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Programmes provinciaux de medicaments
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PEI Pharmacare Bulletin

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NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: DECEMBER 3, 2024)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Eptinezumab	**Vyepti**	**300mg/3mL**	**Vial**	**02542269**	**LUD**
Criteria	See online Formulary for eptinezumab criteria				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

Foslevodopa/Foscarbidopa	**Vyalev**	**240mg/mL / 12mg/mL**	**Vial**	**02537702**	**ABV**
Criteria	For the treatment of patients with advanced levodopa-responsive Parkinson disease (PD) who meet all of the following criteria: • Experiences severe disability associated with at least 25% of the waking day in the off state and/or ongoing, bothersome levodopa-induced dyskinesias, despite having tried frequent dosing of levodopa (at least five doses per day). • Have received an adequate trial of maximally tolerated doses of levodopa, with previously demonstrated clinical response. • Have failed an adequate trial of the following adjunctive medications, if not contraindicated and/or contrary to the clinical judgment of prescriber: maximally tolerated doses of levodopa in combination with carbidopa, a COMT inhibitor, a dopamine agonist, a MAO-B inhibitor, and amantadine. • Must be able to administer the medication and correctly use the delivery system. Alternatively, trained personnel or a care partner must be available to perform these tasks reliably. Exclusion Criteria: • Patients with severe psychosis or severe dementia. Renewal Criteria: • Patients continue to demonstrate a significant reduction in the time spent in the				

	off state and/or in ongoing levodopa-induced dyskinesias, along with an improvement in the related disability. Claim Note: • Must be prescribed by neurologists who are movement disorder subspecialists or who have expertise in managing advanced PD. • Approval period: 1 year
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program

Upadacitinib	**Rinvoq**	**45mg**	**Tablet**	**02539721**	**ABV**
Criteria	**CRITERIA UPDATE** <u>Crohn's Disease (15mg, 30mg & 45mg Tab)</u> For the treatment of patients with moderate to severe Crohn's disease who have active disease and are refractory, intolerant or have contraindications to: • Prednisone 40mg (or equivalent) daily for ≥ 2 weeks, AND • Azathioprine ≥ 2 mg/kg/day for ≥ 3 months, OR • Mercaptopurine ≥ 1 mg/kg/day for ≥ 3 months, OR • Methotrexate (SC or IM) ≥ 15 mg/week for ≥ 3 months Clinical Notes: • Refractory is defined as lack or loss 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. • Consideration will be given for the approval of a biologic DMARD (disease modifying antirheumatic drug) without a trial of a traditional DMARD for patients who have an aggressive/severe disease course (e.g. extensive disease, a modified Harvey Bradshaw Index score > 16) and are refractory, intolerant or have contraindications to systemic corticosteroids. Claim notes: • Approvals will be for a maximum of 45mg daily for 12 weeks, followed by a maximum of 30mg daily. • Initial approval period: 16 weeks • Renewal Approval: 1 year. Maximum approved dose is 30 mg daily. Confirmation of continued response is required. • Combined use of more than one biologic DMARD or other JAK inhibitor treatment for CD will not be reimbursed. <u>Ulcerative Colitis (15mg, 30mg & 45mg Tab)</u> 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. aminosalicylates for a minimum of four 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.

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 (partial Mayo > 6) do not require a trial of 5-ASA

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Approvals will be for a maximum of 45 mg daily for 8 weeks followed by a maximum of 30 mg daily. 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.
- Initial Approval: 12 weeks
- Renewal Approval: 1 year. Maximum approved dose is 30 mg daily
- Combined use of more than one biologic DMARD or JAK inhibitor for UC will not be reimbursed.

<u>Ankylosing Spondylitis (15mg Tab)</u>

For the treatment of patients with moderate to severe ankylosing spondylitis (Bath AS Disease Activity Index (BASDAI) score ≥ 4 on 10 point scale) who:

a) have axial symptoms and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation or in whom NSAIDs are contraindicated OR
b) have peripheral symptoms and who have failed to respond to, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

*Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication to axial disease, do not require a trial of NSAIDs alone.

