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PHARMACISTS' EDITION

NOVA SCOTIA

PharmacareNEWS

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Nova Scotia Formulary Updates

Reminder: Palliative Care Drug Program

Please be reminded that claims for the Palliative Care Drug Program are to be submitted **online only**, as per other programs, using the patient identification number and a carrier ID of NS. Further information is available in the Pharmacists' Guide.

New Exception Status Benefits

The following product will be listed with the following criteria, effective **February 1, 2017**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Valcyte (valganciclovir)	50mg/mL pws	02306085	DNP	E (SF)	HLR
Criteria	• For the treatment of cytomegalovirus (CMV) retinitis in HIV-positive patients, upon the request of an infectious disease specialist or prescriber with a specialty in infectious disease • for the prevention of CMV disease post solid organ transplantation in patients at high-risk (D+ / R-) (i.e., donor positive/recipient negative). Coverage will be for a maximum of 90 days • for the treatment of patients with CMV infection who have received a solid organ transplant. Note: • Requests for oral suspension will be considered for patients when oral tablets are not an option.				

Criteria Updates

The following criteria updates will be effective February 1, 2017.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Methylphenidate ER (Biphentin, Concerta and generics)	Various	Various	DN	E (SF)	VAR
Criteria	• for patients diagnosed with attention deficit hyperactivity disorder (ADHD) who require 12-hour continuous coverage due to academic and/or psychosocial needs, and who meet the following: o patients who demonstrate significant and problematic disruptive behaviour or who have problems with inattention that interfere with learning AND o have been tried on immediate release or slow release methylphenidate with unsatisfactory results Note: • Requests will be considered from prescribers with expertise in ADHD				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Vyvanse (lisdexamfetamine)	10mg Cap	02439603	DNP	E (SF)	SHI
	20mg Cap	02347156	DNP	E (SF)	SHI
	30mg Cap	02322951	DNP	E (SF)	SHI
	40mg Cap	02347164	DNP	E (SF)	SHI
	50mg Cap	02322978	DNP	E (SF)	SHI
	60mg Cap	02347172	DNP	E (SF)	SHI
Criteria	• for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients who: o demonstrate significant and problematic disruptive behaviour or who have problems with inattention that interfere with learning; and o have been tried on methylphenidate (immediate release or long-acting formulation) or dexamphetamine with unsatisfactory results. Notes: • Requests will be considered from prescribers with expertise in ADHD • The maximum dose reimbursed is 60mg daily.				

Criteria Updates Continued…

The following product was reviewed by the Canadian Drug Expert Committee (CDEC) and will be listed with the following additional criteria effective February 1, 2017.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Simponi (golimumab)	50mg/0.5mL Prefilled Syr	02324776	DNP	E (SF)	JAN
	50mg/0.5mL Autoinjector	02324784	DNP	E (SF)	JAN
	100mg/1.0mL Prefilled Syr	02413175	DNP	E (SF)	JAN
	100mg/1.0mL Autoinjector	02413183	DNP	E (SF)	JAN

Criteria

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.

Criteria Updates Continued…

The following product was reviewed by the Atlantic Common Drug Review (ACDR) and will be listed with the following additional criteria effective February 1, 2017.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Carnitor (levocarnitine)	100mg/mL O/L 330mg Tab	02144336 02144328	DNP DNP	E (SF) E (SF)	QGT QGT
Criteria	• For the treatment of patients with primary systemic carnitine deficiency. • For the treatment of patients with an inborn error of metabolism that results in secondary carnitine deficiency.				

New Products

The following products are new listings to the Nova Scotia Formulary, effective February 1, 2017. The benefit status within the Nova Scotia Pharmacare Programs is indicated.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Claforan	2g/Vial Inj	02225107	DNP	SFC	SAV
Cefotaxime Sodium	2g/Vial Inj	02434105	DNP	SFC	STR
Dermaflex HC	1% Cr	00681989	DNP	SF	PAL
Dermaflex HC	1% Lot	00681997	DNP	SF	PAL
Pediapharm Naproxen	25mg/mL Susp	02162431	DNPM	SFC	PED
Valacyclovir	1000mg Tab	Various	DNPM	SFC	VAR

