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PHARMACISTS' 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
Zejula (niraparib)	100mg Cap	02489783	DNP	E (SFC)	GSK

Criteria

Newly Diagnosed Advanced Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer

- As monotherapy maintenance treatment of patients with newly-diagnosed ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to at least 4 cycles of first-line platinum-based chemotherapy. Eligible patients should have high-grade serous or endometrioid tumours classified as stage III or IV according to the International Federation of Gynecology and Obstetrics (FIGO) criteria.

Clinical Notes:

- Patients should have a good performance status.
- Maintenance therapy with niraparib should begin within 12 weeks of completion of platinum- based chemotherapy and may continue for up to 3 years, or until disease progression or unacceptable toxicity, whichever occurs first.
- Patients who have stable brain metastases are eligible for treatment with niraparib.
- Patients who are unable to tolerate platinum-based chemotherapy (due to allergic reaction) and otherwise meet criteria, will be assessed on a case by case basis to determine eligibility for treatment with niraparib.
- Niraparib in combination with bevacizumab is not funded.

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Zejula (niraparib)	100mg Cap	02489783	DNP	E (SFC)	GSK
Criteria	**Relapsed, Platinum Sensitive Advanced Epithelial Ovarian, Fallopian tube or Primary Peritoneal Cancer** • As monotherapy maintenance treatment for patients with relapsed, platinum-sensitive high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have completed at least two previous lines of platinum-based chemotherapy, and have achieved a complete or partial response to the most recent platinum-based chemotherapy regimen. **Clinical Notes:** • Platinum-sensitive disease is defined as disease progression occurring at least six months after completion of platinum-based chemotherapy. • Patients should have a good performance status. • Patients must have received at least 4 cycles of the most recent platinum-based chemotherapy before starting treatment with niraparib. • Maintenance therapy with niraparib should begin within 12 weeks of the last chemotherapy treatment and may continue until disease progression or unacceptable toxicity, whichever occurs first. • Patients who have stable brain metastases are eligible for treatment with niraparib. • Patients who are unable to tolerate platinum-based chemotherapy (due to allergic reaction) and otherwise meet criteria, will be assessed on a case by case basis to determine eligibility for treatment with niraparib.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Adlyxine (lixisenatide)	0.05mg/mL Prefilled Pen 0.1mg/mL Prefilled Pen	02464276 02464284	DNP DNP	E (SF) E (SF)	SAV SAV

Criteria	• For the treatment of type 2 diabetes mellitus when added to:
	  ○ basal insulin for patients who have inadequate glycemic control on basal insulin; or
	  ○ basal insulin and metformin for patients who have inadequate glycemic control on metformin and basal insulin				

New Exception Status Benefits Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Entyvio (vedolizumab)	108mg/0.68mL Prefilled Syringe	02497875	DNP	E (SF)	TAK
	108mg/0.68mL Prefilled Pen	02497867	DNP	E (SF)	TAK
Criteria	• See *Criteria Updates* below.				

Criteria Updates

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Entyvio (vedolizumab)	300mg Vial	02436841	DNP	E (SF)	TAK
	108mg/0.68mL Prefilled Syringe	02497875	DNP	E (SF)	TAK
	108mg/0.68mL Prefilled Pen	02497867	DNP	E (SF)	TAK
Criteria	**Crohn's Disease** • For patients with moderate to severely active Crohn's disease and are: ○ refractory or have contraindications to an adequate course of 5-aminosalicylic acid and 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. **Claim Notes:** • Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology. • Combined use of more than one biologic DMARD will not be reimbursed. • Intravenous infusion: Initial reimbursement is restricted to induction doses of 300mg at Weeks 0, 2 and 6. Clinical response to be assessed prior to the administration of the fourth dose. • Subcutaneous injection: Initial reimbursement is for at least two doses of intravenous infusions of vedolizumab. Clinical response to be assessed prior to the administration of the first subcutaneous dose. Subsequent reimbursement for maintenance dosing is 108mg subcutaneously every 2 weeks. • Initial Approval: 16 weeks • Renewal Approval: 1 year				

Criteria Updates Continued…

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Entyvio	300mg Vial	02436841	DNP	E (SF)	TAK
(vedolizumab)	108mg/0.68mL Prefilled Syringe	02497875	DNP	E (SF)	TAK
	108mg/0.68mL Prefilled Pen	02497867	DNP	E (SF)	TAK

Criteria

Ulcerative Colitis

- For the treatment of adult 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 of more than one biologic DMARD will not be reimbursed.
- Intravenous infusion: Initial reimbursement is restricted to induction doses of 300mg at Weeks 0, 2 and 6. Clinical response to be assessed prior to the administration of the fourth dose.
- Subcutaneous injection: Initial reimbursement is for at least two doses of intravenous infusions of vedolizumab. Clinical response to be assessed prior to the administration of the first subcutaneous dose. Subsequent reimbursement for maintenance dosing is 108mg subcutaneously every 2 weeks.
- Initial Approval: 16 weeks
- Renewal Approval: 1 year

Criteria Updates Continued…

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Lenvima (lenvatinib)	4mg Cap 8mg Cap 12mg Cap	02484056 02468220 02484129	DNP DNP DNP	E (SFC) E (SFC) E (SFC)	EIS EIS EIS
Criteria	• For the treatment of adult patients with unresectable or metastatic hepatocellular carcinoma as either first-line treatment, or second-line treatment following atezolizumab in combination with bevacizumab, who meet all the following criteria: ○ Child-Pugh class status of A ○ ECOG performance status of 0 or 1 ○ Less than 50% liver involvement and no invasion of the bile duct or main portal vein ○ 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.				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Nexavar (sorafenib)	200mg Tab	02284227	DNP	E (SFC)	BAY
Criteria	• For the treatment of adult patients with a diagnosis of hepatocellular carcinoma (HCC) as either first line-treatment, or second-line treatment following atezolizumab in combination with bevacizumab, who meet all the following criteria: ○ Child-Pugh Class A liver dysfunction (mild hepatic impairment) ○ ECOG performance status of 0 or 1 ○ 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.				

New Benefits

Effective **immediately,** the following 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
Ceftazidime	1g/vial Pws Inj	02437848	DNP	SFC	STR
Ceftazidime	2g/vial Pws Inj	02437856	DNP	SFC	STR
Ceftazidime	6g/vial Pws Inj	02437864	DNP	SFC	STR