JANUARY 2020 • VOLUME 20-01
PHYSICIANS' EDITION

NOVA SCOTIA

PharmacareNEWS

inside

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
Skyrizi (risankizumab)	75mg/ 0.83mL Pre-filled Inj	02487454	DNP	E (SF)	ABV
Criteria	• For patients with severe, debilitating chronic plaque psoriasis (PsO) who meet all of the following criteria: ○ Body Surface Area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genitals ○ Failure to respond to, contraindication to or intolerant of methotrexate and cyclosporine ○ Failure to respond 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: ○ ≥75% reduction in the Psoriasis Area and Severity Index (PASI) score, OR ○ ≥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				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Skyrizi (risankizumab)	75mg/ 0.83mL Pre-filled Inj	02487454	DNP	E (SF)	ABV
Criteria	**Clinical Note:** • Treatment should be discontinued if a response has not been demonstrated by 16 weeks.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Probuphine (buprenorphine hydrochloride)	80mg Implant Kit	02474921	DN	E (SF)	KNI
Criteria	• For the treatment of patients with opioid use disorder who have been stabilized on a daily dose of no more than 8mg of sublingual buprenorphine for the preceding 90 days.				

Criteria Update

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Kalydeco (ivacaftor)	150mg Tab	02397412	DNP	E (SF)	VTX
Criteria	• For the treatment of cystic fibrosis in patients who are: ○ age 6 years and older and have one of the following cystic fibrosis transmembrane conductance regulator (CFTR) gene mutations: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R; or ○ age 18 years and older with an R117H mutation in the CFTR gene.				

Criteria Update Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Kalydeco (ivacaftor)	150mg Tab	02397412	DNP	E (SF)	VTX

Criteria

Renewal criteria[1]:

- Renewal requests will be considered in patients with documented response to treatment as evidenced by the following:
    - In cases where the baseline sweat chloride levels were greater than 60 mmol/L:
        - the patient's sweat chloride level fell below 60 mmol/L; or
        - the patient's sweat chloride level falls by at least 30%
    - In cases where the baseline sweat chloride levels were below 60 mmol/L:
        - the patient's sweat chloride level falls by at least 30%; or
        - the patient demonstrates a sustained absolute improvement in FEV_1 of at least 5% when compared to the FEV_1 test conducted prior to starting therapy. FEV_1 will be compared with the baseline pre-treatment level one month and three months after starting treatment

Clinical Note:

- The patient's sweat chloride level and FEV_1 must be provided with each request.
- A sweat chloride test must be performed within a few months of starting ivacaftor therapy to determine if sweat chloride levels are reducing.
    - If the expected reduction occurs, a sweat chloride test must be performed again 6 months after starting therapy to determine if the full reduction has been achieved. Thereafter, sweat chloride levels must be checked annually.
    - If the expected reduction does not occur, a sweat chloride test should be performed again one week later. If the criteria are not met, coverage will be discontinued.

Claim Notes:

- Approved dose: 150mg every 12 hours.
- Approval period: 1 year.

1. It should be noted that, while baseline sweat chloride levels and FEV_1 are not required to meet initial approval criteria for ivacaftor, these parameters may be used to evaluate the effect of ivacaftor upon renewal of the request. It is important that the physician measures baseline sweat chloride levels and FEV_1 and provides this information upon renewal to avoid delays in the assessment of the renewal funding decision as these measurements may be required to evaluate renewal requests.

Non-Insured Products

The following product 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
Biktarvy	50mg/200mg/25mg Tab	02478579	N/A	**Not Insured**	GIL

The following product will not be insured in the Pharmacare Programs; however, it will be funded through the Exception Drug Fund.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Brineura	150mg/5mL	02484013	N/A	**Not Insured**	BMR

Change in Benefit Status

Effective immediately, Lansoprazole Oral Suspension (PIN 00903192) will be a full benefit for patients 19 years and under.

Criteria Codes for Prevacid FasTab 15mg and 30mg

Effective immediately, criteria codes have been added for the use of standard dose* Prevacid FasTab 15mg and 30mg.

[**Criteria code 37]** For patients who require the use of a proton pump inhibitor and require administration through a feeding tube.

[Criteria code 38] For patients 19 years of age and younger, who require the use of a proton pump inhibitor and who cannot use a tablet or capsule.

***Maximum 425 tablets per year**

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ABV - AbbVie Corporation
N - Nurse Practitioner	F - Community Services Pharmacare	BMR - BioMarin Pharmaceuticals Canada
P - Pharmacist	- Family Pharmacare	
M - Midwife	C - Drug Assistance for Cancer Patients	GIL - Gilead Sciences Inc.
O - Optometrist	D - Diabetes Assistance Program	KNI - Knight Therapeutics Inc.
	E - Exception status applies	VTX - Vertex Pharmaceuticals

FEBRUARY 2020 • VOLUME 20-02
PHYSICIANS' EDITION

NOVA SCOTIA

PharmacareNEWS

inside

Nova Scotia Formulary Updates

New Form for Oral Diabetes Treatments

The request form for oral diabetes agents has been revised to provide clarity to coverage parameters, in particular when insulin is not an option. The new form also requires that prescribers provide the patient's most recent A1C.

The request form for second line therapy for patients at high cardiovascular risk remains the same.

The new form can found at the following link:
https://novascotia.ca/dhw/pharmacare/exception-status-drugs.asp

New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Cubicin RF (Daptomycin)	500mg/ 10mL Single-Use Vial	02465493	DNP	E (SFC)	SNV
Criteria	• For the treatment of patients with resistant gram-positive infections, including methicillin-resistant Staphylococcus aureus (MRSA) who failed to respond, or have a contraindication or intolerance to vancomycin, or for whom IV vancomycin is not appropriate. **Clinical Note:** • Daptomycin is inhibited by pulmonary surfactant and should not be used to treat respiratory tract infections. **Claim Note:** • Must be prescribed by, or in consultation with, an infectious disease specialist or medical microbiologist.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Duodopa (levodopa/ carbidopa)	20mg/5mg Intestinal Gel Cassettes	02292165	DNP	E (SF)	ABV

Criteria	• For the treatment of patients with advanced levodopa-responsive Parkinson's Disease (PD) who meet all of the following criteria:
	  ○ Experiences severe disability with at least 25% of the waking day in the off state and/or ongoing levodopa-induced dyskinesias, despite having tried frequent dosing of levodopa (at least five doses per day).
	  ○ Have received an adequate trial of maximally tolerated doses of levodopa, with demonstrated clinical response.
	  ○ Have failed an adequate trial of the following adjunctive medications, if not contraindicated and/or contrary to the clinical judgment of prescriber: entacapone, a dopamine agonist, a monoamine oxidase-B (MAO-B) inhibitor and amantadine.
	  ○ Must be able to administer the medication and care for the administration port and infusion pump. Alternatively, trained personnel or a care partner must be available to perform these tasks reliably.
	Exclusion Criteria:
	• Patients with a contraindication to the insertion of a PEG-J tube.
	• Patients with severe psychosis or dementia.
	Renewal Criteria:
	• Patients continue to demonstrate a significant reduction in the time spent in the off state and/or in ongoing levodopa-induced dyskinesias, along with and an improvement in the related disability.
	Clinical Note:
	• Time in the off state, frequency of motor fluctuations, and severity of associated disability should be assessed by a movement disorder subspecialist and be based on an adequate and reliable account from longitudinal specialist care, clinical interview of a patient and/or care partner, or motor symptom diary.
	Claim Notes:
	• Must be prescribed by a movement disorder subspecialist who has appropriate training in the use of Duodopa and is practicing in a movement disorder clinic that provides ongoing management and support for patients receiving treatment with Duodopa.
	• Approval period: 1 year.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Glatect (glatiramer acetate)	20mg Pre-Filled Syringe	02460661	DNP	E (SF)	PDP
Criteria	**For glatiramer acetate-naïve patients whose glatiramer acetate therapy is initiated after April 1, 2020, the Glatect brand will be the product approved.** Prescribed by a neurologist with experience in the treatment of multiple sclerosis for patients who meet the following criteria: **Treatment Initiation:** • Diagnosis of Multiple Sclerosis with a relapsing course*: o Includes relapsing-remitting MS and secondary progressive MS with clear superimposed relapses; o Does not include primary progressive MS, progressive-relapsing or secondary progressive MS without relapses; and o Disability judged to be equivalent to Expanded Disability Status Score (EDSS) of 5.5 or less (exceptions are permitted in special cases). **Renewal:** • EDSS not greater than 6.0 for at least 12 months in the absence of relapses. • Patients must be assessed for compliance and for any therapy related side effects that are intolerable. **Exclusions:** • Concurrent illness likely to alter compliance or substantially reduce life expectancy * Relapsing course is defined as evidence of one relapse in the past 18 months or two relapses in the past 3 years.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tygacil (tigecycline)	50mg Vial	02285401	DNP	E (SFC)	PFI
Criteria	• For the treatment of patients with multi-drug resistant infections when alternative agents are not an option. **Claim Note:** • Must be prescribed by, or in consultation with, an infectious disease specialist or medical microbiologist.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Zerbaxa (ceftolozane/ tazobactam)	1g/0.5g Vial	02446901	DNP	E (SFC)	FRS
Criteria	• For the treatment of patients with multidrug-resistant gram-negative infections, specifically caused by extended spectrum beta lactamase (ESBL)-producing Enterobacteriaceae and multidrug-resistant Pseudomonas aeruginosa when alternative agents are not an option. **Claim Notes:** • Must be prescribed by, or in consultation with, an infectious disease specialist or medical microbiologist.				