Change of Benefit Status

Effective February 1, 2017, the following products will move to full benefit status and will no longer require special authorization.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Apo-Cyclosporine	100mg/mL O/L	02244324	DNP	SF	APX
Climara 25	25mcg/day, 2mg/patch	02247499	DNP	SFC	BAY
Climara 50	50mcg/day, 3.9mg/patch	02231509	DNP	SFC	BAY
Climara 75	75mcg/day, 5.7mg/patch	02247500	DNP	SFC	BAY
Climara 100	100mcg/day, 7.8mg/patch	02231510	DNP	SFC	BAY
CO Etidronate	200mg Tab	02248686	DNP	SFC	ATV
CO Etidrocal Kit		02263866	DNP	SFC	ATV
Estradot Patch	25mg/day	02245676	DNP	SFC	NVR
Estradot Patch	37.5mcg/day	02243999	DNP	SFC	NVR

Change of Benefit Status Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Estradot Patch	50mcg/day	02244000	DNP	SFC	NVR
Estradot Patch	75mcg/day	02244001	DNP	SFC	NVR
Estradot Patch	100mcg/day	02244002	DNP	SFC	NVR
Estalis Transdermal Patch	140/50mcg	02241835	DNP	SFC	NVR
Estalis Transdermal Patch	250/50mcg	02241837	DNP	SFC	NVR
Levetiracetam	Various	Various	DNP	SF	VAR
Neoral	10mg Cap	02237671	DNP	SF	NVR
Neoral	25mg Cap	02150689	DNP	SF	NVR
Neoral	50mg Cap	02150662	DNP	SF	NVR
Neoral	100mg Cap	02150670	DNP	SF	NVR
Neoral	100mg/mL O/L	02150697	DNP	SF	NVR
Sandoz Cyclosporine	25mg Cap	02247073	DNP	SF	SDZ
Sandoz Cyclosporine	50mg Cap	02247074	DNP	SF	SDZ
Sandoz Cyclosporine	100mg Cap	02242821	DNP	SF	SDZ
Sandoz Estradiol Derm 50	50mcg/patch	02246967	DNP	SFC	SDZ
Sandoz Estradiol Derm 75	75mcg/patch	02246968	DNP	SFC	SDZ
Sandoz Estradiol Derm 100	100mcg/patch	02246969	DNP	SFC	SDZ

Effective February 1, 2017, the following products will move to non-benefit status and will no longer be covered under the Nova Scotia Pharmacare Programs.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Bacitracin	50.000iu Pdr/Vial	00030708	Not Insured	PFI
Chloromycetin Succinate	1g/vial Inj	00312363	Not Insured	ERF
Dinoprostone (Prostin E2)	0.5mg Tab	00400688	Not Insured	PAL
pms-Dexamethasone	0.75mg Tab	01964968	Not Insured	PMS

Notification of Quinine Delisting

Although quinine sulfate has been marketed in Canada since 1951, there have been ongoing safety concerns with its use. Despite only being approved by Health Canada for the treatment of malaria, quinine has been widely used "off label" to treat and prevent nocturnal leg cramps. The efficacy of quinine for leg cramps; however, is limited and is outweighed by the risk of serious adverse reactions that may require hospital admission or be life-threatening. These adverse reactions are unpredictable and may occur at any time, even in an individual who has been taking quinine sulfate on a chronic basis without problems.

For a summary of adverse reaction reports associated with the use of quinine, please see: http://www.hc-sc.gc.ca/dhp-mps/medeff/bulletin/carn-bcei_v21n2-eng.php

Given these concerns, quinine will no longer be listed as a benefit on the Nova Scotia Pharmacare Programs Formulary effective February 1, 2017. Please note that patients who have had a quinine prescription covered in the last 6 months prior to the delisting date will continue to have it covered. It is strongly recommended; however, that prescribers and pharmacists discuss these safety warnings with their patients and review other ways to manage nocturnal leg cramps.

Medical Assistance in Dying: Adjudication of Claims

In June of 2016 amendments to the Criminal Code of Canada enabled access to medical assistance in dying (MAiD) in Canada. The Nova Scotia Department of Health and Wellness will provide coverage for Nova Scotia residents for medications related to the provision of MAiD.

