FEBRUARY 2024 • VOLUME 24-04
PHYSICIAN EDITION

NOVA SCOTIA

PharmacareNEWS

inside

Nova Scotia Formulary Updates

New Exception Status Benefits
- Kerendia (finerenone)
- Saphnelo (anifrolumab)
- Zeposia (ozanimod)

Criteria Update
- Brukinsa (zanubrutinib)

New Benefits

Temporary Benefit – US-Labelled Glucagon Injection

Pharmacare News Bulletins Online

Nova Scotia Formulary Updates

New Exception Status Benefits

The following new products have been listed with the following criteria, effective **March 1, 2024**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Kerendia	10mg Tab	02531917	DNP	E (SF)	BAY
(finerenone)	20mg Tab	02531925	DNP	E (SF)	BAY

Criteria

- For the treatment of patients with chronic kidney disease (CKD) and type 2 diabetes (T2D) who have an estimated glomerular filtration rate (eGFR) level of at least 25 mL/min/1.73 m^2 and albuminuria level of at least 30 mg/g (or 3 mg/mmol).

Exclusion Criteria:

- Patients with chronic heart failure (CHF) New York Heart Association (NYHA) class II to IV; OR
- Patients receiving a mineralocorticoid receptor antagonist (MRA).

Discontinuation Criteria:

- eGFR less than 15 mL/min/1.73 m^2; OR
- Urinary albumin-to-creatinine ratio (UACR) increased from baseline level.

Claim Notes:

- Must be prescribed by, or in consultation with, a nephrologist with experience in the diagnosis and management of patients with CKD and T2D.
- Approval: 1 year

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Saphnelo (anifrolumab)	150mg/mL IV Inj	02522845	DNP	E (SF)	AZE

Criteria	• For the treatment of adult patients with active, autoantibody positive, systemic lupus erythematosus (SLE), in addition to standard therapy, who meet all the following criteria:
	  ○ Moderate to severe SLE, defined as Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) score of at least 6; AND
	  ○ Unable to control their disease while using an oral corticosteroid (OCS) dose of at least 10mg/day of prednisone or equivalent.
	Exclusion Criteria:
	• Severe or unstable neuropsychiatric SLE
	• Active severe SLE nephritis
	Initial Renewal Criteria:
	• OCS dose decreased to ≤ 7.5mg/day of prednisone or equivalent, or OCS dose decreased by at least 50% from baseline; AND
	• Reduction in disease activity measured by:
	  ○ Reducing the SLEDAI-2K score to 5 or less; OR
	  ○ British Isles Lupus Activity Group (BILAG) improvement in organ systems and no new worsening.
	Subsequent Renewal Criteria:
	• The initial response achieved after the first 12 months of therapy has been maintained.
	Clinical Notes:
	• SLEDAI-2K and BILAG scores must be provided.
	Claim Notes:
	• Approval: 12 months.
	• Patient should be under the care of a physician with expertise in the diagnosis and management of SLE.
	• Not to be used in combination with other biologic treatments.				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Zeposia (ozanimod)	0.23mg & 0.46mg Initiation Pack	02506009	DNP	E (SF)	CEL
	0.92mg Cap	02505991	DNP	E (SF)	CEL

Criteria	• For the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have a partial Mayo score > 4, and have a rectal bleeding subscore ≥ 2, and are:
	  ○ refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); OR
	  ○ corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)
	• Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:
	  ○ a decrease in the partial Mayo score ≥ 2 from baseline, AND
	  ○ a decrease in the rectal bleeding subscore ≥ 1.
	Clinical Notes:
	• Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
	• Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.
	• Patients with severe disease do not require a trial of 5-ASA.
	Claim Notes:
	• Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
	• Concurrent use of biologics or Janus kinase inhibitors not approved.
	• Initial Approval: 16 weeks.
	• Maximum dose of 0.92mg daily with no dose escalation permitted.
	• Renewal Approval: 1 year.				

Criteria Update

The following new indications have been added to existing criteria effective **March 1, 2024.**

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Brukinsa (zanubrutinib)	80mg Cap	02512963	DNP	E (SFC)	BGN

Criteria

Previously Untreated Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)

- As monotherapy for the treatment of 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 a high risk of relapse or refractory disease based on prognostic biomarkers.

Clinical Notes:

- Patients should have a good performance status.
- Treatment should be continued until disease progression or unacceptable toxicity.
- High risk for relapse or refractory disease includes 17p deletion, TP53 mutation, 11q deletion and unmutated IGHV.

Claim Notes:

- Patients are not eligible if they have prolymphocytic leukemia or Richter's transformation.
- 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 zanubrutinib treatment, provided all other funding eligibility criteria are met.

Relapsed/Refractory Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)

- As monotherapy for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least one prior systemic therapy.

Clinical Notes:

- Patients should have a good performance status.
- Treatment should be continued until disease progression or unacceptable toxicity.

Claim Notes:

- Patients are not eligible if they have prolymphocytic leukemia or Richter's transformation.
- Requests will not be considered for patients who experience disease progression on a Bruton's tyrosine kinase (BTK) inhibitor or idelalisib.

New Benefits

Effective **March 1, 2024,** the following products will be added as benefits in the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Bijuva	1mg/100mg Cap	02505223	DNP	SF	KNI
Mezera	500mg DR Tab	02524481	DNP	SF	AVI

Temporary Benefit – US-Labelled Glucagon Injection

Amphastar Pharmaceuticals Inc. has received approval from Health Canada for the import and release of US-labelled glucagon injection to help mitigate shortages in Canada.

The Nova Scotia Pharmacare Programs will be adding this product as a temporary benefit effective immediately.

When prescribing or dispensing this product, pharmacists may consult Amphastar Pharmaceuticals Inc. Dear Healthcare Professional at the following link: risk-communication-letter-glucagon-en.pdf (amphastar.com)

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Glucagon	1mg/1mL Inj	09858279	DNP	SFD*	APM

*quantity limit of two (2) kits per fiscal year. The prescriber can submit a request for consideration should beneficiaries require more than two (2) kits per fiscal year.

Pharmacare News Bulletins Online

If you are reading a paper copy of this bulletin, we would like to remind you that all bulletins can be found on our website at the following link: https://novascotia.ca/dhw/pharmacare/pharmacare-news-bulletins.asp

Legend

PRESCRIBER CODES		BENEFIT STATUS		MANUFACTURER CODES	
D	- Physician / Dentist	S	- Seniors' Pharmacare	APM	- Amphastar Pharmaceuticals
N	- Nurse Practitioner	F	- Community Services Pharmacare	AVI	- Avir Pharma Inc
P	- Pharmacist		- Family Pharmacare	AZE	- AstraZeneca Canada Inc.
M	- Midwife	C	- Drug Assistance for Cancer Patients	BAY	- Bayer Inc.
O	- Optometrist	D	- Diabetes Assistance Program	BGN	- Beigene (Canada) ULC
		E	- Exception status applies	CEL	- Celgene
				KNI	- Knight Therapeutics Inc