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
AmBisome	50mg/Vial	02241630	DNP	SFC	GIL
Cancidas IV	50mg Pwd for Inj	02244265	DNP	SFC	FRS
Cancidas IV	70mg Pwd for Inj	02244266	DNP	SFC	FRS
Fulvestrant	50mg/mL	Various	DNP	SFC	VAR
pms-Fluoxetine	40mg Cap	02464640	DNP	SFC	PMS
pms-Fluoxetine	60mg Cap	02464659	DNP	SFC	PMS

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ABV - AbbVie Corporation
N - Nurse Practitioner	F - Community Services Pharmacare	FRS - Merck Canada Ltd.
P - Pharmacist	- Family Pharmacare	GIL - Gilead Sciences Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	PDP - PendoPharm, Division of Pharmascience Inc.
O - Optometrist	D - Diabetes Assistance Program	PFI - Pfizer Canada Inc.
	E - Exception status applies	PMS - Pharmascience Inc.
		SNV - Sunovion Pharmaceuticals Canada Inc.

APRIL 2020 • VOLUME 20-03
PHYSICIANS' EDITION

NOVA SCOTIA

PharmacareNEWS

inside

Nova Scotia Formulary Updates

Extension of Coverage for Exception Status Medications

To support Nova Scotia residents and healthcare providers during the COVID-19 pandemic and to ensure Pharmacare beneficiaries have continued access to specific medications, the following changes are effective immediately:

- Approvals for coverage of exception status drugs that will be expiring before July 1, 2020 will be extended for an additional three months. For example, requests expiring May 23rd will now expire August 23rd. In addition, those that expired in February and have not already been renewed, have been extended to July 1, 2020.
- Usual quantity limits for biologics will continue to apply as per specific coverage criteria limits.
- This change applies to renewals for coverage. New requests for coverage should continue to be submitted as per usual processes.

New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ocrevus (ocrelizumab)	300mg/10mL Vial	02467224	DNP	E (SF)	HLR

Criteria

Primary Progressive Multiple Sclerosis

- For the treatment of adult patients with early primary progressive multiple sclerosis (PPMS) who meet all of the following criteria:
    - Confirmed diagnosis based on McDonald criteria
    - Recent Expanded Disability Status Scale (EDSS) score between 3.0 and 6.5
    - Recent Functional Systems Scale (FSS) score of at least 2 for the pyramidal functions component due to lower extremity findings
    - Disease duration of 10 years for those with an EDSS of less than or equal to 5 or disease duration less than 15 years for those with an EDSS greater than 5
    - Diagnostic imaging features characteristic of inflammatory activity
    - Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.

Clinical Note:

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

Relapsing Remitting Multiple Sclerosis

- For the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) who meet all of the following criteria:
    - Confirmed diagnosis based on McDonald criteria
    - Experienced one or more disabling relapses or new MRI activity in the last two years
    - Are fully ambulatory without aids (i.e., must provide a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 5.5)
    - Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.

Clinical Note:

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 6.

Claim Notes:

- Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
- Claims for Ocrevus 300mg/10mL Vial 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 PIN:
    - 00904527

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Fulphila (pegfilgrastim)	6mg/0.6mL (10mg/mL) PF Sol for Inj	02484153	DNP	E (SFC)	BGP
Lapelga (pegfilgrastim)	6mg Pre-filled Syringe	02474565	DNP	E (SFC)	APX
Criteria	• For the prevention of febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy with curative intent who: ○ are at high risk of febrile neutropenia due to chemotherapy regimen, co-morbidities or pre-existing severe neutropenia; or ○ have had an episode of febrile neutropenia, neutropenic sepsis or profound neutropenia in a previous cycle of chemotherapy; or ○ have had a dose reduction, or treatment delay greater than one week due to neutropenia. **Clinical Note:** • Patients with non-curative cancer receiving chemotherapy with palliative intent are not eligible for coverage of pegfilgrastim for prevention of febrile neutropenia.				

Criteria Update

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tafinlar (dabrafenib)	50mg Cap	02409607	DNP	E (SFC)	NVR
	75mg Cap	02409615	DNP	E (SFC)	NVR
Mekinist (trametinib)	0.5mg Tab	02409623	DNP	E (SFC)	NVR
	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]				

Criteria Update 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

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.
- 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.

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	APX - Apotex Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	BGP - BGP Pharma Inc
P - Pharmacist	- Family Pharmacare	HLR - Hoffmann-LaRoche Limited
M - Midwife	C - Drug Assistance for Cancer Patients	NVR - Novartis Pharmaceuticals Canada Inc.
O - Optometrist	D - Diabetes Assistance Program	
	E - Exception status applies	

MAY 2020 • VOLUME 20-04
PHYSICIANS' EDITION

NOVA SCOTIA

PharmacareNEWS

inside

Nova Scotia Formulary Updates

Correspondence Address Updates

The correspondence address submitted with your registration as a provider with Medavie will be used for all patient correspondence that Medavie sends you. This address must be accurate and appropriate for receiving and handling private patient information.

You are responsible under the Personal Health Information Act to ensure the patient information sent to your correspondence address is protected from unauthorized disclosure or use. If you need to change your address, prescribers must contact Medavie at provider@medavie.bluecross.ca to update your profile information.

New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Sublocade (buprenorphine)	100mg/0.5mL 300mg/1.5mL	02483084 02483092	DN DN	E (SF) E (SF)	ICL ICL
Criteria	• For the treatment of patients with opioid use disorder who have been stabilized on a dose of 8 mg to 24 mg per day of sublingual buprenorphine for a minimum of seven days. **Clinical Note:** • The patient must be under the care of a prescriber certified under the Sublocade Certification Program. **Claim Note:** • Approvals will be for one prefilled syringe per month.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Cotellic (cobimetinib)	20mg Tab	02452340	DNP	E (SFC)	HLR
Criteria	• For the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma when used in combination with vemurafenib. **Renewal Criteria:** • Written confirmation that the patient has responded to treatment and there is no evidence of disease progression. **Clinical Notes:** • Patients must have a good performance status. • If brain metastases are present, patients should be asymptomatic or have stable symptoms. • Treatment should be discontinued upon disease progression or unacceptable toxicity. **Claim Notes:** • Cobimetinib will not be reimbursed in patients who have progressed on BRAF and/or MEK inhibitor therapy.				