When aware of a prescription for MAiD to be administered in an outpatient setting, community pharmacies are encouraged to contact the Pharmacare office to ensure coverage is in place and the claims are submitted correctly. The Pharmacare office can be reached by phone at 496-7001 or 1-800-305-5026, please choose Option 4 and have the following information ready to provide:

- patient's Nova Scotia Health Card Number
- patient's date of birth
- provider number
- prescriber
- medications (DINs) and supplies to be dispensed
- dispense date

Pharmacies are eligible to receive usual dispensing fees and mark-up for each drug in each kit as per the Pharmacare Tariff Agreement as well as a dispensing fee for the supplies.

Pharmacies can be compensated for excess and unusable drug that cannot be returned to the wholesaler/ manufacturer and kits that are ultimately not dispensed. Pharmacies can contact the Pharmacare office for a Request for Credit Form which must be submitted within six months of the prescription date.

Pharmacare Programs Renewal

The annual renewal for the Pharmacare Programs is underway.

Renewal packages for Family Pharmacare will be in the mail the third week of February; packages for Seniors' Pharmacare will be in the mail the first week of March. Please note there are no changes to the fees for these programs for the 2017-2018 year.

Please contact 1-800-305-5026 with questions.

Changes to Maximum Reimbursable Prices

Provinces and territories continue to work together to lower generic drug prices through the pan-Canadian Pharmaceutical Alliance.

Effective April 1, 2017, the Maximum Reimbursable Prices (MRPs) of six drugs will be set at 15% of brand price: Amlodipine, Atorvastatin, Clopidogrel, Pantoprazole Sodium, Ramipril and Simvastatin.

DRUG PRODUCT	PRICE
Amlodipine Besylate 2.5mg	0.1150
Amlodipine Besylate 5mg	0.2014
Amlodipine Besylate 10mg	0.2990
Atorvastatin Calcium 10mg	0.2615
Atorvastatin Calcium 20mg	0.3268
Atorvastatin Calcium 40mg	0.3513
Atorvastatin Calcium 80mg	0.3513
Clopidogrel Bisulfate 75mg	0.3946
Pantoprazole Sodium 20mg	0.2705
Pantoprazole Sodium 40mg	0.3024
Ramipril 1.25mg	0.1062
Ramipril 2.5mg	0.1225
Ramipril 5mg	0.1225
Ramipril 10mg	0.1551
Simvastatin 5mg	0.1534
Simvastatin 10mg	0.3035
Simvastatin 20mg	0.3751
Simvastatin 40mg	0.3751
Simvastatin 80mg	0.3751

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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.

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Nova Scotia Formulary Updates

New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Forxiga	5mg Tab	02435462	DNP	E (SF)	AZE
(dapagliflozin)	10mg Tab	02435470	DNP	E (SF)	AZE
Criteria	• For the treatment of Type II diabetes when: ○ Added on to metformin for patients: ▪ Who have inadequate glycemic control on metformin and ▪ Who have a contraindication or intolerance to a sulfonylurea and ▪ For whom insulin is not an option ○ Added on to a sulfonylurea for patients: ▪ Who have inadequate glycemic control on a sulfonylurea and ▪ Who have a contraindication or intolerance to metformin and ▪ For whom insulin is not an option				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Xigduo (dapagliflozin and metformin hydrochloride)	5mg/850mg Tab 5mg/1000mg Tab	02449935 02449943	DNP DNP	E (SF) E (SF)	AZE AZE

Criteria	• For the treatment of Type II diabetes for patients:
	  ○ Who are already stabilized on therapy with dapagliflozin and metformin to replace the individual components of dapagliflozin and metformin; and
	  ○ For whom insulin is not an option
	Claim Note:
	• Must have met criteria for dapagliflozin				

Criteria Updates: Antipsychotic Medications

The following criteria updates were effective **August 1, 2017.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Abilify (aripiprazole)	2mg Tab	02322374	DNP	E (SF)	BRI
	5mg Tab	02322382	DNP	E (SF)	BRI
	10mg Tab	02322390	DNP	E (SF)	BRI
	15mg Tab	02322404	DNP	E (SF)	BRI
	20mg Tab	02322412	DNP	E (SF)	BRI
	30mg Tab	02322455	DNP	E (SF)	BRI
Latuda (lurasidone)	20mg Tab	02422050	DNP	E (SF)	SNV
	40mg Tab	02387751	DNP	E (SF)	SNV
	60mg Tab	02413361	DNP	E (SF)	SNV
	80mg Tab	02387778	DNP	E (SF)	SNV
	120mg Tab	02387786	DNP	E (SF)	SNV
Zeldox (ziprasidone)	20mg Cap	02298597	DNP	E (SF)	PFI
	40mg Cap	02298600	DNP	E (SF)	PFI
	60mg Cap	02298619	DNP	E (SF)	PFI
	80mg Cap	02298627	DNP	E (SF)	PFI
Criteria	• For the treatment of schizophrenia and related psychotic disorders (not dementia related) in patients with a history of failure, intolerance, or contraindication to at least one less expensive antipsychotic agent				

