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PHYSICIANS' EDITION

NOVA SCOTIA

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Nova Scotia Formulary Updates

New Exception Status Benefit

The following products have been listed with the following criteria, effective **immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
pdp-Amlodipine	1mg/mL Oral Sol	02484706	DNP	E (SF)	PDP
Criteria	• For patients who require administration through a feeding tube. **[Criteria Code 37]** • For patients 19 years of age and younger, who cannot use a tablet or capsule. **[Criteria Code 38]**				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Cystadrops (cysteamine)	3.8mg/mL Oph Sol	02485605	DNP	E (SF)	RRD
Criteria	• For the treatment of corneal cystine crystal deposits (CCCDs) in patients 2 years of age and older with cystinosis. **Clinical Note** • Diagnosis of cystinosis confirmed by cystinosin (lysosomal cystine transporter) gene mutation or elevated white blood cell cystine levels. Documentation must be provided. **Claim Note** • Must be prescribed by an ophthalmologist experienced in the treatment of CCCDs.				

Criteria Updates

The following indications have been added to existing criteria effective **immediately.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Lynparza (olaparib)	50mg Cap	02454408	DNP	E (SFC)	AZE
	100mg Tab	02475200	DNP	E (SFC)	AZE
	150mg Tab	02475219	DNP	E (SFC)	AZE

Criteria

- As monotherapy maintenance treatment of patients with newly-diagnosed, advanced, BRCA-mutated (germline or somatic), high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to at least 4 cycles of first-line platinum-based chemotherapy.

Clinical Notes:

- Patients should have a good performance status.
- Maintenance therapy with olaparib should begin within 12 weeks of completion of platinum-based chemotherapy.
- Patients who are unable to tolerate platinum-based chemotherapy (due to allergic reaction) and otherwise meet criteria, will be assessed on a case by case basis to determine eligibility for treatment with olaparib.
- Treatment should continue until unacceptable toxicity, disease progression, or to a maximum of 2 years of therapy if no evidence of disease, whichever comes first.[1]
- Imaging is required for patients who are delayed in starting olaparib therapy, i.e. greater than 12 weeks after completion of platinum-based chemotherapy, or who have had a break in therapy for more than 14 days, to rule out progression prior to starting or re-starting olaparib.
- Olaparib in combination with bevacizumab is not funded. Patients already on bevacizumab maintenance at the time of olaparib funding may be switched to olaparib, as long as there is no evidence of progression on imaging and is within 12 weeks of completion of chemotherapy.

1. Patients with a partial response or stable disease at 2 years may continue to receive olaparib at the discretion of the treating physician.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Xalkori (crizotinib)	200mg Cap	02384256	DNP	E (SFC)	PFI
	250mg Cap	02384264	DNP	E (SFC)	PFI

Criteria

- For the first-line treatment of patients with ROS-1 positive non-small cell lung cancer (NSCLC).

Clinical Notes:

- Eligible patients should be previously untreated and have a good performance status.
- Treatment may continue until disease progression or unacceptable toxicity.
- Patients with ROS-1 positive NSCLC who are currently receiving first-line chemotherapy or have been previously treated with chemotherapy or immunotherapy will be eligible for treatment with crizotinib.

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Xeljanz	5mg Tab	02423898	DNP	E (SF)	PFI
(tofacitinib)	10mg Tab	02480786	DNP	E (SF)	PFI

Criteria	• 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 corticosteroid 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 with one or more biologic DMARD will not be reimbursed.
	• Approvals will be for a maximum dose of 10 mg twice daily (Xeljanz).
	• Initial Approval: 16 weeks.
	• Renewal Approval: 1 year.				

New Products

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Emerade	0.15mg Prefilled Pen	02458438	DNP	SF*	BSL
Emerade	0.3mg Prefilled Pen	02458446	DNP	SF*	BSL
Emerade	0.5mg Prefilled Pen	02458454	DNP	SF*	BSL
Vesanoid	10mg Cap	02145839	DNP	SFC	XPI
Zeulide Depot	3.75 mg Kit	02429977	DNP	SFC	VRT
Zeulide Depot	22.5 mg Kit	02462699	DNP	SFC	VRT

* Regular benefit, but with a quantity limit of two injections per fiscal year. Additional units require an exception status request.

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	AZE - AstraZeneca Canada Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	BSL - Bausch Health, Canada Inc.
P - Pharmacist	- Family Pharmacare	PDP - PendoPharm, Division of Pharmascience Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	PFI - Pfizer Canada Inc.
O - Optometrist	D - Diabetes Assistance Program	RRD - Recordati Rare Diseases Canada Inc.
	E - Exception status applies	VRT - Verity Pharmaceuticals
		XPI - Xediton Pharmaceuticals Inc.

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Nova Scotia Formulary Updates

New Exception Status Benefit

The following products have been listed with the following criteria, effective **immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Vigamox and generic brands (moxifloxacin)	0.5% Oph Sol	Various	DNPO	E (SF)	VAR
Criteria	• For the treatment of eye infections upon the order of an ophthalmologist, ophthalmology resident, prescribing optometrist or other prescriber who has a specialty in ophthalmology **[Criteria Code 01]**				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Zymar and generic brands (gatifloxacin)	0.3% Oph Sol	Various	DNPO	E (SF)	VAR
Criteria	• For the treatment of eye infections upon the order of an ophthalmologist, ophthalmology resident, prescribing optometrist or other prescriber who has a specialty in ophthalmology **[Criteria Code 01]**				

Criteria Updates

The following criteria has been updated effective **immediately.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Abilify Maintena (aripiprazole)	300mg/vial Inj	02420864	DNP	E (SF)	OTS
	400mg/vial Inj	02420872	DNP	E (SF)	OTS