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 advanced or metastatic renal cell carcinoma (RCC) who have received at least one prior vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) therapy. Treatment may continue until clinically meaningful disease progression or unacceptable toxicity. **Clinical Notes:** • Patients with any histology (clear cell or non-clear cell) and IMDC risk are eligible. • For patients treated with a VEGF-TKI (sunitinib or pazopanib) first-line, cabozantinib may be used as either a second or third-line treatment option. If cabozantinib is used as second-line therapy, nivolumab may be used as third-line therapy or vice-versa. • For patients treated with nivolumab + ipilimumab first-line and VEGF TKI (sunitinib or pazopanib) second-line, either cabozantinib or axitinib may be used as third-line therapy. • Sequential use of cabozantinib and axitinib (as a single agent) is not funded except in the case of intolerance or contraindication.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Xeljanz XR (tofacitinib)	11mg XR Tab	02470608	DNP	E (SF)	PFI
Criteria	• 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 ≥ 20mg weekly (≥15mg if patient is ≥ 65 years of age) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks; OR ○ initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs such as hydroxychloroquine and sulfasalazine, for a minimum of 24 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 may take up to 24 weeks; however coverage of tofacitinib can be considered if no improvement is seen after 12 weeks of triple DMARD use. • If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) 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 or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented. • Must be prescribed by a rheumatologist. • Combined use with biologic DMARD will not be reimbursed				

Criteria Updates

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tagrisso (osimertinib)	40mg Tab 80mg Tab	02456214 02456222	DNP DNP	E (SFC) E (SFC)	AZE AZE
Criteria	• For the first-line treatment of patients with locally advanced (not amenable to curative-intent therapy) or metastatic non-small cell lung cancer (NSCLC) whose tumors have the following epidermal growth factor receptor (EGFR) mutations: exon 19 deletions [exon 19 del] or exon 21 [L858R] mutations. Eligible patients should be previously untreated in the locally advanced or metastatic setting and have a good performance status. Treatment may continue until clinically meaningful disease progression or unacceptable toxicity.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tagrisso (osimertinib)	40mg Tab 80mg Tab	02456214 02456222	DNP DNP	E (SFC) E (SFC)	AZE AZE
Criteria	• For the treatment of patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC) who have progressed on EGFR tyrosine kinase inhibitor (TKI) therapy, or as initial therapy in patients with a *de novo* EGFR T790M mutation. **Clinical Notes:** • Patients currently receiving alternate first-line EGFR TKI's (e.g. erlotinib, gefitinib, afatinib) whose tumors have the noted EGFR mutations (exon 19 del or L858R) may be switched to osimertinib provided they meet all other funding criteria and have not experienced disease progression. • Patients who have initiated treatment with chemotherapy prior to receiving results of the EGFR mutation status may be switched to osimertinib if otherwise eligible. • Osimertinib may be continued until there is evidence of disease progression or the development of unacceptable toxicity.				

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Zelboraf (vemurafenib)	240mg Tab	02380242	DNP	E (SFC)	HLR
Criteria	• For the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma when used alone or in combination with cobimetinib. **Renewal Criteria:** • Written confirmation that the patient has responded to treatment and there is no evidence of disease progression. **Clinical Notes:** • Patients must have a good performance status. • If brain metastases are present, patients should be asymptomatic or have stable symptoms. • Treatment should be discontinued upon disease progression or unacceptable toxicity. **Claim Note:** • Vemurafenib will not be reimbursed in patients who have progressed on BRAF and/or MEK inhibitor therapy.				

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
Izba	0.003% Oph Sol	02457997	DNP	SF	NVR

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	AZE - AstraZeneca Canada Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	HLR - Hoffmann-LaRoche Limited
P - Pharmacist	- Family Pharmacare	ICL - Indivior Canada Limited
M - Midwife	C - Drug Assistance for Cancer Patients	IPS - Ipsen Biopharmaceuticals Canada Inc.
O - Optometrist	D - Diabetes Assistance Program	NVR - Novartis Pharmaceuticals Canada Inc.
	E - Exception status applies	PFI - Pfizer Canada Inc.

JUNE 2020 • VOLUME 20-05
PHYSICIANS' EDITION

NOVA SCOTIA

PharmacareNEWS

inside

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
Erleada (apalutamide)	60mg Tab	02478374	DNP	E (SFC)	JAN

Criteria

- In combination with androgen deprivation therapy (ADT) for the treatment of patients with castration-resistant prostate cancer (CRPC) who have no detectable distant metastasis (M0) by either CT, MRI or technetium-99m bone scan and who are at high risk of developing metastases[1].
- Patients should have a good performance status and no risk factors for seizures. 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.
- Castrate levels of testosterone must be maintained.
- Patients with N1 disease, pelvic lymph nodes < 2cm in short axis located below the common iliac vessels are eligible for apalutamide.
- Apalutamide will not be funded for patients who experience disease progression on enzalutamide.
- Patients receiving apalutamide 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 apalutamide.

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Erleada (apalutamide)	60mg Tab	02478374	DNP	E (SFC)	JAN
Criteria	• Either abiraterone or enzalutamide may be used to treat metastatic CRPC in patients who discontinued apalutamide 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
Radicava (edaravone)	30mg/100mL IV Inj	02475472	DNP	E (SF)	MBT
Criteria	For the treatment of amyotrophic lateral sclerosis (ALS), if the following criteria are met: **Initiation Criteria** • Patient with a diagnosis of probable ALS or definite ALS; AND • Patient who meets all of the following: o has scores of at least two points on each item of the ALS Functional Rating Scale – Revised (ALSFRS-R) o has a forced vital capacity greater than or equal to 80% of predicted o has had ALS symptoms for two years or less o patient is not currently requiring permanent non-invasive or invasive ventilation. **Renewal Criteria** • Reimbursement of treatment should be discontinued in patients who meet any one of the following criteria: o patient becomes non-ambulatory (ALSFRS-R score ≤ 1 for item 8) AND is unable to cut food and feed themselves without assistance, irrespective of whether a gastrostomy is in place (ALSFRS-R score < 1 for item 5a or 5b); OR o patient requires permanent non-invasive or invasive ventilation. **Claim Notes:** • Patient must be under the care of a specialist with experience in the diagnosis and management of ALS. • Claims for Radicava 30mg/100mL IV Injection 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 PIN: o 00904538				

Criteria Updates

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Afinitor	2.5mg Tab	02369257	DNP	E (SFC)	NVR
(everolimus)	5mg Tab	02339501	DNP	E (SFC)	NVR
	10mg Tab	02339528	DNP	E (SFC)	NVR
Criteria	• For the treatment of patients with advanced or metastatic renal cell carcinoma following disease progression on tyrosine kinase inhibitor therapy. **Clinical Notes**: • Patients must have a good performance status. • Treatment should be discontinued upon disease progression or unacceptable toxicity. • Requests for everolimus will not be considered for patients who experience disease progression on axitinib, cabozantinib or nivolumab monotherapy.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Fibristal	5mg Tab	02408163	DNP	E (F)	ALL
(ulipristal acetate)					
Criteria	• For the treatment of adult women of reproductive age with moderate to severe uterine fibroids as either: o Pre-operative treatment in patients who are eligible for surgery; OR o Intermittent treatment in patients who are not eligible for surgery. **Clinical Note:** • Each course of treatment is three months in duration. **Claim Notes:** • The maximum quantity reimbursed is limited to four courses of treatment. • The patient must be under the care of a physician experienced in the management of gynecological conditions such as uterine fibroids.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Inlyta	1mg Tab	02389630	DNP	E (SFC)	PFI
(axitinib)	5mg Tab	02389649	DNP	E (SFC)	PFI
Criteria	• As second-line therapy for the treatment of patients with advanced or metastatic renal cell carcinoma (RCC), after failure of first-line tyrosine kinase inhibitor therapy. **OR** • As third-line therapy for the treatment of patients with advanced or metastatic renal cell carcinoma (RCC), after failure of first-line immunotherapy, and second-line tyrosine kinase inhibitor therapy. **Clinical Notes:** • Patients must have a good performance status. • Treatment should be discontinued upon disease progression or unacceptable toxicity. • Sequential use of axitinib and everolimus is not permitted except in the case of intolerability or contraindication. • 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. • Sequential use of cabozantanib and axitinib (as a single agent) is not funded except in the case of intolerance or contraindication. • Both clear cell and non-clear cell histology are eligible for treatment.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Nexavar	200mg Tab	02284227	DNP	E (SFC)	BAY
(sorafenib)					
Criteria	• For the treatment of patients with advanced or metastatic renal cell carcinoma when used as a second-line therapy following disease progression on cytokine therapy. **Clinical Notes:** • Patients must have a good performance status. • Treatment should be discontinued upon disease progression or unacceptable toxicity.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Sutent (sunitinib)	12.5mg Cap 25mg Cap 50mg Cap	02280795 02280809 02280817	DNP DNP DNP	E (SFC) E (SFC) E (SFC)	PFI PFI PFI
Criteria	• For patients with advanced or metastatic renal cell carcinoma as either first-line therapy, or second-line therapy after failure of first-line immunotherapy. **Clinical Notes:** • Patients must have a good performance status. • Treatment should be discontinued upon disease progression or unacceptable toxicity. • Sunitinib may not be used after another tyrosine kinase inhibitor (i.e., sorafenib, or pazopanib) as sequential therapy. • In the event of significant toxicity, a switch to another tyrosine kinase inhibitor (i.e., sorafenib or pazopanib) may be allowed. • Both clear cell and non-clear cell histology are eligible for treatment.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Votrient (pazopanib)	200mg Tab	02352303	DNP	E (SFC)	NVR
Criteria	• For patients with advanced or metastatic renal cell carcinoma as either first-line therapy, or second-line therapy after failure of first-line immunotherapy. **Clinical Notes:** • Patients must have a good performance status. • Treatment should be discontinued upon disease progression or unacceptable toxicity. • Pazopanib may not be used after another tyrosine kinase inhibitor (i.e., sorafenib, or sunitinib) as sequential therapy. • In the event of significant toxicity, a switch to another tyrosine kinase inhibitor (i.e., sorafenib or sunitinib) may be allowed. • Both clear cell and non-clear cell histology are eligible for treatment.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Venclexta (venetoclax)	10mg Tab	02458039	DNP	E (SFC)	ABV
	50mg Tab	02458047	DNP	E (SFC)	ABV
	100mg Tab	02458055	DNP	E (SFC)	ABV
	Starter Pack	02458063	DNP	E (SFC)	ABV
Criteria	• In **combination** with rituximab for the treatment of adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) who have received at least one prior therapy, irrespective of their 17p deletion status. Treatment should be continued until disease progression or unacceptable toxicity up to a maximum of two years, whichever comes first. **Clinical Notes**: • Patients who were previously treated with and responded to an anti-CD20 therapy (rituximab or obinutuzumab) will be eligible for treatment with the combination of venetoclax plus rituximab if they had a progression-free interval of 12 months or longer. • Patients currently receiving and responding to venetoclax monotherapy, and who have not achieved an adequate response are eligible to have rituximab added to venetoclax. Note: Venetoclax therapy is funded to a maximum of two years from the time rituximab is added. • Patients may be retreated with venetoclax plus rituximab if they responded to and completed two years of therapy with at least 12 months of progression-free interval. • Patients will be eligible for treatment with either ibrutinib, or idelalisib with rituximab following progression on venetoclax with rituximab if they have not received before and otherwise meet eligibility criteria.				