Criteria Updates: Antipsychotic Medications Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Abilify Maintena	300mg Vial Inj	02420864	DNP	E (SF)	OTS
(aripiprazole)	400mg Vial Inj	02420872	DNP	E (SF)	OTS
Invega Sustenna	50mg/0.5mL Inj	02354217	DNP	E (SF)	JAN
(Paliperidone)	75mg/0.75mL Inj	02354225	DNP	E (SF)	JAN
	100mg/mL Inj	02354233	DNP	E (SF)	JAN
	150mg/1.5mL Inj	02354241	DNP	E (SF)	JAN
Risperdal Consta	12.5mg/2mL Inj	02298465	DNP	E (SF)	JAN
(Risperidone)	25mg/2mL Inj	02255707	DNP	E (SF)	JAN
	37.5mg/2mL Inj	02255723	DNP	E (SF)	JAN
	50mg/2mL Inj	02255758	DNP	E (SF)	JAN
Criteria	• For the maintenance treatment of schizophrenia and related psychotic disorders (not dementia related) in patients who are not adherent to an oral antipsychotic OR • Who are currently receiving a long-acting injectable antipsychotic and require an alternative long acting injectable antipsychotic				

Changes in Benefit Status

Effective **August 1, 2017,** the following products have moved to full benefit status.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
amphetamine XR (Adderall XR)	5mg Cap	Various	DNP	SFC	VAR
amphetamine XR (Adderall XR)	10mg Cap	Various	DNP	SFC	VAR
amphetamine XR (Adderall XR)	15mg Cap	Various	DNP	SFC	VAR
amphetamine XR (Adderall XR)	20mg Cap	Various	DNP	SFC	VAR
amphetamine XR (Adderall XR)	25mg Cap	Various	DNP	SFC	VAR
amphetamine XR (Adderall XR)	30mg Cap	Various	DNP	SFC	VAR
Clopixol	10mg Tab	02230402	DNP	SF	VLH
Clopixol	25mg Tab	02230403	DNP	SF	VLH
Intron A (albumin free)	6,000,000iu/mL Inj	02238674	DNP	SFC	FRS
Intron A (albumin free)	10,000,000iu/mL Inj	02238675	DNP	SFC	FRS
Intron A	10,000,000iu/vial Inj	02223406	DNP	SFC	FRS

Changes in Benefit Status Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Intron A	15,000,000iu Multidose Pen	02240693	DNP	SFC	FRS
Intron A	25,000,000iu Multidose Pen	02240694	DNP	SFC	FRS
Intron A	50,000,000iu Multidose Pen	02240695	DNP	SFC	FRS
Pegasys	180mcg/0.5mL Syr Inj	02248077	DNP	SF	HLR
Pegasys Proclick Autoinjector	180mcg/0.5mL Syr Inj	02248077	DNP	SF	HLR
Valganciclovir (Valcyte)	450mg Tab	Various	DNP	SF	VAR

Effective **August 1, 2017,** the following products have moved to exception status and will require special authorization. Existing criteria will apply.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Cetirizine (Reactine)	20mg Tab	Various	DNP	E (SF)	VAR

Effective **August 1, 2017,** the following products have moved to non-benefit status and will no longer be covered under the Nova Scotia Pharmacare Programs.

PRODUCT	STRENGTH	DIN	BENEFIT STATUS	MFR
Alcaine	0.5% Drops	00035076	**Not Insured**	ALC
Proglycem	100mg Cap	00503347	**Not Insured**	FRS
Reactine	5mg Tab	02223546	**Not Insured**	JNJ

New Products

The following new products have been added to the Nova Scotia Formulary, effective **August 1, 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
Asmanex Twisthaler	100mcg/metered Inh	02438690	DNP	F*	FRS
Creon Minimicrospheres MICRO	5000 units/5100 units/320 units	02445158	DNP	SF	BGP
Dovobet	50mcg/g/0.5mg/g Gel (with Applicator)	02319012	DNP	E (SF)	LEO
Jamp Citalopram	10mg Tab	02370085	DNP	SFC	JPC
Mint-Citalopram	10mg Tab	02429691	DNP	SFC	MNT
Zytiga	500mg Film-coated Tab	02457113	DNP	E (SFC)	JAN

