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PHYSICIANS' EDITION

NOVA SCOTIA

PharmacareNEWS

inside

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
Crysvita (burosumab)	10mg/mL Vial	02483629	DNP	E (SF)	UGX
	20mg/mL Vial	02483637	DNP	E (SF)	UGX
	30mg/mL Vial	02483645	DNP	E (SF)	UGX

Criteria

Initiation Criteria:

- For the treatment of patients with X-linked hypophosphatemia (XLH) who meet all the following criteria:
  - Initiated in a pediatric patient who is at least one year of age and in whom epiphyseal closure has not yet occurred
  - Fasting hypophosphatemia
  - Normal renal function (defined as a serum creatinine below the age-adjusted upper limit of normal)
  - Radiographic evidence of rickets with a rickets severity score (RSS) of two or greater
  - Confirmed phosphate-regulating endopeptidase homolog, X-linked (PHEX) gene variant in either the patient or in a directly related family member with appropriate X-linked inheritance

Discontinuation Criteria:

- In pediatric patients under 18 years of age in whom epiphyseal closure has not yet occurred and who met the initiation criteria, treatment should be discontinued if:
  - there is no demonstrated improvement in the 12-month RSS total score from baseline RSS total score; or

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Crysvita (burosumab)	10mg/mL Vial 20mg/mL Vial 30mg/mL Vial	02483629 02483637 02483645	DNP DNP DNP	E (SF) E (SF) E (SF)	UGX UGX UGX
Criteria	○ the patient's RSS total score achieved after the first 12 months of therapy has not been maintained subsequently. • In adolescent patients who are 13 to 17 years of age in whom epiphyseal closure has occurred and who met the initiation criteria and initiated treatment as a pediatric patient, treatment should be discontinued if any of the following occur: ○ Hyperparathyroidism; or ○ Nephrocalcinosis; or ○ Evidence of fracture or pseudo-fracture based on radiographic assessment. • In adult patients who met the initiation criteria and initiated treatment as a pediatric patient, treatment should be discontinued if any of the following occur: ○ Hyperparathyroidism; or ○ Nephrocalcinosis; or ○ Evidence of fracture or pseudo-fracture based on radiographic assessment. **Claim Notes:** • Requests will not be considered for treatment-naïve adults. • Must be prescribed by a physician working in a multidisciplinary team of health care providers who are experienced in the diagnosis and management of XLH. • Approvals for children (1-17 years of age) will be up to a maximum of 90mg every 2 weeks. • Approvals for adults (18 years of age and older) will be up to a maximum of 90mg every 4 weeks. • Approval period: 1 year.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Entuzity (human insulin R)	500 U/mL KwikPen	02466864	DNP	E (SFD)	LIL
Criteria	• For the treatment of patients with diabetes mellitus with unacceptable glycemic control who require more than 200 units of insulin per day, with or without other therapies. **Claims Notes:** • Treatment must be initiated by an endocrinologist or prescriber with a specialty in endocrinology.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Calquence (acalabrutinib)	100mg Cap	02491788	DNP	E (SFC)	AZE
Criteria	**Previously Untreated Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)** • As a single agent treatment option for adult patients with previously untreated chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) for whom a fludarabine-based regimen is considered inappropriate due to high risk of relapse or refractory disease based on prognostic biomarkers. **Clinical Notes:** • High risk for relapse or refractory disease includes 17p deletion, TP53 mutation, 11q deletion and unmutated IGHV. • Patients should have a good performance status. • Treatment should be continued until disease progression or unacceptable toxicity. **Claim Notes:** • Requests will not be considered for patients who experience disease progression on a Bruton's tyrosine kinase (BTK) inhibitor or idelalisib. • Requests will be considered for patients who are not suitable candidates for intravenous therapy. • Venetoclax with or without rituximab is funded as a subsequent line of therapy in patients who have experienced disease progression during first-line acalabrutinib treatment, provided all other funding eligibility criteria are met. **Relapsed/ Refractory Chronic Lymphocytic Leukemia (CLL)/ Small Lymphocytic Lymphoma (SLL)** • As a single agent treatment option for adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least one prior therapy. **Clinical Notes:** • Patients should have a good performance status. • Treatment should be continued until disease progression or unacceptable toxicity. **Claim Notes:** • Requests will not be considered for patients who experience disease progression on a Bruton's tyrosine kinase (BTK) inhibitor or idelalisib.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Mayzent (siponimod)	0.25mg Tab	02496429	DNP	E (SF)	NVR
	2mg Tab	02496437	DNP	E (SF)	NVR
Criteria	**Secondary Progressive Multiple Sclerosis** **Initiation Criteria:** • For the treatment of patients with active secondary progressive multiple sclerosis, who meet all the following criteria: o a history of relapsing-remitting multiple sclerosis (RRMS) o an Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5 o documented EDSS progression during the two years prior to initiating treatment with siponimod (≥ 1 point if EDSS < 6.0; ≥ 0.5 points if EDSS ≥ 6.0 at screening). **Renewal Criteria:** • Patients who do NOT exhibit evidence of disease progression since the previous assessment. Disease progression is defined as: o an increase in the EDSS score of greater than or equal to 1 point if the EDSS score was 3.0 to 5.0 at siponimod initiation *OR* o an increase of greater than or equal to 0.5 points if the EDSS score was 5.5 to 6.5 at siponimod initiation • Patients who do NOT exhibit one of the following: o progression to an EDSS score of equal to or greater than 7.0 at any time during siponimod treatment o confirmed worsening of at least 20% on the timed 25-foot walk (T25W) since initiating siponimod treatment **Clinical Notes:** • Patients should be assessed for a response to siponimod every six months. **Claims Notes:** • The patient is under the care of a neurologist with experience in the diagnosis and management of multiple sclerosis. • Siponimod should not be used in combination with other disease-modifying treatments (DMTs) used to treat multiple sclerosis. • Approval period: 1 year				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Tegsedi (inotersen)	189 mg/mL Prefilled Syringe	02481383	DNP	E (SF)	AKT