New Diabetic Product

The following product is a new listing to the Nova Scotia Formulary, effective immediately. The benefit status within the Nova Scotia Pharmacare Programs is indicated.

PRODUCT	DIN/PIN	PRESCRIBER	BENEFIT STATUS	MFR
Droplet Micron Pen Needle 34G x 3.5mm	97799086	DNP	SFD	SFA

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ABV - AbbVie Corporation
N - Nurse Practitioner	F - Community Services Pharmacare	ALL - Allergan Inc.
P - Pharmacist	- Family Pharmacare	BAY - Bayer Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	JAN - Janssen-Ortho Inc.
O - Optometrist	D - Diabetes Assistance Program	MBT - Mitsubishi Tanabe Pharma Canada
	E - Exception status applies	NVR - Novartis Pharmaceuticals Canada Inc.
		PFI - Pfizer Canada Inc.
		SFA - Strefa

JULY 2020 • VOLUME 20-06
PHHYSICIANS' EDITION

NOVA SCOTIA

PharmacareNEWS

inside

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
Elelyso (taliglucerase alfa)	200U/Vial Pws for Inj	02425637	DNP	E (SF)	PFI
Criteria	• For the treatment of patients with symptomatic Gaucher disease type 1 (GD1) for whom treatment with velaglucerase alfa is not tolerated or contraindicated. **Clinical Notes:** • Velaglucerase alfa is the preferred reimbursed enzyme replacement therapy for GD1. • Requests for patients currently using taliglucerase alfa who do not have a contraindication or intolerance to velaglucerase alfa will be considered for coverage of velaglucerase alfa only. • Requests for coverage must meet the criteria for diagnosis of GD1, indication for therapy and expected response to enzyme replacement therapy outlined below: **Initial Coverage** **Diagnosis** • The diagnosis of GD1 must have been established by the demonstration of specific deficiency of glucocerebrosidase (GCase) in tissue or cultured skin fibroblasts, or by demonstration of the presence, in tissue or peripheral blood leukocytes, of mutations in the GCase gene known to result in severe enzyme deficiency.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Elelyso (taliglucerase alfa)	200U/Vial Pws for Inj	02425637	DNP	E (SF)	PFI
Criteria	• Other potentially confounding diagnoses, such as Hodgkin disease or other storage disorders, must have been ruled out. The symptoms experienced by the patient should be shown to be attributable to GD1 and not another condition that might mimic it. • The patient should not have any GD1-related or other medical condition that might reasonably be expected to compromise their response to treatment. In some patients with GD1, secondary pathologic changes, such as avascular necrosis of bone, may already have occurred that would not be expected to respond to enzyme replacement. In such patients, reversal of the pathology is unlikely. **Disease Severity** Evidence of disease severity must be provided, and include at least one of the following: • **Hematological complications** o Hemoglobin <85% of lower limit of age- and sex-appropriate normal after other causes of anemia, such as iron deficiency, have been treated or ruled out. o Platelet count <50 x 10^9/L on two separate occasions at least one month apart. Higher cut offs may be considered in the event the patient is symptomatic with bleeding or bruising. o At least two episodes of severely symptomatic splenic infarcts confirmed by CT or other imaging of the abdomen. • **Skeletal complications** o A single acute bone crisis severe enough to require hospitalization or marked incapacitation. o Radiographic or MRI evidence of incipient destruction of any major joint (e.g., hips and shoulders) or significant worsening of bony pathology (e.g. marrow infiltration, avascular necrosis, and infarcts). o Spontaneous fractures with evidence from imaging studies that recurrence is likely. o Chronic bone pain causing significant loss of time from work or school and not controlled by administration of non-narcotic analgesics or anti-inflammatory drugs. o Note: Patients who are scheduled for major joint replacement surgery, made necessary by skeletal complications of GD1, should be treated with enzyme therapy at a dosage of at least 30 units/kg every 2 weeks for at least 6 months before the joint replacement surgery and the dose continued until rehabilitation from the surgery is complete.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Elelyso (taliglucerase alfa)	200U/Vial Pws for Inj	02425637	DNP	E (SF)	PFI

Criteria	• **Gastrointestinal complications**
	  ○ Evidence of significant liver dysfunction attributable to GD1, such as portal hypertension or impaired hepatic synthetic function. Elevation of transaminase levels with no evidence of portal hypertension or impairment in synthetic function is not an indication for ERT.
	  ○ Significant discomfort due to enlargement of the spleen or liver.
	• **Pulmonary complications**
	  ○ Evidence of clinically significant and/or progressive pulmonary disease due to GD1.
	• **Systemic complications**
	  ○ Growth failure in children: significant decrease in percentile linear growth over a 3 - 6 month period.
	Exclusion Criteria
	• Due to the absence of data demonstrating therapy of asymptomatic patients alters long term outcomes, asymptomatic patients will not be considered for coverage.
	• Data does not suggest that ERT is effective in improving central nervous system involvement in patients with Type 2 and 3 disease. Therefore, patients exhibiting primary neurological disease due to GD1 will not be considered for coverage. Treatment for patients at risk of neuronopathic disease should be guided by the non-neurological manifestations of their disease as outlined above and ERT should not be initiated in asymptomatic patients who have a genotype that increases their risk of neuronopathic involvement.
	Continued Coverage
	• Patients' disease severity must be re-assessed annually.
	• A patient may receive approval for further coverage for treatment where there is demonstrated clinical improvement based on the expected response outlined below:				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Elelyso (taliglucerase alfa)	200U/Vial Pws for Inj	02425637	DNP	E (SF)	PFI