* full benefit for children ages 4-11

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Nova Scotia Formulary Updates

Mifegymiso

Effective **November 1, 2017** coverage is available for Mifegymiso for women in Nova Scotia with a valid health card number. Any other sources of insurance, such as a private plan, must be billed first. The method for claims submission is outlined below, should you have any questions please contact the Pharmacare Office.

CPhA Claim Standard Field	CPhA Claim Standard Field Name	Content
D56.03	DIN/GP#/PIN	02444038
D.58.03	Quantity	000001 (one)
D.61.03	Prescriber ID	Prescriber ID
D.66.03	Drug Cost/Product Value	DDDDD (MLP dollar value)
D 67.03	Cost Upcharge	DDDDD (usual Pharmacare upcharge)
D.68.03	Professional Fee	DDDDD (usual Pharmacare dispensing fee)

New Exception Status Benefits

The following product has been listed with the following criteria, effective **immediately.**

Product	Strength	DIN	Prescriber	Benefit Status	MFR
Prozac (fluoxetine)	20mg/5mL Syr	Various	DNP	E (SFC)	VAR
Criteria	• For use in patients for whom oral capsules are not an option				

New Exception Status Benefits Continued…

The following products were reviewed by the Canadian Drug Expert Committee (CDEC) and were listed with the following criteria effective **immediately.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Brenzys	50 mg/mL Prefilled Pen	02455331	DNP	E (SF)	FRS
(etanercept)	50 mg/mL Prefilled Syringe	02455323	DNP	E (SF)	FRS

Criteria

For etanercept-naïve patients whose etanercept therapy is initiated after November 1, 2017, the biosimilar will be the product that is approved for the following indications.

Ankylosing Spondylitis

- For the treatment of patients with moderate to severe ankylosing spondylitis (Bath AS Disease Activity Index (BASDAI) score ≥4 on 10 point scale) who:
    - have axial symptoms and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation, or in whom NSAIDs are contraindicated; OR
    - have peripheral symptoms and who have failed to respond to, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD

Notes:

- Must be prescribed by a rheumatologist or prescriber with a specialty in rheumatology.
- Requests for renewal must include information showing the beneficial effects of the treatment, specifically:
    - a decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score; OR
    - patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as HAQ or "ability to return to work")
- Initial coverage period 6 months, maximum dose 50mg per week and not in combination with other anti-TNF agents
- Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication of axial disease, do not require a trial of 2 NSAIDs

Rheumatoid Arthritis

- For the treatment of severely active rheumatoid arthritis, in combination with methotrexate or other disease modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:
    - methotrexate (oral or parenteral) at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age), or
    - use in combination with another DMARD, for a minimum of 12 weeks **AND**

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Brenzys	50 mg/mL Prefilled Pen	02455331	DNP	E (SF)	FRS
(etanercept)	50 mg/mL Prefilled Syringe	02455323	DNP	E (SF)	FRS
Criteria	○ methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks **Clinical Notes:** • For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered • Optimal treatment response to DMARDs may take up to 24 weeks, however coverage of a biologic therapy can be considered if no improvement is seen after 12 weeks of triple DMARD use • If patient factors (e.g. intolerance) prevent the use of triple DMARD therapy, these must be described and dual therapy with DMARDs must be tried • 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 **Claim Notes:** • Must be prescribed by a rheumatologist • Combined use of more than one biologic DMARD will not be reimbursed • Initial Approval: 6 months • Renewal Approval: 1 year. Confirmation of continued response is required • Maximum Dosage Approved: 50mg once per week with no dose escalation permitted				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Neupro	2mg/24hr Patch	02403900	DNP	E (SF)	UCB
(rotigotine)	4mg/24hr Patch	02403927	DNP	E (SF)	UCB
	6mg/24hr Patch	02403935	DNP	E (SF)	UCB
	8mg/24hr Patch	02403943	DNP	E (SF)	UCB
Criteria	• For adjunctive therapy to levodopa for the treatment of patients with advanced stage Parkinson's disease (APD)				

