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NOVA SCOTIA

PharmacareNEWS

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Nova Scotia Formulary Updates

New Exception Status Benefits

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Livtencity (maribavir)	200mg Tab	02530740	DNP	E (SF)	TAK

Criteria

For the treatment of adult patients with post-transplant cytomegalovirus (CMV) infection/disease who are refractory[1] (with or without genotypic resistance) to 1 or more of the following antiviral therapies: valganciclovir, ganciclovir, foscarnet, or cidofovir.

[1]Refractory to an antiviral is defined as a lack of change in CMV viral load or increase in CMV viral load after at least 2 weeks of appropriately dosed treatment.

Renewal Criteria:

- Subsequent treatment may be considered for patients who have a recurrence of CMV viremia after a previous successful course of therapy with maribavir.

Discontinuation Criteria:

- Patients exhibit any of the following:
  - No change or an increase in CMV viral load after at least 2 weeks of maribavir treatment; OR
  - Confirmed CMV genetic mutation associated with resistance to maribavir.

Claim Notes:

- Must be prescribed by clinicians with experience and expertise in transplant medicine, transplant infectious disease, or infectious diseases.
- Approvals: 6 month

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Oxlumo (lumasiran)	94.5mg/0.5mL Vial	02525755	DNP	E (SF)	ALN

Criteria

For the treatment of pediatric and adult patients with primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels who meet the following criteria:

- A confirmed genetic diagnosis of PH1.
- In whom urinary oxalate can be measured must be unable to normalize urine oxalate excretion while staying compliant with standard of care therapy, including vitamin B6 for a duration of 3 to 6 months.

Renewal Criteria:

- Has not undergone a liver transplant with or without a kidney transplant.
- Has not shown evidence of loss of response or no response, defined as lowering 24-hour urine oxalate to less than 1.5 times the ULN or patients in whom urinary oxalate can be measured.

Claim Notes:

- Must be initially prescribed by a nephrologist or metabolic diseases specialist with experience in the diagnosis and management of PH1.
- Renewals can be through a pediatrician instead of nephrologist or metabolic diseases physician.
- Approvals will be for a maximum of:

Body Weight Range (kg)	Loading Dose	Maintenance Dose
Less than 10 kg	6mg/kg once monthly for 3 doses	3 mg/kg once monthly, beginning 1 month after the last loading dose.
10 kg to less than 20 kg	6mg/kg once monthly for 3 doses	6 mg/kg once every 3 months: give the first maintenance dose 1 month after the last loading dose and quarterly thereafter
20 kg and above	3mg/kg once monthly for 3 doses	3 mg/kg once every 3 months: give the first maintenance dose 1 month after the last loading dose and quarterly thereafter.

- Initial Approval: 6 months
- Renewals: 12 months

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Posaconazole (Posanol)	100mg DR Tab	Various	DNP	E (SFC)	VAR
Criteria	For the prevention of invasive fungal infection (IFI) in allogeneic stem cell transplant recipients with a contraindication or intolerance to voriconazole. • From time of engraftment until day +90 OR • With graft versus host disease (GVHD) taking prednisone 1 mg/kg/day or more, until dose is less than 20 mg/day.				

Criteria Updates

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Lonsurf (trifluridine/tipiracil)	15mg/6.14mg Tab 20mg/8.19mg Tab	02472104 02472112	DNP DNP	E (SFC) E (SFC)	TAI TAI
Criteria	In combination with bevacizumab for the treatment of adult patients with unresectable or metastatic colorectal cancer who: • Have previously been treated with, or are not candidates for, available therapies including fluoropyrimidine-, oxaliplatin, and irinotecan-based chemotherapies, anti-VEGF biological agents, and, if RAS wild-type, anti-EGFR agents; and • Have disease progression or demonstrated intolerance to a maximum of 2 prior chemotherapy regimens for the treatment of unresectable or metastatic colorectal cancer. **Clinical Notes:** • Patients should have a good performance status. • Treatment should continue until disease progression or unacceptable toxicity. • No active CNS metastases (eligible if treated/stable). • Patients with small bowel or appendiceal adenocarcinoma are eligible. • Patients who were unable to receive bevacizumab in a prior line of therapy due to a contraindication will be eligible. • Patients who have received adjuvant/neoadjuvant chemotherapy and had recurrence during or within 6 months of completion can count the adjuvant/neoadjuvant therapy as 1 of the maximum of 2 required prior chemotherapy regimens. If bevacizumab is discontinued due to intolerance or contraindication, trifluridine-tipiracil can be continued at the discretion of the physician				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Lynparza (olaparib)	100mg Tab	02475200	DNP	E (SFC)	AZE
	150mg Tab	02475219	DNP	E (SFC)	AZE
Criteria	In combination with abiraterone and prednisone for the first-line treatment of adult patients with deleterious or suspected deleterious germline and/or somatic BRCA-mutated metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated. **Clinical Notes:** • Patients should have a good performance status. • Treatment should continue until disease progression or unacceptable toxicity. • Eligible patients must have a confirmed germline and/or somatic BRCA1 or BRCA2 gene alteration prior to starting treatment. • Patients should not have received prior treatment with a poly - (ADP ribose) polymerase (PARP) inhibitor, or with androgen-receptor-axis-targeted (ARAT) therapy (e.g., apalutamide, darolutamide, enzalutamide). • Patients should not have received prior treatment with abiraterone, or are within 4 months of initiating abiraterone in the mCRPC setting with no disease progression.				

