply.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Afinitor	7.5 mg Tab	02450267	DNP	E	NVR
Apo-Brimonidine P	0.15% Oph Sol	02301334	DNP	SF	AAP
Alphagan P	0.15% Oph Sol	02248151	DNP	SF	ALL
Backup Plan Onestep	1.5mg Tab	02433532	DNP	F	APX
Contingency One	1.5mg Tab	02425009	DNP	F	MYL
Plan B	1.5mg Tab	02293854	DNP	F	PAL

New Ostomy Products

Effective **April 15, 2017**, a number of Coloplast ostomy products were added as full benefits under the Nova Scotia Pharmacare Programs. The specific products and associated billing PINs (as per the OPINIONS website) can be found in the next update of the Nova Scotia Formulary, which will be available on the Nova Scotia Pharmacare website.

New Diabetic Products

The following products are new listings to the Nova Scotia Formulary, effective **April 15, 2017**. The benefit status and reimbursement price within the Nova Scotia Pharmacare Programs is indicated.

PRODUCT	DIN/PIN	PRESCRIBER	BENEFIT STATUS	MFR
Accu-Chek Guide Test strips (50)	97799178	DNP	SFD	BOM
Accu-Chek Guide Test strips (100)	97799177	DNP	SFD	BOM

Minor Ailments Demonstration Project

As a pilot project, minor ailments assessment services have been eligible for coverage since May 4, 2015 as outlined in a Pharmacare News Bulletin (April 2015, Vol. 15-03).

This project has now come to a close and claims related to this service will no longer adjudicate effective April 15, 2017.

Thank you to all pharmacists who have participated. If you have questions regarding the project, please contact the Pharmacy Association of Nova Scotia at 1-902-422-9583. If you have questions regarding the payment of past claims, please contact the Pharmacare Office at 1-800-305-5026.

Auditor's Corner

Please refer to the Nova Scotia Pharmacare Programs website for an updated version of the Pharmacare Audit Guide.

Claims submitted after April 3, 2017 will be subject to these guidelines.