Criteria	**Polyneuropathy in Hereditary Transthyretin-Mediated Amyloidosis**
	• 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
	  ○ Does not have New York Heart Association class III or IV heart failure
	  ○ Has not previously undergone a liver transplant
	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:
	• Symptomatic early-stage neuropathy is defined as polyneuropathy disability stage I to IIIB or familial amyloidotic polyneuropathy stage I or II.
	Claims Note:
	• 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.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Baqsimi (glucagon)	3mg Nasal Powder	02492415	DNP	E (SFD)	LIL
Criteria	• For the emergency treatment of severe hypoglycemia (SH) reactions for patients who are receiving insulin and at high risk for SH, when impaired consciousness precludes oral carbohydrate. **Claim Notes:** • Approval duration: long term. • Quantity limit: up to two devices per year. The prescriber or pharmacist can request additional devices if clinically required.				

Criteria Updates

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Forxiga (dapagliflozin)	5mg Tab	02435462	DNP	E (SF)	AZE
	10mg Tab	02435470	DNP	E (SF)	AZE
Criteria	**Heart Failure with Reduced Ejection Fraction** • For the treatment of adult patients with New York Heart Association (NYHA) class II or III heart failure with reduced ejection fraction (left ventricular ejection fraction ≤ 40%) as an adjunct to standard of care therapies. **Clinical note:** • Standard of care therapies include beta-blockers, angiotensin converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs), plus a mineralocorticoid receptor antagonist.				

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Rituximab Biosimilars	10mg/mL Vial	Various	DNP	E (SF)	VAR
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 rheumatoid arthritis[1], vasculitis[2], or other autoimmune diseases[3]. **Clinical Notes:** 1. Severe intolerance or other contraindication to an anti-TNF agent or failed an adequate trial of an anti-TNF agent. 2. Severe intolerance or other contraindication to cyclophosphamide or failed an adequate trial of cyclophosphamide. 3. Previously failed treatments must be provided if applicable. **Claims Notes:** • Must be prescribed by a specialist. • Approval period: long term				

*Form for rituximab biosimilars available at https://novascotia.ca/dhw/pharmacare/documents/forms/Rituximab-Request-for-Coverage.pdf

Criteria Updates Continued…

The following criteria has been updated **effective immediately** and applies to the following new and existing indications.