Criteria	Indication for therapy	Expected Response
	Hemoglobin < 85% of lower limit of age and sex-appropriate normal	Increase hemoglobin levels to > 110 for women and children and > 120 for men
	Platelet count < 50 x 10^9/L on two separate occasions, or bleeding complications associated with thrombocytopenia irrespective of the platelet count	Increase platelet count to level sufficient to prevent spontaneous bleeding
		Normalization of platelet count in splenectomized patients
		In patients with intact spleen, an increase of at least 1.5X baseline value
	Two episodes of severely symptomatic splenic infarcts	Reduction of spleen volume by 50%
		Prevention of further splenic infarcts
	Acute bone crises	Prevent bone crises
	Radiographic or MRI evidence of incipient destruction of any major joint	Improvement in imaging parameters (either MRI, QCSI[1], or BMD)
	Spontaneous fractures	Prevention of further fractures
	Chronic bone pain	Reduce bone pain
	Major joint replacement surgery	Optimize surgical outcome
	Significant hepatic dysfunction	Improvement in hepatic function
	Symptomatic hepatosplenomegaly	Reduction of spleen volume by 50%
		Reduction in liver volume by 30%

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Elelyso (taliglucerase alfa)	200U/Vial Pws for Inj	02425637	DNP	E (SF)	PFI

Criteria	Indication for therapy	Expected Response
	Progressive pulmonary disease due to GD1	Improvement in pulmonary hypertension[2]
		Improvement in oxygenation
		Reversal of hepatopulmonary syndrome
	Growth failure in children	Return to normal range of growth parameters

1. QCSI- quantitative chemical shift imaging
2. May require adjuvant treatment for pulmonary hypertension

Discontinuation of Coverage

- Renewals will NOT be approved if:
  - The patient or the patient's specialist fails to comply adequately with treatment or measures taken to evaluate the effectiveness of the therapy (e.g. monitoring for expected response).
  - Therapy fails to relieve the symptoms of disease that originally resulted in the patient being approved for treatment.

Claim Notes:

- Approvals will be for a maximum of 60 units/kg every 2 weeks.
- Initial Approval: 6 months.
- Renewal Approval: 1 year.
- 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:
  - 00904383
  - 00904385

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Mavenclad (cladribine)	10mg Tab	02470179	DNP	E (SF)	EMD

Criteria

- For the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) who meet all the following criteria:
  - Confirmed diagnosis based on McDonald criteria.
  - Has experienced one or more disabling relapses or new MRI activity in the past year.

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Mavenclad (cladribine)	10mg Tab	02470179	DNP	E (SF)	EMD
Criteria	○ Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5). ○ Refractory or intolerant to at least one disease modifying therapy (e.g., interferon, glatiramer, dimethyl fumarate, teriflunomide, ocrelizumab). **Clinical Notes:** • Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7. • A relapse is defined as the appearance of new or worsening neurological symptoms in the absence of fever or infection, lasting at least 24 hours yet preceded by stability for at least one month and accompanied by new objective neurological findings observed through evaluation by a neurologist. **Claim Notes:** • Must be prescribed by a neurologist with experience in the treatment of multiple sclerosis. • Approvals will be for 1.75mg/kg to a maximum of 200mg per treatment year. • Approval period: 2 years. • 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: ○ 00904524 ○ 00904525 ○ 00904526				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Mictoryl (propiverine hydrochloride)	5mg Tab	02460289	DNP	E (F)	DUI
Criteria	• For the treatment of overactive bladder with symptoms of urgency incontinence and/or urinary frequency and urgency in pediatric patients under 18 years of age.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
VPRIV (velaglucerase alfa)	400U/Vial Pws for Inj	02357119	DNP	E (SF)	SHI

Criteria

- For the treatment of patients with symptomatic Gaucher disease type 1 (GD1) for whom treatment with velaglucerase alfa is tolerated or not contraindicated.

Clinical Notes:

- Velaglucerase alfa is the preferred reimbursed enzyme replacement therapy (i.e. first tier) for all new and existing GD1.
- Requests for patients currently using taliglucerase alfa who do not have a contraindication or intolerance to velaglucerase alfa will be switched to velaglucerase alfa only.
- Requests for coverage must meet the criteria for diagnosis of GD1, indication for therapy and expected response to enzyme replacement therapy outlined below:

Initial Coverage

Diagnosis

- The diagnosis of GD1 must have been established by the demonstration of specific deficiency of glucocerebrosidase (GCase) in tissue or cultured skin fibroblasts, or by demonstration of the presence, in tissue or peripheral blood leukocytes, of mutations in the GCase gene known to result in severe enzyme deficiency.
- Other potentially confounding diagnoses, such as Hodgkin disease or other storage disorders, must have been ruled out. The symptoms experienced by the patient should be shown to be attributable to GD1 and not another condition that might mimic it.
- The patient should not have any GD1-related or other medical condition that might reasonably be expected to compromise their response to treatment. In some patients with GD1, secondary pathologic changes, such as avascular necrosis of bone, may already have occurred that would not be expected to respond to enzyme replacement. In such patients, reversal of the pathology is unlikely.

Disease Severity

Evidence of disease severity must be provided, and include at least one of the following:

- **Hematological complications**
  - Hemoglobin <85% of lower limit of age- and sex-appropriate normal after other causes of anemia, such as iron deficiency, have been treated or ruled out.
  - Platelet count <50 x 10^9/L on two separate occasions at least one month apart. Higher cut offs may be considered in the event the patient is symptomatic with bleeding or bruising.
  - At least two episodes of severely symptomatic splenic infarcts confirmed by CT or other imaging of the abdomen.
- **Skeletal complications**
  - A single acute bone crisis severe enough to require hospitalization or marked incapacitation.

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
VPRIV (velaglucerase alfa)	400U/Vial Pws for Inj	02357119	DNP	E (SF)	SHI

Criteria

- Radiographic or MRI evidence of incipient destruction of any major joint (e.g., hips and shoulders) or significant worsening of bony pathology (e.g. marrow infiltration, avascular necrosis, and infarcts).
- Spontaneous fractures with evidence from imaging studies that recurrence is likely.
- Chronic bone pain causing significant loss of time from work or school and not controlled by administration of non-narcotic analgesics or anti-inflammatory drugs.
- Note: Patients who are scheduled for major joint replacement surgery, made necessary by skeletal complications of GD1, should be treated with enzyme therapy at a dosage of at least 30 units/kg every 2 weeks for at least 6 months before the joint replacement surgery and the dose continued until rehabilitation from the surgery is complete.

- **Gastrointestinal complications**
  - Evidence of significant liver dysfunction attributable to GD1, such as portal hypertension or impaired hepatic synthetic function. Elevation of transaminase levels with no evidence of portal hypertension or impairment in synthetic function is not an indication for ERT.
  - Significant discomfort due to enlargement of the spleen or liver.
- **Pulmonary complications**
  - Evidence of clinically significant and/or progressive pulmonary disease due to GD1.
- **Systemic complications**
  - Growth failure in children: significant decrease in percentile linear growth over a 3 - 6 month period.

Exclusion Criteria

- Due to the absence of data demonstrating therapy of asymptomatic patients alters long term outcomes, asymptomatic patients will not be considered for coverage.
- Data does not suggest that ERT is effective in improving central nervous system involvement in patients with Type 2 and 3 disease. Therefore, patients exhibiting primary neurological disease due to GD1 will not be considered for coverage. Treatment for patients at risk of neuronopathic disease should be guided by the non-neurological manifestations of their disease as outlined above and ERT should not be initiated in asymptomatic patients who have a genotype that increases their risk of neuronopathic involvement.