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Rinvoq (upadacitinib)	15mg Tab	02495155	DNP	E (SF)	ABV
	30mg Tab	02520893	DNP	E (SF)	ABV
	45mg Tab	02539721	DNP	E (SF)	ABV
Criteria	**Crohn Disease** • For the treatment of patients with moderately to severely active Crohn's disease who are refractory to, intolerant or have contraindications to corticosteroids and other immunosuppressive therapy. **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 to treatments. The nature of intolerance(s) must be clearly documented. **Claim Notes:** • Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology. • Combined use with other biologic drugs or janus kinase (JAK) inhibitors will not be reimbursed.				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Rinvoq	15mg Tab	02495155	DNP	E (SF)	ABV
(upadacitinib)	30mg Tab	02520893	DNP	E (SF)	ABV
	45mg Tab	02539721	DNP	E (SF)	ABV

Criteria

- Initial reimbursement will be for an induction dose of 45mg once daily, with a clinical response to be assessed prior to week 12. Subsequent reimbursement for maintenance dosing will be for a maximum dose of up to 30mg once daily.
- Initial Approval: 12 weeks
- Renewal Approval: 1 year

Ulcerative Colitis

- For the treatment of patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:
    - refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); OR
    - corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of 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.
- Combined use with biologic drugs or other JAK inhibitors will not be reimbursed.
- Initial Approval: 8 weeks at a maximum dose of 45mg once daily
- Renewal Approval: 1 year at a maximum dose of 30mg once daily.

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Rinvoq (upadacitinib)	15mg Tab	02495155	DNP	E (SF)	ABV
	30mg Tab	02520893	DNP	E (SF)	ABV
	45mg Tab	02539721	DNP	E (SF)	ABV
Criteria	**Ankylosing Spondylitis** • For treatment of patients with moderate to severe ankylosing spondylitis (Bath AS Disease Activity Index (BASDAI) score ≥4 on 10 point scale) who are refractory to, intolerant or have contraindications to a biologic disease-modifying antirheumatic drug (bDMARD). **Renewal Criteria:** • A decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score; OR • Patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as HAQ or "ability to return to work"). **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 to treatments. The nature of intolerance(s) must be clearly documented. **Claim Notes:** • Must be prescribed by a rheumatologist or prescriber with a specialty in rheumatology. • Combined use with biologic drugs or other JAK inhibitors will not be reimbursed. • Approvals will be for a maximum of 15 mg daily. • Initial Approval: 6 months • Renewal Approval Period: 1 year.				

Change in Benefit Status

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Almotriptan	12.5mg Tab	Various	DNP	SF	VAR

Legend

PRESCRIBER CODES	BENEFIT STATUS	MANUFACTURER CODES
D - Physician / Dentist	S - Seniors' Pharmacare	ABV - AbbVie Corporation
N - Nurse Practitioner	F - Community Services Pharmacare	ALN - Alnylam Netherlands BV
P - Pharmacist	- Family Pharmacare	AZE - AstraZeneca Canada Inc.
M - Midwife	C - Drug Assistance for Cancer Patients	TAI - Taiho Pharma Canada
O - Optometrist	D - Diabetes Assistance Program	TAK - Takeda Canada Inc.
	E - Exception status applies	VAR - *various manufacturers*
	G - Sensor-based Glucose Monitoring Program	