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

Venetoclax with obinutuzumab for previously untreated chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

- In combination with obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who are fludarabine ineligible.

Clinical Notes:

- Treatment should be given for a total of 12 months (six 28-day cycles in combination with obinutuzumab, followed by six months of monotherapy), or until disease progression or unacceptable toxicity, whichever occurs first.
- Retreatment with a venetoclax based regimen is funded if relapse is greater than 12 months from completion of venetoclax in combination with obinutuzumab.
- Either ibrutinib or acalabrutinib is funded as a subsequent treatment option, provided all other funding criteria are met.

Venetoclax with Azacitidine for newly diagnosed acute myeloid leukemia (AML)

- In combination with azacitidine for the treatment of patients with newly diagnosed acute myeloid leukemia (AML) who are 75 years of age or older, or who have comorbidities that preclude the use of intensive induction chemotherapy.

Clinical Notes:

- Treatment should continue until disease progression or unacceptable toxicity.
- All newly diagnosed AML patients who are ineligible for induction chemotherapy are eligible regardless of cytogenetic risk.,
- On a time-limited need, patients who are currently receiving azacitidine for newly diagnosed AML may have venetoclax added to their treatment provided there is no disease progression and patient otherwise meets criteria.

Claim Notes:

- Patients who have been previously treated with a hypomethylating agent or chemotherapy for the treatment of myelodysplastic syndromes (MDS) are not eligible for treatment with venetoclax in combination with azacitidine.
- Patients with high risk MDS are not eligible for treatment with venetoclax in combination with azacitidine.

Venetoclax monotherapy for chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in patients who have received at least one prior therapy

- As a single agent treatment option for patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least one prior therapy, and

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	who have failed a B-cell receptor inhibitor (BCRi). Treatment should be continued until disease progression or unacceptable toxicity. **Clinical Notes:** • Patients who have an intolerance or a contraindication to a B-cell receptor inhibitor (BCRi) will be eligible for treatment with venetoclax. Intolerance to BCRi would be determined by the clinician. **Venetoclax with rituximab for chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in patients who have received at least one prior therapy** • 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 an anti-CD20 therapy (rituximab or obinutuzumab) will be eligible if they had a progression-free interval of 6 months or longer. For patients previously treated with venetoclax, the progression-free interval must be 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 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.				

Non-Insulin Antidiabetic Agents (SGLT-2 Inhibitors and DPP-4 Inhibitors)

Please be advised that we will now be considering additional reasons why insulin is not an option (e.g., for patients who are not amenable to taking daily injections of insulin). The form is available at:
https://novascotia.ca/dhw/pharmacare/documents/forms/Oral-Diabetes-Treatments.pdf

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
BD AutoShield Duo Pen Needles	97799433	DNP	F*	BTD

* funded for children requiring administration of insulin in school

Non-Insured Products

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Cabenuva	400mg/2mL/600mg/2mL Vial	02497220	N/A	**Not Insured**	VIV
Cabenuva	600mg/3mL/900mg/3mL Vial	02497247	N/A	**Not Insured**	VIV
Vocabria	30mg Tab	02497204	N/A	**Not Insured**	VIV

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ABV - AbbVie Corporation
N - Nurse Practitioner	F - Community Services Pharmacare	AKT - Akcea Therapeutics, Inc.
P - Pharmacist	- Family Pharmacare	AZE - AstraZeneca Canada Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	BTD - Becton Dickinson Canada
O - Optometrist	D - Diabetes Assistance Program	LIL - Eli Lilly Canada Inc.
	E - Exception status applies	NVR - Novartis Pharmaceuticals Canada Inc.
		UGX - Ultragenyx Pharmaceutical Inc.
		VAR - *various manufacturers*
		VIV - ViiV Health Care Inc.