Criteria	• For the treatment of patients who are:
	  ○ not adherent to an oral antipsychotic, OR
	  ○ currently receiving a long-acting injectable antipsychotic and require an alternative long-acting injectable antipsychotic.
	Claim Note:
	• Requests will not be considered for the treatment of psychotic symptoms related to dementia.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Aptiom (eslicarbazepine)	200mg Tab	02426862	DNP	E (SF)	SNV
	400mg Tab	02426870	DNP	E (SF)	SNV
	600mg Tab	02426889	DNP	E (SF)	SNV
	800mg Tab	02426897	DNP	E (SF)	SNV
Criteria	• For the adjunctive treatment of refractory partial-onset seizures (POS) in patients who are currently receiving two or more antiepileptic drugs, and have had an inadequate response or intolerance to at least three other antiepileptic drugs. **Claim Notes:** • The patient must be under the care of a physician experienced in the treatment of epilepsy.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Bosulif (bosutinib)	100mg Tab	02419149	DNP	E (SFC)	PFI
	500mg Tab	02419157	DNP	E (SFC)	PFI
Criteria	• For the treatment of adult patients with chronic, accelerated, or blast phase Philadelphia chromosome positive (Ph +) chronic myelogenous leukemia (CML) who have resistance or intolerance to prior tyrosine kinase inhibitor (TKI) therapy.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Brivlera (brivaracetam)	10mg Tab	02452936	DNP	E (SF)	UCB
	25mg Tab	02452944	DNP	E (SF)	UCB
	50mg Tab	02452952	DNP	E (SF)	UCB
	75mg Tab	02452960	DNP	E (SF)	UCB
	100mg Tab	02452979	DNP	E (SF)	UCB
Criteria	• For the adjunctive treatment of refractory partial-onset seizures (POS) in patients who are currently receiving two or more antiepileptic drugs, and who have had an inadequate response or intolerance to at least three other antiepileptic drugs. **Claim Notes:** • The patient must be under the care of a physician experienced in the treatment of epilepsy.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Fycompa (perampanel)	2mg Tab	02404516	DNP	E (SF)	EIS
	4mg Tab	02404524	DNP	E (SF)	EIS
	6mg Tab	02404532	DNP	E (SF)	EIS
	8mg Tab	02404540	DNP	E (SF)	EIS
	10mg Tab	02404559	DNP	E (SF)	EIS
	12mg Tab	02404567	DNP	E (SF)	EIS
Criteria	• For the adjunctive treatment of refractory partial-onset seizures or primary generalized tonic-clonic seizures in patients who are currently receiving two or more antiepileptic drugs, and who have had an inadequate response to at least three other antiepileptic drugs. **Claim Notes:** • The patient must be under the care of a physician experienced in the treatment of epilepsy.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Inlyta (axitinib)	1mg Tab	02389630	DNP	E (SFC)	PFI
	5mg Tab	02389649	DNP	E (SFC)	PFI
Criteria	• For the treatment of patients with advanced or metastatic renal cell carcinoma when used as: o first-line therapy in combination with pembrolizumab OR o second-line therapy following disease progression on a vascular endothelial growth factor receptor tyrosine kinase inhibitor (VEGFR TKI)				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Inlyta (axitinib)	1mg Tab 5mg Tab	02389630 02389649	DNP DNP	E (SFC) E (SFC)	PFI PFI
Criteria	OR ○ third-line therapy following disease progression on first-line nivolumab and ipilimumab combination therapy, and a second-line VEGFR TKI. • Patients must have a good performance status. Treatment should be discontinued upon disease progression or unacceptable toxicity. **Clinical Notes:** • Sequential use of axitinib and everolimus is not permitted except in the case of intolerability or contraindication. • Sequential use of axitinib (as a single agent) and cabozantanib is not permitted except in the case of intolerance or contraindication. Note: Cabozantinib is funded for patients following progression on first-line axitinib + pembrolizumab. • For patients treated with nivolumab + ipilimumab first-line and VEGF TKI (sunitinib or pazopanib) second line, either cabozantanib **or** axitinib may be used as third-line therapy. • Both clear cell and non-clear cell histology are eligible for treatment.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Lyrica and generic brands (pregabalin)	Various	Various	DNP	E (SFC)	VAR
Criteria	• For the treatment of post-herpetic neuralgia, diabetic peripheral neuropathy, and post-traumatic neuropathic pain.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Neurontin and generic brands (gabapentin)	Various	Various	DNP	E (SFC)	VAR
Criteria	• For the treatment of post-herpetic neuralgia, diabetic peripheral neuropathy, and post-traumatic neuropathic pain.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Risperdal Consta	12.5mg/vial Inj	02298465	DNP	E (SF)	JAN
(risperidone)	25mg/vial Inj	02255707	DNP	E (SF)	JAN
	37.5mg/vial Inj	02255723	DNP	E (SF)	JAN
	50mg/vial Inj	02255758	DNP	E (SF)	JAN

Criteria	• For the treatment of patients who are:
	  ○ not adherent to an oral antipsychotic, OR
	  ○ currently receiving a long-acting injectable antipsychotic and require an alternative long-acting injectable antipsychotic.
	Claim Note:
	• Requests will not be considered for the treatment of psychotic symptoms related to dementia.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tafinlar	50mg Cap	02409607	DNP	E (SFC)	NVR
(dabrafenib)	75mg Cap	02409615	DNP	E (SFC)	NVR
Mekinist	0.5mg Tab	02409623	DNP	E (SFC)	NVR
(trametinib)	2mg Tab	02409658	DNP	E (SFC)	NVR
Criteria	• Dabrafenib-trametinib combination therapy as a first-line BRAF-mutation targeted treatment for patients with BRAF V600 mutation positive, unresectable or metastatic melanoma and who have an ECOG performance status of 0 or 1. Treatment should continue until disease progression. If brain metastases are present, patients should be asymptomatic or have stable symptoms. • In the event that a patient is initiated on dabrafenib-trametinib combination therapy and has to discontinue one agent due to toxicity, dabrafenib or trametinib monotherapy as a first-line BRAF-mutation targeted treatment for patients with BRAF V600 mutation positive, unresectable or metastatic melanoma and who have an ECOG performance status of 0 or 1, will be funded, should that be the chosen treatment option. Treatment should continue until disease progression. If brain metastases are present, patients should be asymptomatic or have stable symptoms. For clarity, initiation of treatment with dabrafenib or trametinib monotherapy will not be funded. • For the adjuvant treatment of patients with stage IIIA (limited to lymph node metastases of > 1 mm) to stage IIID (8th edition of American Joint Committee on Cancer [AJCC] staging system) BRAF-mutated (all BRAF V600 mutations) cutaneous melanoma. Disease must be completely resected including in-transit metastases; however, presence of regional lymph nodes with micrometastases after sentinel lymph node biopsy alone is allowed. **Clinical Notes:** • Patients should have a good performance status.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tafinlar	50mg Cap	02409607	DNP	E (SFC)	NVR
(dabrafenib)	75mg Cap	02409615	DNP	E (SFC)	NVR
Mekinist	0.5mg Tab	02409623	DNP	E (SFC)	NVR
(trametinib)	2mg Tab	02409658	DNP	E (SFC)	NVR
Criteria	• Treatment with dabrafenib plus trametinib should continue until disease recurrence, unacceptable toxicity, or up to a maximum of 12 months. • Patients are eligible to receive 12 months of adjuvant treatment with immunotherapy or BRAF targeted therapy. Patients who are unable to tolerate initial adjuvant therapy, within the first 3 months of treatment, may switch to alternate funded treatment, provided criteria are met. • Patients with mucosal or ocular melanoma are not eligible for treatment with dabrafenib/trametinib. • Patients who relapse during, or at any time after adjuvant dabrafenib/trametinib therapy, are eligible for treatment with combination immunotherapy (i.e. nivolumab with ipilimumab) in the metastatic setting. Patients who are not candidates for combination immunotherapy are eligible for single agent nivolumab or pembrolizumab immunotherapy in the metastatic setting. • Re-treatment with BRAF targeted therapy is funded if the treatment-free interval is ≥ 6 months from the completion of adjuvant BRAF therapy. • For BRAF-positive patients, BRAF-targeted therapy and immunotherapy (including nivolumab plus ipilimumab combination therapy) may be sequenced in either order upon treatment failure, based on clinician assessment.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Vimpat and generic brands	50mg Tab	Various	DNP	E (SF)	VAR
	100mg Tab	Various	DNP	E (SF)	VAR
(lacosamide)	150mg Tab	Various	DNP	E (SF)	VAR
	200mg Tab	Various	DNP	E (SF)	VAR
Criteria	• For the adjunctive treatment of refractory partial-onset seizures (POS) in patients who are currently receiving two or more antiepileptic drugs, and who have had an inadequate response or intolerance to at least three other antiepileptic drugs. **Claim Notes:** • The patient must be under the care of a physician experienced in the treatment of epilepsy.				

