PEI Pharmacare
P.O. Box 2000
Charlottetown, PE
C1A 7N8
www.princeedwardisland.ca

Programmes provinciaux de medicaments
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PEI Pharmacare Bulletin

Issue (2025-13) **July 2, 2025**

NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: JULY 16, 2025)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Bimekizumab	**Bimzelx**	**320mg/2mL**	**Pre-filled Syringe Autoinjector**	**02553619 02553627**	**UCB**
Criteria	**PLAQUE PSORIASIS** For patients with severe, debilitating chronic plaque psoriasis who meet all of the following: • Body surface area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genitals; • Failure to, contraindication to or intolerant of methotrexate (oral or parenteral) at a dose of ≥ 20mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks or cyclosporine for a minimum of 6 weeks; AND • Failure to, intolerant of or unable to access phototherapy. Continued coverage is dependent on evidence of improvement, specifically: • A >75% reduction (provide baseline and current score) in the Psoriasis Area and Severity Index (PASI) score ; or • A >50% reduction (provide baseline and current score) in PASI with a > 5 point improvement in DLQI (Dermatology Life Quality Index); or • Significant reduction in BSA involved, with consideration of important regions such as the face, hands, feet or genitals. Clinical Notes: • For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered. • Failure is defined as lack of effect at the recommended doses and for duration of treatments specified above. • Treatment should be discontinued if a response has not been demonstrated after 16 weeks.				

	• Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented. Claim Notes: • Concurrent use of biologics not approved. • Approvals will be for 320mg given every 4 weeks for 16 weeks then 320 mg every 8 weeks thereafter. • Initial Approval: 16 weeks • Renewal Approval: 1 year
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program

CRITERIA UPDATE

Effective July 16, 2025, special authorization criteria for currently listed **bimekizumab (Bimzelx)** products have been amended to include the following indications:

ANKYLOSING SPONDYLITIS

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 160mg by subcutaneous injection every 4 weeks.
- Must be prescribed by a rheumatologist or prescriber with a specialty in rheumatology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial period: 6 months
- Renewal Approval: 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).

PSORIATIC ARTHRITIS

1) For the treatment of predominantly axial psoriatic arthritis who are refractory, intolerant or have contraindications to the sequential use of at least two NSAIDs for a minimum of two weeks each.
2) For the treatment of predominantly peripheral psoriatic arthritis who are refractory or intolerant to:
    - Sequential use of at least two NSAIDs for a minimum of two weeks each; and
    - Methotrexate (oral or parenteral) at a dose of ≥ 20mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 8 weeks; and
    - Leflunomide for a minimum of 10 weeks or sulfasalazine for a minimum of 3 months

Clinical Notes:

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
- 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.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for 160mg by subcutaneous injection every 4 weeks.
- Initial Approval: 6 months
- Renewal Approval: 1 year