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PRESCRIBER EDITION

NOVA SCOTIA

PharmacareNEWS

inside

Nova Scotia Formulary Updates

New Exception Status Benefit

The following new product has been listed with the following criteria, effective **July 1, 2024**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Empaveli (pegcetacoplan)	1080mg/20mL (54mg/mL) Vial	02533294	DNP	E (SF)	SBI

Criteria

Initiation Criteria:

For the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) who meet all the following criteria:

- The diagnosis of PNH has been made based on the following confirmatory results:
  - Flow cytometry/FLAER exam with granulocytes or monocyte clone ≥ 10%; AND
  - LDH > 1.5 ULN; AND
  - At least one of the following:
    - A thrombotic or embolic event which required the institution of therapeutic anticoagulant therapy,
    - Minimum transfusion requirement of 4 units of red blood cells in the previous 12 months,
    - Chronic or recurrent anemia where causes other than hemolysis have been excluded and demonstrated by more than one measure of less than or equal to 70g/L or by more than one measure of less than or equal to 100g/L with concurrent symptoms of anemia,
    - Pulmonary insufficiency: Debilitating shortness of breath and/or chest pain resulting in limitation of normal activity (New York Heart Association Class III)

New Exception Status Benefit Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Empaveli (pegcetacoplan)	1080mg/20mL (54mg/mL) Vial	02533294	DNP	E (SF)	SBI

Criteria

and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded,

- Renal insufficiency: History of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded,
- Smooth muscle spasm: Recurrent episodes of severe pain requiring hospitalization and/or narcotic analgesia, where causes other than PNH have been excluded.

- Have persistent anemia with hemoglobin levels < 105 g/L, despite an adequate trial of C5 inhibitor treatment and where causes other than extravascular hemolysis have been excluded, or have intolerable adverse events from C5 inhibitor treatment.

Renewal Criteria:

- Renewals will be considered for patients who;
  - Demonstrate clinical improvement while on therapy or
  - Where therapy has been shown to stabilize the patient's condition
- Requests for renewal should be accompanied by confirmation of granulocyte clone size (by flow cytometry).

Exclusion Criteria:

Exclusion criteria for both initiation and renewal requests:

- Small granulocyte or monocyte clone size - the treatment of patients with a granulocyte and monocyte clone size below 10% will not be eligible for treatment; OR
- Aplastic anemia with two or more of the following: neutrophil count below 0.5 x 10^9/L, platelet count below 20 x 10^9/L, reticulocytes below 25 x 10^9/L, or severe bone marrow hypocellularity; OR
- Patients afflicted with PNH and another life-threatening or severe disease where the long term prognosis is unlikely to be influenced by therapy (for example acute myeloid leukemia or high-risk myelodysplastic syndrome); OR
- The presence of another medical condition that might reasonably be expected to compromise a response to therapy.

Exclusion criteria for renewal requests:

- The patient or treating physician fails to comply adequately with treatment or measures, including monitoring requirements, taken to evaluate the effectiveness of the therapy; OR
- If therapy fails to relieve the symptoms of disease that originally resulted in the patient being approved for subsidized treatment.

New Exception Status Benefit Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Empaveli (pegcetacoplan)	1080mg/20mL (54mg/mL) Vial	02533294	DNP	E (SF)	SBI
Criteria	**Claim Notes:** • Approvals will be for a maximum of 1080mg twice a week (Day 1 and Day 4). • If lactate dehydrogenase (LDH) levels are greater than 2x the upper limit of normal (ULN) on twice weekly dosing, 1080mg every three days may be approved. • Initial Approval: 6 months • Renewal Approval: 1 year • The patient must be under the care of a pediatric nephrologist, a nephrologist, a pediatric hematologist or a hematologist. • Pegcetacoplan will not be reimbursed in combination with other complement inhibitors except in the first 4 weeks of treatment. • 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 00904879				

Temporary Benefit – US – Labelled Carbamazepine Extended-Release (ER) Tablets

Septa Pharmaceuticals Inc. has received approval from Health Canada for the import and release of US-labelled carbamazepine extended release tablets 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 the Healthcare Professional Risk Communication at the following link https://recalls-rappels.canada.ca/en/alert-recall/importation-usa-authorized-carbamazepine-extended-release-tablets-usp-200-mg-and-400

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Carbamazepine Extended-Release, USP	200mg Tab	09858341	DNP	SFC	SPT
Carbamazepine Extended-Release, USP	400mg Tab	09858342	DNP	SFC	SPT

Temporary Benefit – US – Labelled Orencia SC Prefilled Syringe

Bristol-Myers Squibb Canada has received approval from Health Canada for the import and release of US-labelled Orencia SC prefilled syringes to help mitigate shortages in Canada.

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

Information about US-labelled Orencia SC for health care professionals is available for reference at https://www.bms.com/patient-and-caregivers/our-medicines.html

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Orencia	125mg/mL Prefilled Syringe	09858343	DNP	E (SF)	BRI

Change in Benefit Status

Effective **July 1, 2024,** the following products will move to full benefit and no longer require exception status approval.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Darifenacin	7.5mg ER Tab	Various	DNP	SF	VAR
Darifenacin	15mg ER Tab	Various	DNP	SF	VAR
Sumatriptan	50mg Tab	Various	DNP	SF	VAR
Sumatriptan	100mg Tab	Various	DNP	SF	VAR
Trospium	20mg Tab	Various	DNP	SF	VAR

Effective **July 1, 2024,** the following products will be delisted as benefits under the Pharmacare Programs.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Fungizone	50mg/Vial Inj	00029149	N/A	**Not Insured**	XPI
Plerixafor	24mg/1.2mL (20mg/mL) Sol	02529815	N/A	**Not Insured**	JPC
Mozobil	24mg/1.2mL (20mg/mL) Sol	02377225	N/A	**Not Insured**	SAV
Suprefact Depot	6.3mg Implant	02228955	N/A	**Not Insured**	XPI
Viskazide	10mg/25mg Tab	00568627	N/A	**Not Insured**	XPI
Viskazide	10mg/50mg Tab	00568635	N/A	**Not Insured**	XPI
Zomig	2.5mg Nasal Spray	02248992	N/A	**Not Insured**	XPI
Zomig	5mg Nasal Spray	02248993	N/A	**Not Insured**	XPI

Magic Mouthwash

The following formulations will be referenced in the June Pharmacy Guide as approved formulations:

Diphenhydramine Syrup
Lidocaine Viscous 2%
Magnesium/Aluminum Conc. Suspension

Diphenhydramine Syrup
Hydrocortisone Tablet
Nystatin Suspension
Distilled Water

Diphenhydramine Syrup
Magnesium/Aluminum Suspension

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	BRI - Bristol-Myers Squibb Canada Inc.
N - Nurse Practitioner	F - Community Services Pharmacare	JPC - Jamp Pharma Corporation
P - Pharmacist	- Family Pharmacare	SAV - Sanofi-Aventis Canada Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	SBI - Sobi Canada Inc
O - Optometrist	D - Diabetes Assistance Program	SPT - Septa Pharmaceuticals
	E - Exception status applies	VAR - *various manufacturers*
	G - Sensor-based Glucose Monitoring Program	XPI - Xediton Pharmaceuticals Inc.