Continued Coverage

- Patients' disease severity must be re-assessed annually.
  - A patient may receive approval for further coverage for treatment where there is demonstrated clinical improvement based on the expected response outlined below:

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
VPRIV (velaglucerase alfa)	400U/Vial Pws for Inj	02357119	DNP	E (SF)	SHI

Criteria	Indication for therapy	Expected Response
	Hemoglobin < 85% of lower limit of age and sex-appropriate normal	Increase hemoglobin levels to > 110 for women and children and > 120 for men
	Platelet count < 50 x 10^9/L on two separate occasions, or bleeding complications associated with thrombocytopenia irrespective of the platelet count	Increase platelet count to level sufficient to prevent spontaneous bleeding
		Normalization of platelet count in splenectomized patients
		In patients with intact spleen, an increase of at least 1.5X baseline value
	Two episodes of severely symptomatic splenic infarcts	Reduction of spleen volume by 50%
		Prevention of further splenic infarcts
	Acute bone crises	Prevent bone crises
	Radiographic or MRI evidence of incipient destruction of any major joint	Improvement in imaging parameters (either MRI, QCSI[1], or BMD)
	Spontaneous fractures	Prevention of further fractures
	Chronic bone pain	Reduce bone pain
	Major joint replacement surgery	Optimize surgical outcome
	Significant hepatic dysfunction	Improvement in hepatic function
	Symptomatic hepatosplenomegaly	Reduction of spleen volume by 50%
		Reduction in liver volume by 30%
	Progressive pulmonary disease due to GD1	Improvement in pulmonary hypertension[2]
		Improvement in oxygenation
		Reversal of hepatopulmonary syndrome
	Growth failure in children	Return to normal range of growth parameters

1. QCSI- quantitative chemical shift imaging
2. May require adjuvant treatment for pulmonary hypertension

Discontinuation of Coverage

- Renewals will NOT be approved if:
  - The patient or the patient's specialist fails to comply adequately with treatment or measures taken to evaluate the effectiveness of the therapy (e.g. monitoring for expected response).
  - Therapy fails to relieve the symptoms of disease that originally resulted in the patient being approved for treatment.

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
VPRIV (velaglucerase alfa)	400U/Vial Pws for Inj	02357119	DNP	E (SF)	SHI
Criteria	**Claim Notes:** • Approvals will be for a maximum of 60 units/kg every 2 weeks. • Initial Approval: 6 months. • Renewal Approval: 1 year. • 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: o 00904378 o 00904379 o 00904380				

Criteria Updates

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Lenvima (lenvatinib)	4mg Compliance Pack	02484056	DNP	E (SFC)	EIS
	8mg Compliance Pack	02468220	DNP	E (SFC)	EIS
	12mg Compliance Pack	02484129	DNP	E (SFC)	EIS
Criteria	• For the first-line treatment of adult patients with unresectable or metastatic hepatocellular carcinoma who meet all the following criteria: o Child-Pugh class status of A. o ECOG performance status of 0 or 1. o Less than 50% liver involvement and no invasion of the bile duct or main portal vein. o No brain metastases or prior liver transplantation. **Clinical Notes:** • Treatment should be continued until disease progression or unacceptable toxicity. • Patients who are unable to tolerate lenvatinib may be switched to sorafenib if there is no disease progression and provided all other funding criteria are met. • Patients with disease progression on lenvatinib are not eligible for reimbursement of sorafenib.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Nexavar (Sorafenib)	200mg Tab	02284227	DNP	E (SFC)	BAY
Criteria	• As a single agent first line systemic therapy option in adult patients with a diagnosis of hepatocellular carcinoma (HCC) with Child-Pugh Class A liver dysfunction (mild hepatic impairment) with ECOG performance status 0-1; and who have either progression of disease, or who are not candidates for curative intent treatments (transplantation, hepatic resection), or other well established palliative interventions (ablation, transcatheter arterial chemo-embolization (TACE), internal radiation). **Clinical Note:** • Patients who are unable to tolerate sorafenib may be switched to lenvatinib if there is no disease progression and provided all other funding criteria are met. • Patients with disease progression on sorafenib are not eligible for reimbursement of lenvatinib.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Stivarga (Regorafenib)	40mg Tab	02403390	DNP	E (SFC)	BAY

Criteria	• For the treatment of patients with unresectable hepatocellular carcinoma (HCC) who have experienced disease progression on sorafenib or lenvatinib and meet all of the following criteria:
	  ○ Child-Pugh class status of A.
	  ○ ECOG performance status of 0 or 1.
	Clinical Note:
	• Treatment should continue until disease progression or unacceptable toxicity.
	• Patients with disease progression on sorafenib must have tolerated a minimum dose of 400 mg per day for at least 20 of the last 28 days of treatment.				

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
Nucala	100mg/mL Autoinjector	02492989	DNP	E (SF)	GSK
Nucala	100mg/mL Pre-filled Syringe	02492997	DNP	E (SF)	GSK
Vyzulta	0.024% Oph Sol	02484218	DNP	SF	BSL

New Form

New request form for Ocrevus can be found at the following link:

https://novascotia.ca/dhw/pharmacare/exception-status-drugs.asp

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	BAY - Bayer Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	BSL - Bausch Health, Canada Inc.
P - Pharmacist	- Family Pharmacare	DUI - Duchesnay Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	EIS - Eisai Limited
O - Optometrist	D - Diabetes Assistance Program	EMD - EMD Serono Canada Inc.
	E - Exception status applies	GSK - GlaxoSmithKline Inc.
		PFI - Pfizer Canada Inc.
		SHI - Shire Canada Inc.

AUGUST 2020 • VOLUME 20-07
PHYSICIANS' EDITION

NOVA SCOTIA

PharmacareNEWS

inside

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
Hemangiol (propranolol)	3.75mg/mL Sol	02457857	DNP	E (F)	PFB
Criteria	• For the treatment of patients with proliferating infantile hemangioma that is: ○ Life-or function-threatening OR ○ Ulcerated with pain or not responding to simple wound care measures OR ○ At risk of permanent scarring or disfigurement				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Strensiq (asfotase alfa)	18mg/0.45 mL Single Use Vial	02444615	DNP	E (F)	ALX
	28mg /0.7mL Single Use Vial	02444623	DNP	E (F)	ALX
	40mg/1mL Single Use Vial	02444631	DNP	E (F)	ALX
	80mg/0.8mL Single Use Vial	02444658	DNP	E (F)	ALX
Criteria	• For the treatment of patients with perinatal, infantile, or juvenile-onset hypophosphatasia (HPP).				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Strensiq	18mg/0.45 mL Single Use Vial	02444615	DNP	E (F)	ALX
(asfotase alfa)	28mg /0.7mL Single Use Vial	02444623	DNP	E (F)	ALX
	40mg/1mL Single Use Vial	02444631	DNP	E (F)	ALX
	80mg/0.8mL Single Use Vial	02444658	DNP	E (F)	ALX
Criteria	**Clinical Note:** • Eligibility for the treatment of HPP is determined by the Canadian HPP Clinical Expert Committee. Please contact the Nova Scotia Pharmacare Programs via fax at 1-888-594-4440 for the request form. **Claim Notes:** • Must be prescribed by a metabolic specialist with expertise in the diagnosis and management of HPP. • Claims for Strensiq 18mg/0.45mL, 28mg/0.7mL, 40mg/1mL and 80mg/0.8mL Single Use Vials that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions. Please refer to Appendix III of the Nova Scotia Formulary for additional PINs.				

Criteria Update

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Botox	50U/Vial	00999443	DNP	E (SF)	ALL
(Onabotulinumt-oxin A)	100U/Vial	01981501	DNP	E (SF)	ALL
Criteria	• For the treatment of overactive bladder (OAB) with symptoms of urgency, urgency incontinence, and urinary frequency, in adult patients who have an intolerance or insufficient response to an adequate trial of at least two other pharmacologic treatments (e.g. anticholinergics, mirabegron). **Renewal criteria:** • Requests for renewal should provide objective evidence of a treatment response, defined as a reduction of at least 50% in the frequency of urinary incontinence episodes. **Claim Notes:** • Must be prescribed and administered by a urologist. • Initial approval period: 12 weeks (one dose). • Renewal approval period: Maximum of 3 doses per year in responders, at a frequency of no more than once every twelve weeks.				

Changes to Insured Oral Compounded Solutions

Effective September 1st, 2020, all oral compounds listed on the Nova Scotia Formulary for children 12 years and under will now be benefits for individuals 19 years and younger if they clinically require this specialized format. Also, a number of oral compounds were added to the existing list of oral compounds under the Nova Scotia Pharmacare programs. The specific products can be found in the next update of the Nova Scotia Formulary.

The following oral compounds have moved to non-benefit status and will no longer be covered under the Nova Scotia Pharmacare Programs.

- Clotrimazole Oral Suspension
- Labetalol Oral Suspension
- Naproxen Oral Suspension

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

If the above information is not included and clearly legible, responses may be prevented or delayed.

Correction

Please be advised that there was an error made in the July 2020 Physicians' Bulletin concerning the benefit status of the following product. We apologize for any inconvenience.