New Product

Effective **immediately,** the following new product has been added to the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Allerject	0.3mg/0.3mL Inj	02382067	DNP	SF*	KLO
Allerject	0.15mg/0.15mL Inj	02382059	DNP	SF*	KLO

* Regular benefit, but with a quantity limit of two injections per fiscal year. Additional units require an exception status request.

Changes in Benefit Status

Effective **immediately,** the following products have moved to full benefit status and no longer require exception status approval.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Jamp-Sodium Bicarbonate	500mg Tab	80030520	DNP	SF	JPC
Sandoz Sodium Bicarbonate	500mg Tab	80022194	DNP	SF	SDZ

Non-Insured Products

The following products will not be insured in the Pharmacare Programs; however, it will be funded through the Exception Drug Fund as per other HIV medications.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Delstrigo	100mg/300mg/300mg Tab	02482592	N/A	**Not Insured**	FRS
Pifeltro	100mg Tab	02481545	N/A	**Not Insured**	FRS

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	EIS - Eisai Limited
N - Nurse Practitioner	F - Community Services Pharmacare - Family Pharmacare	FRS - Merck Canada Ltd.
P - Pharmacist	C - Drug Assistance for Cancer Patients	JAN - Janssen-Ortho Inc.
M - Midwife	D - Diabetes Assistance Program	JPC - Jamp Pharma Corporation
O - Optometrist	E - Exception status applies	KLO - Kaleo Inc
		NVR - Novartis Pharmaceutical
		OTS - Otsuka Canada Pharmaceuticals
		PFI - Pfizer Canada Inc.
		SDZ - Sandoz Canada Inc.
		SNV - Sunvoion Pharmaceuticals Canada Inc.
		UCB - UCB Pharma Canada Inc.
		VAR - *Various manufacturers*

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Nova Scotia Formulary Updates

New Exception Status Benefit

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Truxima (rituximab)	10mg/mL Vial	02478382	DNP	E (SF)	TEV
	10mg/mL Vial	02478390	DNP	E (SF)	TEV
Criteria	***For rituximab-naïve patients whose rituximab therapy is initiated after November 1, 2020, a rituximab biosimilar will be the product approved.*** • For the treatment of adult patients with severe active rheumatoid arthritis who have failed to respond to an adequate trial with an anti-TNF agent. • Cannot be used concomitantly with anti-TNF agents. • Written request from a rheumatologist or prescriber with a specialty in rheumatology. • Approval for re-treatment with rituximab will only be considered for patients who have achieved a response, followed by a subsequent loss of effect and, after an interval of no less than six months from the previous dose. • For the induction of remission in patients with severely active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) who have severe intolerance or other contraindication to cyclophosphamide, or who have failed an adequate trial of cyclophosphamide.				

Criteria Updates

The following indications have been added to existing criteria effective **immediately.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Lyrica and generic brands (pregabalin)	Various	Various	DNP	E (SF)	VAR
Criteria	• For treatment of fibromyalgia.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Neurontin and generic brands (gabapentin)	Various	Various	DNP	E (SF)	VAR
Criteria	• For treatment of fibromyalgia. • For treatment of alcohol use disorder.				

The following criteria has been updated effective **immediately.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Myrbetriq (mirabegron)	25mg ER Tab 50mg ER Tab	02402874 02402882	DNP DNP	E (SF) E (SF)	ASL 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.				

New Products

Effective **immediately,** the following new products have been added to the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated. Where applicable, existing criteria applies.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Fragmin	16 500 IU (anti-factor Xa) /0.66mL Inj	02494582	DNP	SFC	PFI
Janumet XR	50mg/500mg Tab	02416786	DNP	E (SF)	FRS
Janumet XR	100mg/1000mg Tab	02416808	DNP	E (SF)	FRS

Delisted Product

Effective **April 30, 2021,** the following product has moved to non-benefit status and will no longer be covered under the Nova Scotia Pharmacare Programs.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Cipro XL	1000mg Tab	02251787	N/A	Not Insured	BAY

Reminder: Prescriber Identification on Exception Status Request

Please ensure the prescriber information section is complete when submitting exception status drug request forms. The following information must be included:

- Prescriber name
- License number
- Signature
- Address

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ASL - Astellas Pharma Canada Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	BAY - Bayer Inc.
P - Pharmacist	C - Family Pharmacare	FRS - Merck Canada Ltd.
M - Midwife	D - Drug Assistance for Cancer Patients	PFI - Pfizer Canada Inc.
O - Optometrist	E - Diabetes Assistance Program	TEV - Teva Canada Ltd.
	- Exception status applies	VAR - *various manufacturers*

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Nova Scotia Formulary Updates

New Exception Status Benefits

The following products have been listed with the following criteria, effective **immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Kanuma (sebelipase alfa)	2mg/mL IV Sol	02469596	DNP	E (SF)	ALX

Criteria

For the treatment of patients diagnosed with lysosomal acid lipase (LAL) deficiency who meet all of the following criteria:

- Documented biochemical evidence of deficient LAL activity and two documented pathogenic mutations in the LIPA gene

  AND

- Patients who:
  - Have onset of clinical manifestations[1] of LAL deficiency before six months of age.

    OR

  - Have at least one of the following clinical manifestations[1] of LAL deficiency at 6 months of age and older:
    - Persistently elevated transaminases (ALT > 1.5 x ULN[2] or AST > 1.5 x ULN[2]) as measured by two assessments three to six months apart.
    - Persistent dyslipidemia (LDL-c and/or TG values in the top 5th percentile based on sex and age) as measured by two assessments three to six months apart.
    - Any documented hepatomegaly or hepatosplenomegaly.

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Kanuma (sebelipase alfa)	2mg/mL IV Sol	02469596	DNP	E (SF)	ALX

Criteria

- Liver fibrosis confirmed by biopsy.
- Failure to thrive.
- Growth impairment[3].
- Evidence of intestinal affection and/or malabsorption.

AND

- Must not demonstrate evidence of any of the following:
  - Increased portal vein pressures, or de novo evidence of portal hypertension on ultrasound and Doppler, or new clinical presentation of portal hypertension (e.g., esophageal varices).
  - Severe hepatic dysfunction (Child-Pugh Class C).
  - End-stage liver disease.

Discontinuation Criteria:

- For patients with onset of clinical manifestations of LAL deficiency at six months of age and older if the patient:
  - Progresses to end-stage liver failure or multi-organ failure.