Criteria Updates

The following criteria have been updated effective **immediately:**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tarceva	100mg Tab	Various	DNP	E (SFC)	VAR
(erlotinib)	150mg Tab	Various	DNP	E (SFC)	VAR
Criteria	• For the first-line treatment of patients with EGFR mutation positive locally advanced or metastatic NSCLC with a good performance status • For the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen and whose EGFR mutation status is positive or unknown **Renewal Criteria:** • Written confirmation that the patient has responded to treatment and there is no evidence of disease progression **Claim Notes:** • Use of erlotinib precludes the use of any other EGFR inhibitor as a subsequent line of therapy • Approval period: 6 months • In the absence of disease progression and in the event of severe toxicity within the first 12 weeks of therapy, a switch to another approved EGFR inhibitor may be allowed				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Metadol	1mg Tab	02247698	DN	E (SFC)	PAL
(methadone)	5mg Tab	02247699	DN	E (SFC)	PAL
	10mg Tab	02247700	DN	E (SFC)	PAL
	25mg Tab	02247701	DN	E (SFC)	PAL
Criteria	• for the management of severe chronic or malignant pain as an alternative to other opiates • written request of a physician authorized to prescribe methadone **Clinical note:** • In the case of comorbid opioid use disorder (past or current), methadone oral liquid would normally be prescribed as per treatment standards. If methadone tablets are requested in this context, a specialist consult may be required.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Enablex	7.5mg Tab	02273217	DNP	E (SF)	MRS
(darifenacin)	15mg Tab	02273225	DNP	E (SF)	MRS
Toviaz	4mg Tab	02380021	DNP	E (SF)	PFI
(fesoterodine)	8mg Tab	02380048	DNP	E (SF)	PFI
Trosec (trospium)	20mg Tab	02275066	DNP	E (SF)	SNV
Criteria	• For the treatment of overactive bladder (OAB) with symptoms of urgency, urgency incontinence, and urinary frequency in patients who have an intolerance or insufficient response to an adequate trial of immediate-release oxybutynin, solifenacin or tolterodine				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Myrbetriq	25mg ER Tab	02402874	DNP	E (SF)	ASL
(mirabegron)	50mg ER Tab	02402882	DNP	E (SF)	ASL
Criteria	• For the treatment of overactive bladder (OAB) with symptoms of urgency, urgency incontinence, and urinary frequency in patients who have an intolerance or insufficient response to an adequate trial of immediate-release oxybutynin, solifenacin or tolterodine **Note:** • Not to be used in combination with other pharmacological treatments for OAB.				

New Products

Effective **immediately,** the following new products have been added to the Nova Scotia Formulary. The benefit status within the Nova Scotia Pharmacare Programs is indicated and any existing criteria will apply.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
OptiChamber Diamond		96899961	DNP	SFC	AUT
OptiChamber Diamond with Mask (Sm)		96899960	DNP	SFC	AUT
OptiChamber Diamond with Mask (Med)		96899959	DNP	SFC	AUT
OptiChamber Diamond with Mask (Lg)		96899958	DNP	SFC	AUT

New Products

Basaglar (insulin glargine - Eli Lilly) is a biosimilar product based on Lantus (insulin glargine - Sanofi-Aventis) as a reference product.

Clinical trials have demonstrated that Basaglar has similar efficacy, safety, pharmacodynamics and pharmacokinetics compared to the Lantus brand of insulin glargine. Basaglar was non-inferior in terms of mean change in A1C from baseline at week 24. In addition, the trials studied a group of patients who switched from Lantus to Basaglar, in both studies no statistically significant treatment differences were observed for a mean change in A1C from baseline to week 24 or week 52. The complete Canadian Drug Expert Committee (CDEC) recommendation to fund Basaglar can be accessed at https://www.cadth.ca/sites/default/files/cdr/complete/SE0451_complete_Basaglar-Apr_19-16-e.pdf.