New Products

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	CORRECT BENEFIT STATUS	MFR
Vyzulta	0.024% Oph Sol	02484218	DNP	E (SF)	SF	BSL

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ALL - Allergan Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	ALX - Alexion Pharma Canada Corp.
P - Pharmacist	- Family Pharmacare	BSL - Bausch Health, Canada Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	PFB - Pierre Fabre Dermo-Cosmétique Canada Inc
O - Optometrist	D - Diabetes Assistance Program	
	E - Exception status applies	

NOVEMBER 2020 • VOLUME 20-09
PHYSICIANS' EDITION

NOVA SCOTIA

PharmacareNEWS

inside

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
Kevzara (sarilumab)	150mg/1.14mL Prefilled Pen	02472961	DNP	E (SF)	SAV
	200mg/1.14mL Prefilled Pen	02472988	DNP	E (SF)	SAV
	150mg/1.14mL Prefilled Syringe	02460521	DNP	E (SF)	SAV
	200mg/1.14mL Prefilled Syringe	02460548	DNP	E (SF)	SAV
Criteria	• 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 ○ 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				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Kevzara (sarilumab)	150mg/1.14mL Prefilled Pen	02472961	DNP	E (SF)	SAV
	200mg/1.14mL Prefilled Pen	02472988	DNP	E (SF)	SAV
	150mg/1.14mL Prefilled Syringe	02460521	DNP	E (SF)	SAV
	200mg/1.14mL Prefilled Syringe	02460548	DNP	E (SF)	SAV
Criteria	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.				

Criteria Updates

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ibrance (palbociclib)	75mg Cap	02453150	DNP	E (SFC)	PFI
	100mg Cap	02453169	DNP	E (SFC)	PFI
	125mg Cap	02453177	DNP	E (SFC)	PFI
	75 mg Tab	02493535	DNP	E (SFC)	PFI
	100mg Tab	02493543	DNP	E (SFC)	PFI
	125mg Tab	02493551	DNP	E (SFC)	PFI
Criteria	**ER Positive, HER2-Negative Advanced Breast Cancer in Combination With an Aromatase Inhibitor (AI)** • In combination with an aromatase inhibitor (AI) (i.e. letrozole, anastrozole or exemestane) for the treatment of post-menopausal women with estrogen receptor (ER) positive, human epidermal growth factor receptor 2 (HER 2) negative advanced breast cancer who have not				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ibrance (palbociclib)	75mg Cap	02453150	DNP	E (SFC)	PFI
	100mg Cap	02453169	DNP	E (SFC)	PFI
	125mg Cap	02453177	DNP	E (SFC)	PFI
	75 mg Tab	02493535	DNP	E (SFC)	PFI
	100mg Tab	02493543	DNP	E (SFC)	PFI
	125mg Tab	02493551	DNP	E (SFC)	PFI

Criteria

received any prior endocrine-based treatment for metastatic disease. Patients may have received up to one prior line of chemotherapy for advanced disease.

Clinical Notes:

- Treatment should continue until unacceptable toxicity or disease progression.
- Patients should have a good performance status and not be resistant to prior (neo) adjuvant aromatase inhibitor therapy (i.e. have the potential to benefit from first-line endocrine based therapy), without active or uncontrolled metastases to the central nervous system.
- Patients will be eligible for either palbociclib plus an aromatase inhibitor in the first line setting or everolimus plus exemestane as a subsequent line of therapy, but not both therapies. Patients eligible include:
    - Pre and peri-menopausal patients (should be treated with a luteinizing hormone-releasing hormone (LHRH) agonist)
    - Males
    - Patients with bone-only metastases
    - Patients who are HER2 equivocal by FISH testing (these patients are HER2 negative)
    - Patients currently receiving first line aromatase inhibitor monotherapy for ER positive, HER2-negative metastatic breast cancer may have palbociclib added provided the above criteria is met.

HR Positive, HER2-Negative Advanced or Metastatic Breast Cancer in Combination With Fulvestrant

- In combination with fulvestrant for the treatment of patients with hormone receptor (HR) positive, HER 2 negative advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy. Patients may have also received up to one prior line of chemotherapy for advanced disease. Patients should have a good performance status, without active or uncontrolled metastases to the central nervous system and can be of any menopausal status (Perimenopausal and premenopausal women must be treated with an LHRH agonist).

Clinical Notes:

- Treatment should continue until unacceptable toxicity or disease progression.
- Patients who progress ≤ 12 months from (neo) adjuvant therapy are eligible for treatment with palbociclib plus fulvestrant.

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ibrance (palbociclib)	75mg Cap	02453150	DNP	E (SFC)	PFI
	100mg Cap	02453169	DNP	E (SFC)	PFI
	125mg Cap	02453177	DNP	E (SFC)	PFI
	75 mg Tab	02493535	DNP	E (SFC)	PFI
	100mg Tab	02493543	DNP	E (SFC)	PFI
	125mg Tab	02493551	DNP	E (SFC)	PFI
Criteria	• Patients who experience disease progression on prior CDK 4/6 inhibitor therapy, fulvestrant or everolimus are not eligible for treatment with palbociclib with fulvestrant. • Patients currently receiving fulvestrant monotherapy, and who have not progressed may have palbociclib added, provided they are CDK 4/6 inhibitor naïve and otherwise meet funding criteria. • Patients who previously received everolimus plus exemestane will be eligible for funding of palbociclib plus fulvestrant on progression, provided that treatment was started prior to funding of CDK 4/6 + fulvestrant, patient must be CDK 4/6 naïve and otherwise meet funding criteria.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Kisqali (ribociclib)	200mg Tab	02473569	DNP	E (SFC)	NVR
Criteria	**ER Positive, HER2-Negative Advanced Breast Cancer in Combination With an Aromatase Inhibitor (AI)** • In combination with an aromatase inhibitor (AI) (i.e. letrozole, anastrozole or exemestane) for the treatment of post-menopausal women with estrogen receptor (ER) positive, human epidermal growth factor receptor 2 (HER 2) negative advanced breast cancer who have not received any prior endocrine-based treatment for metastatic disease. Patients may have received up to one prior line of chemotherapy for advanced disease. **Clinical Notes**: • Treatment should continue until unacceptable toxicity or disease progression. • Patients should have a good performance status and not be resistant to prior (neo) adjuvant aromatase inhibitor therapy (i.e. have the potential to benefit from first-line endocrine based therapy), without active or uncontrolled metastases to the central nervous system. • Patients will be eligible for either ribociclib plus an aromatase inhibitor in the first line setting or everolimus plus exemestane as a subsequent line of therapy, but not both therapies. Patients eligible include: o Pre and peri-menopausal patients (should be treated with a luteinizing hormone-releasing hormone (LHRH) agonist) o Males				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Kisqali (ribociclib)	200mg Tab	02473569	DNP	E (SFC)	NVR
Criteria	○ Patients with bone-only metastases ○ Patients who are HER2 equivocal by FISH testing (these patients are HER2 negative) ○ Patients currently receiving first line aromatase inhibitor monotherapy for ER positive, HER2-negative metastatic breast cancer may have ribociclib added provided the above criteria is met. **HR Positive, HER2-Negative Advanced or Metastatic Breast Cancer in Combination With Fulvestrant** • In combination with fulvestrant for the treatment of patients with hormone receptor (HR) positive, HER 2 negative advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy. Patients may have also received up to one prior line of chemotherapy for advanced disease. Patients should have a good performance status, without active or uncontrolled metastases to the central nervous system and can be of any menopausal status (Perimenopausal and premenopausal women must be treated with an LHRH agonist). **Clinical Notes**: • Treatment should continue until unacceptable toxicity or disease progression. • Patients who progress ≤ 12 months from (neo) adjuvant therapy are eligible for treatment with ribociclib plus fulvestrant. Patients who experience disease progression on prior CDK 4/6 inhibitor therapy, fulvestrant or everolimus are not eligible for treatment with palbociclib with fulvestrant. • Patients currently receiving fulvestrant monotherapy, and who have not progressed may have ribociclib added, provided they are CDK 4/6 inhibitor naïve and otherwise meet funding criteria. • Patients who previously received everolimus plus exemestane will be eligible for funding of palbociclib plus fulvestrant on progression, provided that treatment was started prior to funding of CDK 4/6 + fulvestrant, patient must be CDK 4/6 naïve and otherwise meet funding criteria.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Maviret (glecaprevir/ pibrentasvir)	100mg/40mg Tab	02467550	DNP	E (SF)	ABV

Criteria	• For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C virus (HCV) who meet the following criteria:	**Approval Period**
	Genotypes 1, 2, 3, 4, 5 or 6 • Treatment-naïve	8 weeks
	Genotypes 1, 2, 4, 5 or 6 • Treatment-experienced with regimens containing peginterferon/ribavirin (PR) and/or sofosbuvir (SOF)	8 weeks (12 weeks with cirrhosis)
	Genotype 1 • NS5A inhibitor treatment-naïve and treatment-experienced with regimens containing: o Boceprevir/PR; or o Simeprevir (SMV)/SOF; or o SMV/PR; or o Telaprevir/PR	12 weeks
	Genotype 1 • NS3/4A inhibitor treatment-naïve and treatment-experienced with regimens containing: o Daclatasvir (DCV)/SOF; or o DCV/PR; or o Ledipasvir/SOF	16 weeks
	Genotype 3 Treatment-experienced with regimens containing PR and/or SOF	16 weeks
	• The following information is also required: o Lab-confirmed hepatitis C genotype 1, 2, 3, 4, 5 or 6 o Quantitative HCV RNA value within the last 6 months o Fibrosis stage **Clinical Note:** • 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.	