  OR

  - Has at least three out of the following response components compared to baseline values after 12 months of therapy:
    - Less than 10% improvement in ALT or AST.
    - Worsening of liver fibrosis confirmed by biopsy.
    - Persisting growth impairment[3] despite sebelipase alfa therapy and nutritional interventions.
    - At least a 15% increase in spleen volume and/or a greater than 15% increase in liver volume on ultrasound.
    - Increased portal vein pressures, or de novo evidence of portal hypertension on ultrasound and Doppler, or new clinical presentation of portal hypertension (e.g., esophageal varices).
- Regardless of age of onset, for adverse events from sebelipase alfa (particularly hypersensitivity reactions including anaphylaxis, hypotension, or fever), which cannot be managed with standard treatment and/or have a significant impact on the patient's quality of life or are life-threatening.

Clinical Notes:

1. The physician must provide baseline values for the clinical manifestation at the time of initial request for reimbursement.
2. Based on age- and- sex-specific normal values for ALT and AST.

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Kanuma (sebelipase alfa)	2mg/mL IV Sol	02469596	DNP	E (SF)	ALX
Criteria	3. Growth impairment is defined as decreased body weight across at least two of the major centiles on a WHO weight-for-age chart, or body weight below 10th centile and no weight gain within two weeks and/or decreased height across at least two of the major centiles on a WHO height-for-age chart. **Claim Notes:** • The patient must be under the care of a specialist with experience in the diagnosis and management of LAL deficiency. • Initial Approval: 12 months. • Renewals: 6 months. • Claims for Kanuma 2mg/mL IV Solution that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs: o 00904599 o 00904600 o 00904601 Please call the Nova Scotia Pharmacare Programs if additional PINs are required.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Lonsurf (trifluridine/tipiracil)	15mg/6.14mg Tab 20mg/8.19mg Tab	02472104 02472112	DNP DNP	E (SFC) E (SFC)	TAI TAI
Criteria	• For the treatment of adult patients with metastatic gastric cancer or adenocarcinoma of the gastroesophageal junction who meet the following criteria: o Previously treated with at least two prior lines of chemotherapy including a fluoropyrimidine, a platinum, and either a taxane or irinotecan and if appropriate, with HER2-targeted therapy. o Patients should have a good performance status. **Clinical Notes:** • Trifluridine/tipiracil should be used in combination with best supportive care. • Treatment should be discontinued upon disease progression or unacceptable toxicity. • Requests will be considered for patients who have an intolerance or contraindication to platinum-based therapy.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Nubeqa (darolutamide)	300mg Tab	02496348	DNP	E (SFC)	BAY
Criteria	• In combination with androgen deprivation therapy (ADT) for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastases[1]. • Patients should have a good performance status. Treatment should continue until unacceptable toxicity or radiographic disease progression. **Clinical Notes:** • Castration-resistance must be demonstrated during continuous ADT and is defined as 3 PSA rises at least one week apart, with the last PSA > 2 ng/mL. • Patients should have no detectable distant metastases by either CT, MRI or technetium-99m bone scan. • Castrate levels of testosterone must be maintained. • Patients with N1 disease, pelvic lymph nodes < 2cm in short axis located below the aortic bifurcation are eligible for darolutamide. • Darolutamide will not be funded for patients who experience disease progression on apalutamide or enzalutamide. • Patients receiving darolutamide for the treatment of non-metastatic CRPC will be eligible for funding of abiraterone at the time of disease progression to metastatic CRPC. Enzalutamide is not funded for patients who experience disease progression to metastatic CRPC while on darolutamide. • Either abiraterone or enzalutamide may be used to treat metastatic CRPC in patients who discontinued darolutamide in the non-metastatic setting due to intolerance without disease progression. [1] High risk of developing metastases is defined as a prostate-specific antigen (PSA) doubling time of ≤ 10 months during continuous ADT.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Onpattro (patisiran)	2mg/mL IV Sol	02489252	DNP	E (SF)	ALN

Criteria	• For the treatment of polyneuropathy in adult patients with hereditary transthyretin-mediated amyloidosis (hATTR) who meet all of the following criteria:
	  ○ Confirmed genetic diagnosis of hATTR.
	  ○ Symptomatic with early-stage neuropathy[1].
	  ○ Does not have New York Heart Association class III or IV heart failure.
	  ○ Has not previously undergone a liver transplant.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Onpattro (patisiran)	2mg/mL IV Sol	02489252	DNP	E (SF)	ALN
Criteria	**Discontinuation Criteria:** • The patient is permanently bedridden and dependent on assistance for basic activities of daily living. **OR** • The patient is receiving end-of-life care. **Clinical Note:** 1. Symptomatic early-stage neuropathy is defined as polyneuropathy disability stage I to IIIB or familial amyloidotic polyneuropathy stage I or II. **Claim Notes:** • The patient must be under the care of a physician with experience in the diagnosis and management of hATTR. • Combination therapy with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat hATTR will not be reimbursed. • Initial Approval: 9 months. • Renewal Approval: 12 months. Confirmation of continued response is required. • Claims for Onpattro 2mg/mL IV Solution that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs: ○ 00904586 ○ 00904587 ○ 00904588				

Criteria Updates

The following indication has been added to existing criteria effective **immediately.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Everolimus (Afinitor and generic brands)	2.5mg Tab 5mg Tab 10mg Tab	Various Various Various	DNP DNP DNP	E (SFC) E (SFC) E (SFC)	VAR VAR VAR
Criteria	**Neuroendocrine Tumours of Gastrointestinal or Lung Origin** • As a **single agent treatment** for patients with unresectable, locally advanced or metastatic; well-differentiated non-functional neuroendocrine tumours (NETs) of gastrointestinal or lung origin (GIL) in adults with documented radiological disease progression within six months and with a good performance status. Treatment should continue until confirmed disease progression or unacceptable toxicity.				

The following criteria has been updated effective **immediately.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Revestive (teduglutide)	5mg/Vial	02445727	DNP	E (F)	TAK
Criteria	**For the treatment of adult patients with Short Bowel Syndrome (SBS) who have all of the following:** • SBS as a result of major intestinal resection (e.g., volvulus, vascular disease, cancer, Crohn's disease, injury). • dependency on parenteral nutrition (PN) for a least 12 months. • prior to initiating teduglutide, PN required at least three times weekly to meet caloric, fluid or electrolyte needs, due to ongoing malabsorption and stable PN frequency and volume for at least one month. **Renewal Criteria:** • Has maintained at least a 20% reduction in PN volume from baseline at 12 months. **Clinical Note:** • PN is defined as the parenteral delivery of lipids, protein and/or carbohydrates to address caloric needs, and intravenous fluids which addresses fluid and electrolyte needs of patients. **Claim Notes:** • Must be prescribed by a specialist with experience in SBS. • Approval period: 1 year. **For the treatment of pediatric patients 1 year of age and older with Short Bowel Syndrome (SBS) who have all of the following:** • Prior to initiating teduglutide, parenteral support (PS) requirements must be stable or there must have been no improvement in enteral feeding for at least three months.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Revestive (teduglutide)	5mg/Vial	02445727	DNP	E (F)	TAK
Criteria	• PS must provide more than 30% of caloric and/or fluid/electrolyte needs. • The cumulative lifetime duration of PS must be at least 12 months. **Renewal Criteria:** • Has maintained at least a 20% reduction in parenteral support volume from baseline. **Claim Notes:** • Must be prescribed by a pediatric gastroenterologist or other prescriber currently working within a specialized multi-disciplinary intestinal rehabilitation program with expertise in the diagnosis and management of SBS. • Initial approval period: 6 months. • Renewal approval period: 6 months. **Clinical Note:** • PS is defined as the parenteral delivery of lipids, protein and/or carbohydrates to address caloric needs, and intravenous fluids which addresses fluid and electrolyte needs of patients.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Revlimid (lenalidomide)	Various	Various	DNP	E (SFC)	CEL