Basaglar is available as a full benefit to Pharmacare clients which provides access to a long acting insulin without the need for prior approval of coverage.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Basaglar	100iu/mL Cartridge	02444844	DNP	SF	LIL
Basaglar	100iu/mL Kwikpen	02461528	DNP	SF	LIL
Basaglar	100iu/mL Kwikpen	02444852	DNP	SF	LIL

Change in Benefit Status

Effective **immediately,** the following products have moved to full benefit status.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Dalacin Vag Cr	100mg/dose	02060604	DNP	SFC	PAL
Solifenacin	5mg Tab	Various	DNP	SF	VAR
Solifenacin	10mg Tab	Various	DNP	SF	VAR
Tolterodine	1mg Tab	Various	DNP	SF	VAR
Tolterodine	2mg Tab	Various	DNP	SF	VAR
Tolterodine	2mg ER Cap	Various	DNP	SF	VAR
Tolterodine	4mg ER Cap	Various	DNP	SF	VAR

Non Insured Products

The following products will not be insured in the Pharmacare Programs, however, they will be funded through the Exception Drug Fund as per other interferon products in the treatment of Multiple Sclerosis.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Plegridy Admin Pack	125mcg/0.5mL pre-filled syringe/pen for S/C inj	02444399	N/A	**N/A**	BIG
Plegridy Starter Pack	63mcg/0.5mL and 94mcg/0.5mL pre-filled syringes/pens for S/C inj	02444402	N/A	**N/A**	BIG

Delisted Products

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Flagystatin Vag Cr		01926829	N/A	**Not Insured**	SAV
Flagystatin Vag Ovules		01926845	N/A	**Not Insured**	SAV
Linctus Codeine Blanc	0.2% Liq	00380571	N/A	**Not Insured**	ATL
Sufentanil Citrate	50mcg/mL Inj	Various	N/A	**Not Insured**	VAR

Notification of Delisting of Butalbital-Containing Products

Butalbital-containing capsules will no longer be benefits with the Nova Scotia Pharmacare Programs (i.e., Fiorinal and generics, Fiorinal C1/4 and generics and Fiorinal C1/2 and generics). Butalbital-containing products have a high risk of dependence and abuse, a potential for development of medication overuse headache and the possibility of a withdrawal syndrome and there is a lack of evidence of superiority to standard drugs. Coverage will be continued for Pharmacare beneficiaries who are currently using this therapy. However reassessment of their therapy should be considered.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Fiorinal Cap and generics	330mg/50mg/40mg Cap	Various	N/A	**Not Insured**	VAR
Fiorinal C1/4 and generics	330mg/50mg/40mg/30mg Cap	Various	N/A	**Not Insured**	VAR
Fiorinal C1/2 and generics	330mg/50mg/40mg/15mg Cap	Various	N/A	**Not Insured**	VAR
ratio-Tecnal	50mg Tab	00608211	N/A	**Not Insured**	TEV

Administration of Publicly-Funded Influenza Vaccine by Pharmacists for the 2017-2018 Influenza Season

Who is eligible to have publicly-funded influenza vaccine administered by a pharmacist?

All individuals 5 years of age and over can have publicly-funded influenza vaccine administered by a pharmacist. As publicly-funded influenza vaccine is available free of charge, no individual is to be charged for the vaccine.

Who is eligible to have the influenza vaccine administration fee publicly-funded?

Only residents with a valid Nova Scotia Health Card Number are eligible to have the influenza vaccine administration fee billed to Pharmacare. There are no copayments or deductibles associated with the administration of the influenza vaccine to residents with a valid Nova Scotia Health Card Number. All other individuals are responsible for paying the applicable administration fee.

Administration of Publicly-Funded Influenza Vaccine by Pharmacists for the 2017-2018 Influenza Season Continued…

Which pharmacies are eligible to bill for the administration of publicly-funded influenza vaccine?
Pharmacies set up as providers to bill publicly-funded influenza vaccine administration fees last year are already set up for the 2017-2018 influenza season. However, all pharmacies are still required to contact their local Nova Scotia Health Authority public health office to confirm their email, dispensary telephone number, and their preferred method for being contacted by public health.

Pharmacies that have not yet been set up as a provider to bill publicly-funded influenza vaccine administration must:

1. Comply with the required training and application expectations set out by the *Pharmacist Extended Practice Regulations* and the NSCP's *Standards of Practice: Drug Administration*.
2. Sign the *Confirmation of Agreement Form for Pharmacist Administered Publicly Funded Seasonal Influenza Vaccine* (available in the Pharmacists' Guide) and submit it to Medavie Blue Cross. Medavie Blue Cross will confirm by email or facsimile that the pharmacy has been set up as a provider to bill influenza vaccine administration fees.
3. Provide their local public health office with their provider confirmation and any other information the public health office requires to issue influenza vaccine to the pharmacy.