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Maviret (glecaprevir/ pibrentasvir)	100mg/40mg Tab	02467550	DNP	E (SF)	ABV
Criteria	**Claim Notes:** • Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other physician experienced in treating a patient with hepatitis C infection). • Claims will be limited to a 28-day supply.				

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ABV - AbbVie Corporation
N - Nurse Practitioner	F - Community Services Pharmacare - Family Pharmacare	NVR - Novartis Pharmaceuticals Canada Inc.
P - Pharmacist	C - Drug Assistance for Cancer Patients	PFI - Pfizer Canada Inc.
M - Midwife	D - Diabetes Assistance Program	SAV - Sanofi-Aventis Canada Inc.
O - Optometrist	E - Exception status applies	

DECEMBER 2020 • VOLUME 20-10
PHYSICIANS' EDITION

NOVA SCOTIA

PharmacareNEWS

inside

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
Cresemba	100mg Cap	02483971	DNP	E (SFC)	AVI
(isavuconaz-ole)	200mg Vial	02483998	DNP	E (SFC)	AVI
Criteria	• For the treatment of adult patients with invasive aspergillosis who have a contraindication, intolerance or have failed to respond to oral voriconazole and caspofungin. • For the treatment of adult patients with invasive mucormycosis. **Claim Notes:** • Must be prescribed by a hematologist or specialist in infectious diseases or medical microbiology. • Initial requests will be approved for a maximum of 3 months.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Triamcinolone Hexacetonide	20mg/mL Inj	02470632	DNP	E (F)	MDX
Criteria	• For the treatment of juvenile idiopathic arthritis.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Xarelto (rivaroxaban)	2.5mg Tab	02480808	DNP	E (SF)	BAY

Criteria

For use in combination with acetylsalicylic acid (75 mg to 100 mg) for the prevention of atherothrombotic events[1] in patients with concomitant coronary artery disease (CAD) and peripheral artery disease (PAD) who meet the following criteria:

- Patients with CAD are defined as having one or more of the following:
  - Myocardial infarction within the last 20 years.
  - Multi-vessel CAD (i.e., stenosis of ≥ 50% in two or more coronary arteries, or in one coronary territory if at least one other territory has been revascularized) with symptoms or history of stable or unstable angina.
  - Multi-vessel percutaneous coronary intervention.
  - Multi-vessel coronary artery bypass graft surgery.

  AND
- Patients with CAD as defined above, must also meet one of the following criteria:
  - Aged 65 years or older; OR
  - Aged younger than 65 years with documented atherosclerosis or revascularization involving at least two vascular beds (coronary and other vascular) or at least two additional risk factors (current smoker, diabetes mellitus, estimated glomerular filtration rate < 60 mL/min, heart failure, non-lacunar ischemic stroke 1 month or more ago).
- Patients with PAD are defined as having one or more of the following:
  - Previous aorto-femoral bypass surgery, limb bypass surgery, or percutaneous transluminal angioplasty revascularization of the iliac or infrainguinal arteries.
  - Previous limb or foot amputation for arterial vascular disease.
  - History of intermittent claudication and one or more of the following: an ankle-brachial index of less than 0.90, OR significant peripheral artery stenosis greater than or equal to 50% documented by angiography or duplex ultrasound.
  - Previous carotid revascularization or asymptomatic carotid artery stenosis greater than or equal to 50% diagnosed by angiography or duplex ultrasound.

Exclusion Criteria:

- Patients who have CAD or PAD alone; OR

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Xarelto (rivaroxaban)	2.5mg Tab	02480808	DNP	E (SF)	BAY
Criteria	• In patients with any one of the following characteristics: ○ At high risk of bleeding. ○ A history of stroke within one month of treatment initiation or any history of hemorrhagic or lacunar stroke. ○ Severe heart failure with a known ejection fraction less than 30% or New York Heart Association class III or IV symptoms. ○ An estimated glomerular filtration rate less than 15 mL/min. ○ Require dual antiplatelet therapy, other non-ASA antiplatelet therapy, or oral anticoagulant therapy. **Clinical Notes:** 1. Atherothrombotic events include stroke, myocardial infarction, cardiovascular death, acute limb ischemia and mortality.				

* The request form for Xarelto 2.5mg Tab can be found at the following link:

https://novascotia.ca/dhw/pharmacare/exception-status-drugs.asp

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ziextenzo (pegfilgrastim)	10mg/mL Inj	02497395	DNP	E (SFC)	SDZ
Criteria	• For the prevention of febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy with curative intent who: ○ are at high risk of febrile neutropenia due to chemotherapy regimen, co-morbidities or pre-existing severe neutropenia; or ○ have had an episode of febrile neutropenia, neutropenic sepsis or profound neutropenia in a previous cycle of chemotherapy; or ○ have had a dose reduction, or treatment delay greater than one week due to neutropenia. **Clinical Note:** • Patients with non-curative cancer receiving chemotherapy with palliative intent are not eligible for coverage of pegfilgrastim for prevention of febrile neutropenia.				

Criteria Updates

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Xtandi (enzalutamide)	40mg Cap	02407329	DNP	E (SFC)	ASL

Criteria

Metastatic Castration-Resistant Prostate Cancer (mCRPC)

- For the treatment of patients with metastatic castration-resistant prostate cancer.

Clinical Notes:

1. Patients should have a good performance status and no risk factors for seizures.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Requests for enzalutamide will not be considered for patients who experience disease progression on apalutamide.

Non-Metastatic Castration-Resistant Prostate Cancer (nmCRPC)

- 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 and no risk factors for seizures. 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.
- Castrate levels of testosterone must be maintained.
- Patients with N1 disease, pelvic lymph nodes < 2cm in short axis located below the common iliac vessels are eligible for enzalutamide.
- Enzalutamide will not be funded for patients who experience disease progression on apalutamide.
- Patients receiving enzalutamide for the treatment of non-metastatic CRPC will be eligible for funding of abiraterone at the time of disease progression to metastatic CRPC.

[1] High risk of developing metastases is defined as a prostate-specific antigen (PSA) doubling time of ≤ 10 months during continuous ADT

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Zytiga (abiraterone)	250mg Tab 500mg Tab	02371065 02457113	DNP DNP	E (SFC) E (SFC)	JAN JAN
Criteria	• For the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC). **Clinical Notes:** 1. Patients should have a good performance status. 2. Treatment should be discontinued upon disease progression or unacceptable toxicity.				

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
Amlodipine	2.5mg Tab	02492199	DNP	SF	JPC
Mezera	1g/ACT Foam Enema	02474026	DNP	SF	AVI
Mezera	1g/Supp	02474018	DNP	SF	AVI

Non-Insured Product

The following product 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
Dovato	50mg/300mg Tab	02491753	N/A	**Not Insured**	VIV

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	AVI - AVIR Pharma Inc.
P - Pharmacist	- Family Pharmacare	BAY - Bayer Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	JAN - Janssen-Orthho Inc.
O - Optometrist	D - Diabetes Assistance Program	JPC - Jamp Pharma Corporation
	E - Exception status applies	MDX - Medexus Inc.
		SDZ - Sandoz Canada Incorporated
		VIV - ViiV Health Care Inc.