Criteria	**Multiple Myeloma (MM-AOPT)**
	• For the treatment of relapsed or refractory multiple myeloma when used:
	  ○ In combination with dexamethasone for patients who have received at least one prior treatment; or
	  ○ In combination with carfilzomib and dexamethasone (KRd regimen) for patients who have received at least one prior treatment; or
	  ○ In combination with daratumumab and dexamethasone (DRd regimen) for patients who have received at least one prior treatment.
	Newly Diagnosed Multiple Myeloma Post-Autologous Stem Cell Transplant (NDMM POST-ASCT)
	• For the maintenance treatment of patients with newly diagnosed multiple myeloma who have stable or improved disease following autologous stem-cell transplantation (ASCT) and no evidence of disease progression.
	Multiple Myeloma Not Eligible For Autologous Stem Cell Transplant (MM-TNE)
	• As first-line treatment for newly diagnosed patients with multiple myeloma who are not eligible for autologous stem cell transplantation when used in combination with				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Revlimid (lenalidomide)	Various	Various	DNP	E (SFC)	CEL
Criteria	dexamethasone, with or without bortezomib. **Clinical Notes:** • Patients should have a good performance status. • Treatment should be continued until unacceptable toxicity or disease progression. **Note:** • Celgene will ensure that the Product will be prescribed and dispensed only by physicians and pharmacists, respectively, who are registered with and agree in writing to adhere to the guidelines of the Company's RevAid® Program, details of which Program are available at https://revaid.ca/revaid				

New Product

Effective **immediately,** the following new product has been added to the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated. Where applicable, existing criteria applies.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Fasenra	30 mg/mL Autoinjector	02496135	DNP	E (SF)	AZE

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ALN - Alnylam Netherlands BV
N - Nurse Practitioner	F - Community Services Pharmacare	ALX - Alexion Pharma Canada Corp
P - Pharmacist	- Family Pharmacare	AZE - AstraZeneca Canada Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	BAY - Bayer Inc.
O - Optometrist	D - Diabetes Assistance Program	CEL - Celgene
	E - Exception status applies	TAI - Taiho Pharma Canada
		TAK - Takeda Canada Inc.
		VAR - *various manufacturers*

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Nova Scotia Formulary Updates

Criteria Update

The following indications have been added to existing criteria **effective immediately**.

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

Criteria

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

Psoriasis

- For patients with severe, debilitating chronic plaque psoriasis who meet all of the following:
- Body surface area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genitals;
- Failure to, contraindication to or intolerant of methotrexate and cyclosporine;
- Failure to, intolerant of or unable to access phototherapy;
- Written request of a dermatologist or prescriber with a specialty in dermatology.

- Continued coverage is dependent on evidence of improvement, specifically:
  - A >75% reduction in the Psoriasis Area and Severity Index (PASI) score; **OR**

Criteria Update Continued…

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

Criteria

- A >50% reduction in PASI with a >5-point improvement in DLQI (Dermatology Life Quality Index); **OR**
- Significant reduction in BSA involved, with consideration of important regions such as the face, hands, feet or genitals.

Clinical Note:

- Treatment should be discontinued if a response has not been demonstrated after 12 weeks.

Claim Note:

- Concurrent use of biologics not approved. Initial duration and maximum dosage approved.

Psoriatic Arthritis

- For the treatment of patients with predominantly axial psoriatic arthritis who are refractory, intolerant or have contraindications to the sequential use of at least two NSAIDs at maximal tolerated dose for a minimum of two weeks each.
- For the treatment of patients with predominantly peripheral psoriatic arthritis who are refractory, intolerant or have contraindications to:
  - The sequential use of at least two NSAIDs at maximal tolerated dose for a minimum of two weeks each;

  AND

  - Methotrexate (oral or parenteral) at a dose of ≥ 20mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 8 weeks;

  AND

  - Leflunomide for a minimum of 10 weeks or sulfasalazine for a minimum of 3 months.

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.
- 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 to treatments. 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.
- Renewal approval: 1 year. Confirmation of continued response required.

Criteria Update Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Brenzys	50mg/mL Prefilled Syringe	02455323	DNP	E (SF)	FRS
(etanercept)	50mg/mL Prefilled Pen	02455331	DNP	E (SF)	FRS
Criteria	**Polyarticular Juvenile Idiopathic Arthritis** • For the treatment of polyarticular juvenile idiopathic arthritis (pJIA) with the following criteria: o For patients aged 4-17 years with moderate or severe pJIA who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs); **AND** o Treatment must be initiated by a rheumatologist who is familiar with the use of DMARDs and/or biologic DMARDs in children.				

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	FRS - Merck Canada Ltd.
N - Nurse Practitioner	F - Community Services Pharmacare	
P - Pharmacist	- Family Pharmacare	
M - Midwife	C - Drug Assistance for Cancer Patients	
O - Optometrist	D - Diabetes Assistance Program	
	E - Exception status applies	

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Nova Scotia Formulary Updates

New Exception Status Benefits

The following products have been listed with the following criteria, effective **immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Prevymis (letermovir)	240mg Tab	02469375	DNP	E (SF)	FRS
	480mg Tab	02469383	DNP	E (SF)	FRS
	240mg IV Sol	02469367	DNP	E (SF)	FRS
	480mg IV Sol	02469405	DNP	E (SF)	FRS

Criteria

- For the prevention of cytomegalovirus (CMV) infection in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT) who have undetectable CMV viremia at baseline and meet one of the following criteria:
  - umbilical cord blood as a stem cell source
  - recipient of a haploidentical transplant
  - recipient of T-cell depleted transplant
  - treated with antithymocyte globulin (ATG) for conditioning
  - requiring high-dose steroids or other immunosuppression for acute graft versus host disease (GVHD)
  - treated with ATG for steroid-refractory acute GVHD
  - documented history of CMV disease prior to transplantation

Clinical Note:

- High-dose steroids is defined as the use of greater than or equal to 1 mg/kg/day of prednisone or equivalent dose of another corticosteroid.