Where do pharmacies get publicly-funded influenza vaccine?
All publicly-funded influenza vaccine must be obtained from the local public health office. All providers are responsible for any transportation costs to obtain publicly-funded vaccine. Pharmacies should contact their local public health office to place their order for vaccine and to arrange pick-up. Review the packing protocol for transporting biologicals in the Nova Scotia Immunization Manual (located at: http://novascotia.ca/dhw/cdpc/documents/Immunization-Manual.pdf) to ensure you have all the required equipment when you pick up your vaccine. Public health can only release vaccine in accordance with this protocol.

When can pharmacists begin administering publicly-funded influenza vaccine?
Pharmacists may begin administering publicly-funded influenza vaccine as soon as they receive it.

How do pharmacies bill Pharmacare for influenza vaccine administration fees?
To ensure claims are adjudicated correctly, all influenza claims must be adjudicated using a quantity of 1, as well as the correct DIN and/or PIN.
Fees for the administration of publicly-funded influenza vaccine to Nova Scotia residents with a valid Nova Scotia Health Card must be billed to Pharmacare online. The electronic claim must contain the following in the patient's insurance field:

- Patient ID – *the patient's Nova Scotia Health Card Number*
- Carrier ID – *NS*

If a patient is already set up in the pharmacy system with Pharmacare coverage (e.g., Seniors' Pharmacare, Family Pharmacare), a separate patient file does not need to be created.

Claims must be submitted using the DIN of the vaccine administered to the patient, unless the patient is pregnant or is a child receiving a second vaccine dose. The following Table provides direction related to submitting claims using a PIN for pregnant women or children receiving a second dose.

Claims are submitted with the administration fee in the professional fee field. Providers are not reimbursed for ingredient costs or markups for these claims as they are able to access publicly-funded vaccine at no charge.

Administration of Publicly-Funded Influenza Vaccine by Pharmacists for the 2017-2018 Influenza Season Continued…

Claims Submission Field Content for Pharmacist-Administered Publicly Funded Influenza Vaccines

CPHA CLAIM STANDARD FIELD #	CPHA CLAIM STANDARD FIELD NAME	CONTENT
D.56.03	DIN/GP#/PIN	**DINs** - Fluzone Quadrivalent MDV 02432730 - FluLaval Tetra 02420783 **PIN for pregnant women** – Fluzone Quadrivalent 93899895 – FluLaval Tetra 93899893 **PIN for second dose for children** – Fluzone Quadrivalent 93899896 – FluLaval Tetra 93899894
D.58.03	Quantity	000001 (one)
D.61.03	Prescriber ID	Pharmacists prescriber ID
D.66.03	Drug Cost/Product Value	DDDDD (dollar value - not adjudicated)
D 67.03	Cost Upcharge	DDDDD (dollar value - not adjudicated)
D.68.03	Professional Fee	$12.00

What documentation does a pharmacy need to retain for audit and other purposes?
Pharmacies must retain the signed patient Consent and Disclosure form for each claim reimbursed by Pharmacare.

Pharmacies are advised to maintain a record of the quantity of influenza vaccine administered to individuals who do not have a valid Nova Scotia Health Card Number, as this information may be requested by public health.

How do I report an adverse event following immunization (AEFI)?
It is possible that reactions may occur after administration of influenza vaccine, without a causal association to the vaccine. ***These reactions must be reported to your local Nova Scotia Health Authority public health office for the appropriate follow-up***. Providers should document an AEFI using the Public Health Agency of Canada AEFI form (located at: http://www.phac-aspc.gc.ca/im/pdf/raefi-dmcisi-eng.pdf) and ***forward the form to the local public health office***. The local public health office reviews these reports and enters them in their local database before they are forwarded to the Public Health Agency of Canada.

What do I do if there is a break in the cold chain?
Cold chain refers to the process used to maintain optimal conditions during the transport, storage, and handling of vaccines, starting with the manufacturer and ending with the administration of the vaccine. When vaccines are exposed to temperatures of less than 2°C or more than 8°C, the result is a break in the cold chain. Vaccines affected by a break in the cold chain must be packaged separately, identified with a sticker reading "DO NOT USE," and stored in a refrigerator at between 2°C and 8°C separately from vaccines in current use. ***Contact your local public health office to determine whether they can be used.***