Claim Notes:

- Approvals will be for a maximum dosage of 15mg once daily
- Combined use with biologic DMARDs or other JAK inhibitor treatments for active AS will not be reimbursed
- Initial Approval: 6 months
- Renewal Approval: Maximum of 12 months.
- Requests for renewal must include information showing the beneficial effects of the treatment, specifically:
    a) a decrease of at least two points on the BASDAI scale, compared with pretreatment score OR
    b) patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as Health Assessment Questionnaire (HAQ) or ability to return to work).

Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program

CRITERIA UPDATE

Effective immediately, special authorization criteria for currently listed Zanubrutinib (Brukinsa) have been amended to include the following indication:

Chronic Lymphocytic Leukemia

1. As monotherapy for adult patients with previously untreated chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL) for whom fludarabine-based treatment is inappropriate due to high-risk cytogenetic markers (i.e., del17p, TP53 mutation, or unmutated IGHV).
2. As monotherapy for the treatment of adult patients with relapsed or refractory CLL / SLL who have received at least one prior systemic therapy.

Clinical Notes:
1. Patients must have a good performance status and no evidence of prolymphocytic leukemia or Richter's transformation.
2. Treatment should be discontinued upon 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.
- Approval period: 1 year.

PROFESSIONAL SERVICE REIMBURSEMENT FRAMEWORK – COMPLIANCE PACKAGING

Compliance packaging fees are available to patients enrolled in certain PEI Pharmacare drug programs, for patients who:

1. Exhibit cognitive impairment or
2. Have shown misuse/abuse of medications or
3. Have complex dosing regimens.

The pharmacy can bill these fees only if the patient meets one or more of the above specific criteria (also outlined in the Professional_Service_Reimbursement_Framework.pdf (available on the Resources for Community Pharmacies | Health PEI | Staff Resource Centre website).

The above criteria can be determined by the prescriber or the pharmacist; the appropriate billing code to identify the eligible criteria the patient meets under must be entered in the Sig field. For specific adjudication steps, refer to the Professional Service Framework document.

Missing or incomplete information in the "sig" field (adjudication process) will result in the reversal of the claim for "Compliance Packaging". If the "sig" field is blank, the claim will be reversed, and the pharmacy will see the reversal on their Pharmacy Claims Detail Report.

COMPLIANCE PACKAGING		Effective Date: July 5th, 2023
Eligibility	**Description / Scope / Documentation**	**Reimbursement Rate**
1. Patient must be covered through one of the following PEI Pharmacare Programs: a. Children-In-Care b. Family Health Benefit c. Financial Assistance d. Diabetes e. Seniors **AND** The physician/pharmacist must have requested/initiated compliance packaging because the patient exhibits cognitive impairment, medication abuse/misuse, and/or complex dosing regimens.	**The pharmacy can bill this service fee in the following circumstances:** Codes (for billing purposes): **Children-In-Care, Family Health Benefit, Financial Assistance, Diabetes and Seniors Drug Programs** • Physician requests this service for: ○ **B1** patient that exhibits cognitive impairment; ○ **B2** misuse/abuse of medications; and/or ○ **B3** complex dosing regimens. **OR** • Upon assessment, the pharmacist identifies that this service is required for ○ **B4** patient that exhibits cognitive impairment; ○ **B5** misuse/abuse of medications; and/or ○ **B6** complex dosing regimens. **Exclusions** • Nursing Home Program patients are not eligible. **Notes** • This paid service cannot be combined with any current billing practices, for the same service. **Adjudication steps** • Submit a claim for "Compliance Packaging", using the PIN (**93899914**), to the eligible PEI Pharmacare Program • Process as per a regular claim with the following consideration: ○ Quantity of one (1) ○ Days supply of one (1) ○ The "sig" field must contain reason for "Compliance Packaging" ▪ Use either code B1, B2, B3, B4, B5, or B6 ▪ Missing or incomplete information in the "sig" field (adjudication process) will result in the reversal of the claim for "Compliance Packaging". If the "sig" field is blank, the claim will be reversed, and the pharmacy will see the reversal on their Pharmacy Claims Detail Report. ○ Claimed amount for the service is to be submitted in the drug cost field ○ Identify the pharmacist as the prescriber **Documentation** • The pharmacist must document in the patient's record the rationale for the decision and any appropriate follow-up plan. • This information can be captured on the hardcopy used to document the billing of the "Compliance Packaging" claim or in an easily retrievable electronic format on the patient's file.	$25.00 per 28 days. Limited to one claim, per client, per 28 day period.