New Exception Status Benefits Continued

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Prevymis	240mg Tab	02469375	DNP	E (SF)	FRS
(letermovir)	480mg Tab	02469383	DNP	E (SF)	FRS
	240mg IV Sol	02469367	DNP	E (SF)	FRS
	480mg IV Sol	02469405	DNP	E (SF)	FRS
Criteria	**Claim Notes:** • Must be prescribed by a medical oncologist, hematologist, or infectious disease specialist or other physician with experience in the management of HSCT. • Approvals will be for a maximum dose of 480 mg per day. • Approval period: 100 days per HSCT.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Takhzyro	300mg/2mL Vial	02480948	DNP	E (SF)	TAK
(lanadelumab)	300mg/2mL Prefilled Syringe	02505614	DNP	E (SF)	TAK
Criteria	• For the routine prevention of attacks of type I or II hereditary angioedema (HAE) in patients 12 years of age and older who have experienced at least three HAE attacks within any four-week period and required the use of an acute injectable treatment. **Discontinuation Criteria:** • No reduction in the number of HAE attacks for which acute injectable treatment was received during the first three months of treatment with lanadelumab compared to the number of attacks observed before initiating treatment with lanadelumab; **OR** • Increase in the number of HAE attacks for which acute injectable treatment was received compared to the number of attacks before initiating treatment with lanadelumab. **Clinical Note:** • The pre-treatment attack rate must be provided for those patients who are already receiving long-term prophylactic treatment for HAE and intend to transition to lanadelumab. **Claim Notes:** • Must be prescribed by a physician experienced in the diagnosis and treatment of HAE. • Combination use of Takhzyro (lanadelumab) with other long-term prophylactic treatment of HAE (e.g., C1 esterase inhibitor) will not be funded. • Approvals will be for a maximum of 300 mg every two weeks. • Initial approval period: 3 months. • Renewal approval period: 6 months.				

New Exception Status Benefits Continued

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Takhzyro (lanadelumab)	300mg/2mL Vial	02480948	DNP	E (SF)	TAK
	300mg/2mL Prefilled Syringe	02505614	DNP	E (SF)	TAK
Criteria	• Claims for Takhzyro 300mg/2mL vial and 300mg/2mL prefilled syringe that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs: o Takhzyro 300mg/2mL Vial ▪ 00904577 ▪ 00904578 o Takhzyro 300mg/2mL Prefilled Syringe ▪ 00904638 ▪ 00904639				

Criteria Updates

The following criteria has been updated effective **immediately.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Biphentin (methylpheni-date)	10mg Cap	02277166	DN	E (SF)	ELV
	15mg Cap	02277131	DN	E (SF)	ELV
	20mg Cap	02277158	DN	E (SF)	ELV
	30mg Cap	02277174	DN	E (SF)	ELV
	40mg Cap	02277182	DN	E (SF)	ELV
	50mg Cap	02277190	DN	E (SF)	ELV
	60mg Cap	02277204	DN	E (SF)	ELV
	80mg Cap	02277212	DN	E (SF)	ELV
Criteria	• For the treatment of patients with attention deficit hyperactivity disorder who have tried other forms of extended-release methylphenidate with unsatisfactory results. **Claim Note:** • The maximum dose reimbursed is 80 mg daily.				

Criteria Updates Continued

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Vyvanse (**lisdexamfeta-mine**)	10mg Cap	02439603	DNP	E (SF)	TAK
	20mg Cap	02347156	DNP	E (SF)	TAK
	30mg Cap	02322951	DNP	E (SF)	TAK
	40mg Cap	02347164	DNP	E (SF)	TAK
	50mg Cap	02322978	DNP	E (SF)	TAK
	60mg Cap	02347172	DNP	E (SF)	TAK
	10mg Chewtab	02490226	DNP	E (SF)	TAK
	20mg Chewtab	02490234	DNP	E (SF)	TAK
	30mg Chewtab	02490242	DNP	E (SF)	TAK
	40mg Chewtab	02490250	DNP	E (SF)	TAK
	50mg Chewtab	02490269	DNP	E (SF)	TAK
	60mg Chewtab	02490277	DNP	E (SF)	TAK
Criteria	• For treatment of patients with attention deficit hyperactivity disorder who have tried extended-release methylphenidate, dexamphetamine or mixed salts amphetamine with unsatisfactory results. **Claim Note:** • The maximum dose reimbursed is 60 mg daily.				

Changes in Benefit Status

Effective immediately, the following products have moved to full benefit status and exception status approvals are no longer required for:

- Abilify and generic brands (aripiprazole)
- Concerta and generics brands (extended-release methylphenidate)

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Abilify and generic brands	Various	Various	DNP	SF	VAR
Concerta and generic brands	Various	Various	DNP	SF	VAR

New Products

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Jamp-K Effervescent	25mEq Tab	80033602	DNP	SF	JPC
Jamp-Potassium Chloride ER	600mg Cap	80062704	DNP	SF	JPC

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
Dobutamine	12.5mg/mL Inj	02242010	N/A	**Not Insured**	SDZ
Neo-Synephrine	10mg/mL Inj	02241980	N/A	**Not Insured**	PFI

New Benefit – US-Labelled Depo-Provera Contraceptive Injection (CI)

Pfizer Canada ULC has received approval from Health Canada for the importation and release of a limited supply of US-labelled Depo-Provera CI (medroxyprogesterone) 150mg/mL prefilled syringes to mitigate the shortage of Depo-Provera in Canada related to the COVID-19 pandemic.

The Nova Scotia Pharmacare Programs will be adding this product as a temporary benefit **effective September 1, 2021.**

The US-labelled Depo-Provera CI has the same active ingredient and route of administration as the Canadian product but pharmacists are advised that the US-labelled Depo-Provera CI is a prefilled syringe and is indicated only for the prevention of pregnancy and is not indicated for the treatment of endometriosis. When prescribing or dispensing this product, pharmacists are directed to consult the Pfizer Dear Healthcare Professional at the following link: https://www.pfizer.ca/sites/default/files/202106/Signed_Final_DHCPL_Depo-Provera_28June2021_EN.pdf.

PRODUCT	STRENGTH	PIN	PRESCRIBER	BENEFIT STATUS	MFR
Depo-Provera	150mg/mL Prefilled Syringe	09858134	DNP	SFC	PFI

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ELV - Elvium Life Sciences
N - Nurse Practitioner	F - Community Services Pharmacare	FRS - Merck Canada Ltd.
P - Pharmacist	- Family Pharmacare	JPC - Jamp Pharma Corporation
M - Midwife	C - Drug Assistance for Cancer Patients	PFI - Pfizer Canada Inc.
O - Optometrist	D - Diabetes Assistance Program	SDZ - Sandoz Canada Incorporated
	E - Exception status applies	TAK - Takeda Canada Inc.
		VAR - *various manufacturers*

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Nova Scotia Formulary Update

New Exception Status Benefit

The following product has been listed with the following criteria, effective **October 31, 2021.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Xospata (gilteritinib)	40mg Tab	02495058	DNP	E (SFC)	ASL

Criteria

- As monotherapy for the treatment of adult patients with relapsed or refractory FMS-like tyrosine kinase 3 (FLT3)-mutated acute myeloid leukemia (AML) who meet the following criteria:
  - Confirmed positive for FLT3 mutation at the time of relapse or determination of refractory disease, eligible FLT3 mutations include FLT3-ITD, and FLT3-TKD.

Clinical Notes:

- Patients should have a good performance status.
- Treatment with gilteritinib should be continued as long as clinical benefit is observed, or until disease progression or unacceptable toxicity, whichever occurs first.
- Patients previously treated with midostaurin are eligible for gilteritinib provided all other criteria are met.
- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs:
  - 00904658
  - 00904659

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ASL - Astellas Pharma Canada Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	
P - Pharmacist	- Family Pharmacare	
M - Midwife	C - Drug Assistance for Cancer Patients	
O - Optometrist	D - Diabetes Assistance Program	
	E - Exception status applies	

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Nova Scotia Formulary Updates

New Exception Status Benefits

The following new products have been listed with the following criteria, effective **November 30, 2021**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Amgevita	20mg/0.4mL Prefilled Syringe	02459310	DNP	E (SF)	AGA
Amgevita	40mg/0.8mL Prefilled Syringe	02459299	DNP	E (SF)	AGA
Amgevita	40mg/0.8mL Autoinjector	02459302	DNP	E (SF)	AGA
Hadlima	40mg/0.8mL Prefilled Syringe	02473097	DNP	E (SF)	ORG
Hadlima	40mg/0.8mL Autoinjector	02473100	DNP	E (SF)	ORG
Hulio	40mg/0.8mL Prefilled Syringe	02502399	DNP	E (SF)	BGP
Hulio	40mg/0.8mL Prefilled Pen	02502402	DNP	E (SF)	BGP
Hyrimoz	20mg/0.4mL Prefilled Syringe	02505258	DNP	E (SF)	SDZ
Hyrimoz	40mg/0.8mL Prefilled Syringe	02492164	DNP	E (SF)	SDZ
Hyrimoz	40mg/0.8mL Autoinjector	02492156	DNP	E (SF)	SDZ
Idacio	40mg/0.8mL Prefilled Pen	02502674	DNP	E (SF)	FKB
(adalimumab biosimilars)					
Criteria	**For adalimumab-naïve pediatric and adult patients whose adalimumab therapy is initiated after December 15, 2021, an adalimumab biosimilar will be the product approved.** • Please refer to the Pharmacare Formulary (https://novascotia.ca/dhw/pharmacare/formulary.asp) for the adalimumab criteria.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Atectura Breezhaler (indacaterol/mometasone furoate)	150mcg/80mcg Cap	02498685	DNP	E (SF)	VAL
	150mcg/160mcg Cap	02498707	DNP	E (SF)	VAL
	150mcg/320mcg Cap	02498693	DNP	E (SF)	VAL
Criteria	• For the treatment of moderate to severe asthma in patients who: ○ are compliant with inhaled corticosteroids at optimal doses; and ○ require additional symptom control, (e.g., cough, awakening at night, missing activities such as school, work or social activities because of asthma symptoms); and ○ require increasing amounts of short-acting beta2-agonists, indicative of poor control.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Enerzair Breezhaler (indacaterol/glycopyrronium/mometasone furoate)	150mcg/50mcg/160mcg Cap	02501244	DNP	E (SF)	VAL
Criteria	• For the treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta2-agonist (LABA) and a medium or high dose of an inhaled corticosteroid (ICS) who experienced one or more asthma exacerbations in the previous 12 months. **Clinical Notes:** • Asthma exacerbation is defined as: worsening signs or symptoms of asthma (shortness of breath, cough, wheezing or chest tightness and progressive decrease in lung function) requiring administration of systemic corticosteroids for at least three days, or asthma-related hospitalization				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Dupixent (dupilumab)	300mg/2mL Prefilled Syringe	02470365	DNP	E (SF)	SAV
	200mg/1.14mL Prefilled Syringe	02492504	DNP	E (SF)	SAV
	300mg/2mL Prefilled Pen	02510049	DNP	E (SF)	SAV
Criteria	• For the treatment of moderate to severe atopic dermatitis in patients 12 years of age and older who meet all of the following criteria: ○ Refractory or have contraindications to an adequate trial of topical prescription therapies.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Dupixent	300mg/2mL Prefilled Syringe	02470365	DNP	E (SF)	SAV
(dupilumab)	200mg/1.14mL Prefilled Syringe	02492504	DNP	E (SF)	SAV
	300mg/2mL Prefilled Pen	02510049	DNP	E (SF)	SAV
Criteria	○ Refractory, intolerant or have contraindications to an adequate trial of phototherapy (where available), methotrexate, and cyclosporine. ○ Baseline Physician Global Assessment score of 3 or greater and Eczema Area and Severity Score of 7.1 or greater. **Renewal criteria:** • Requests for renewal must provide proof of beneficial clinical effect defined as a 75% or greater improvement from baseline in the Eczema Area and Severity Index (EASI-75) score six months after treatment initiation. • Proof of maintenance of EASI-75 response from baseline must be provided for subsequent authorizations. **Clinical Note:** • Not to be used in combination with phototherapy or immunosuppressant drugs (e.g., methotrexate, cyclosporine). **Claim Notes:** • The patient must be under the care of a dermatologist. • Approvals will be for a maximum of 600 mg at week 0, then 300 mg every two weeks thereafter. • Initial approval period: 6 months. • Renewal approval period: 1 year.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Rozlytrek	100mg Cap	02495007	DNP	E (SFC)	HLR
(entrectinib)	200mg Cap	02495015	DNP	E (SFC)	HLR
Criteria	• For the first-line treatment of patients with ROS-1 positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer (NSCLC). **Clinical Notes:** • Patients should have a good performance status. • Treatment should continue until disease progression or unacceptable toxicity.				

Criteria Update

The following indication has been added to existing criteria effective **November 30, 2021.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Cabometyx (cabozantinib)	20mg Tab	02480824	DNP	E (SFC)	IPS
	40mg Tab	02480832	DNP	E (SFC)	IPS
	60mg Tab	02480840	DNP	E (SFC)	IPS
Criteria	• For the treatment of patients with unresectable hepatocellular carcinoma (HCC) in the second line setting who have experienced disease progression on sorafenib or lenvatinib and meet all of the following criteria: o Child-Pugh class status of A o ECOG performance status of 0 or 1 • Treatment should continue until disease progression or unacceptable toxicity. **Clinical Notes:** • Patients with disease progression on regorafenib are not eligible for reimbursement of cabozantinib. • Patients who are unable to tolerate regorafinib may be switched to cabozantinib if there is no disease progression and provided all other funding criteria are met. • Patients with disease progression on atezolizumab in combination with bevacizumab are not eligible for reimbursement of cabozantinib.				

Cystic Fibrosis Therapies

Kalydeco, Orkambi, and Trikafta are not funded in the Pharmacare Programs. However, they are funded through the Cystic Fibrosis Program with specific criteria, effective **November 18, 2021.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Kalydeco	150mg Tab	02397412	N/A	**Non Insured**	VTX
Orkambi	125mg/200mg Tab	02451379	N/A	**Non Insured**	VTX
Orkambi	125mg/100mg Tab	02463040	N/A	**Non Insured**	VTX
Orkambi	125mg/100mg Sachet	02483831	N/A	**Non Insured**	VTX
Orkambi	188mg/150mg Sachet	02483858	N/A	**Non Insured**	VTX
Trikafta	100mg/50mg/75mg and 150mg Tab	02517140	N/A	**Non Insured**	VTX

New Products

Effective **November 30, 2021,** the following new products have been added to the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Creon 35 Minimicrospheres	35000 U/35700 U/2240 U	02494639	DNP	SF	BGP
Jamp-Hydrocortisone Acetate	1% Cream	80057178	DNP	SF	JPC
KYE-Escitalopram	15mg Tab	02512653	DNP	SFC	KYE
Suboxone	2mg/0.5mg Film	02502313	DNP	SF	ICL
Suboxone	4mg/1mg Film	02502321	DNP	SF	ICL
Suboxone	8mg/2mg Film	02502348	DNP	SF	ICL
Suboxone	12mg/3mg Film	02502356	DNP	SF	ICL
Tamsulosin	0.4mg Cap	02319217	DNP	SF	SDZ
Trintellix	5mg Tab	02432919	DNP	SFC	LBK
Trintellix	10mg Tab	02432927	DNP	SFC	LBK
Trintellix	20mg Tab	02432943	DNP	SFC	LBK
Trurapi	100U/mL Cartridges	02506564	DNP	SFD	SAV
Trurapi	100U/mL Prefilled Pen	02506572	DNP	SFD	SAV

Delisted Products

As of December 15, 2021, NovoRapid Penfill and Flextouch will be delisted and existing patients will be grandfathered for coverage. NovoRapid vials will remain a full benefit. Note that effective **November 30, 2021,** Pharmacare will begin funding the first biosimilar insulin aspart – Trurapi as a full benefit.

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	AGA - Amgen Canada Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	BGP - BGP Pharma Inc.
P - Pharmacist	- Family Pharmacare	FKB - Fresenius Kabi Canada
M - Midwife	C - Drug Assistance for Cancer Patients	HLR - Hoffmann-LaRoche Limited
O - Optometrist	D - Diabetes Assistance Program	ICL - Indivior Canada Limited
	E - Exception status applies	IPS - Ipsen Biopharmaceuticals Canada Inc.
		JPC - Jamp Pharma Corporation
		KYE - KYE Pharmaceuticals Inc.
		LBK - Lundbeck Inc.
		ORG - Organon Canada LTD
		SAV - Sanofi-Aventis Canada Inc.
		SDZ - Sandoz Canada Incorporated
		VAL - Valeo Pharma Inc
		VTX - Vertex Pharmaceuticals

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Nova Scotia Formulary Updates

New Exception Status Benefits

The following new products have been listed with the following criteria, effective **immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Avsola (infliximab)	100mg Pws for Inj	02496933	DNP	E (SF)	AGA
Criteria	• Please refer to the Pharmacare Formulary (https://novascotia.ca/dhw/pharmacare/formulary.asp) for the infliximab criteria. **For infliximab-naïve patients whose infliximab therapy is initiated after June 1, 2016, an infliximab biosimilar will be the product approved.**				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Sporanox and generics (itraconazole)	10mg/mL Oral Sol	Various	DNP	E (SFC)	VAR
Criteria	• For the treatment of immunocompromised adult patients with oral and/or esophageal candidiasis. **Clinical Note:** • Itraconazole oral solution is not interchangeable with itraconazole capsules due to differences in bioavailablilty.				

New Products

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Inclunox	30mg/0.3mL Syringe Inj	02507501	DNP	SFC	SDZ
Inclunox	40mg/0.4mL Syringe Inj	02507528	DNP	SFC	SDZ
Inclunox	60mg/0.6mL Syringe Inj	02507536	DNP	SFC	SDZ
Inclunox	80mg/0.8mL Syringe Inj	02507544	DNP	SFC	SDZ
Inclunox	100mg/mL Syringe Inj	02507552	DNP	SFC	SDZ
Inclunox HP	120mg/0.8mL Syringe Inj	02507560	DNP	SFC	SDZ
Inclunox HP	150mg/mL Syringe Inj	02507579	DNP	SFC	SDZ
Jamp-Amlodipine	2.5mg Tab	02357186	DNP	SF	JPC
Nexplanon	68mg Implant	02499509	DNP	F	ORG
Noromby	30mg/0.3mL Syringe Inj	02506459	DNP	SFC	JNO
Noromby	40mg/0.4mL Syringe Inj	02506467	DNP	SFC	JNO
Noromby	60mg/0.6mL Syringe Inj	02506475	DNP	SFC	JNO
Noromby	80mg/0.8mL Syringe Inj	02506483	DNP	SFC	JNO
Noromby	100mg/mL Syringe Inj	02506491	DNP	SFC	JNO
Noromby HP	120mg/0.8mL Syringe Inj	02506505	DNP	SFC	JNO
Noromby HP	150mg/mL Syringe Inj	02506513	DNP	SFC	JNO
Redesca	30mg/0.3mL Syringe Inj	02509075	DNP	SFC	VAL
Redesca	40mg/0.4mL Syringe Inj	02509083	DNP	SFC	VAL
Redesca	60mg/0.6mL Syringe Inj	02509091	DNP	SFC	VAL
Redesca	80mg/0.8mL Syringe Inj	02509105	DNP	SFC	VAL
Redesca	100mg/mL Syringe Inj	02509113	DNP	SFC	VAL
Redesca	300mg/3mL Vial	02509121	DNP	SFC	VAL
Redesca HP	120mg/0.8mL Syringe Inj	02509148	DNP	SFC	VAL
Redesca HP	150mg/mL Syringe Inj	02509156	DNP	SFC	VAL

Delisted Products

As of January 15, 2022, all currently listed Lovenox (enoxaparin) products will be delisted and existing patients will be grandfathered for coverage. Note that effective December 31, 2021, Pharmacare will begin funding enoxaparin biosimilars, Inclunox, Noromby and Redesca, as full benefits.

Changes to Benefit Status

The following categories will be listed as full benefits, effective **January 3, 2022.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Itraconazole (Sporanox and generic brands)	100mg Cap	Various	DNP	SFC	VAR
Terbinafine (Lamisil and generic brands)	250mg Tab	Various	DNP	SF	VAR
Zoledronic Acid (Aclasta and generic brands)	5mg/100mL Inj	Various	DNP	SF	VAR

Legend

PRESCRIBER CODES		BENEFIT STATUS		MANUFACTURER CODES	
D	- Physician / Dentist	S	- Seniors' Pharmacare	AGA	- Amgen Canada Inc
N	- Nurse Practitioner	F	- Community Services Pharmacare	JNO	- Juno Pharmaceuticals Corp
P	- Pharmacist		- Family Pharmacare	JPC	- Jamp Pharma Corporation
M	- Midwife	C	- Drug Assistance for Cancer Patients	ORG	- Organon Canada LTD
O	- Optometrist	D	- Diabetes Assistance Program	SDZ	- Sandoz Canada Incorporated
		E	- Exception status applies	VAL	- Valeo Pharma Inc.
				VAR	- *various manufacturers*