



PEI Pharmacare
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Programmes provinciaux de médicaments
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PEI Pharmacare Bulletin

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BIOSIMILAR INSULIN UPDATE

- **Compatibility with the insulin pump make and model must be confirmed prior to switching a patient to the biosimilar insulin.** Information regarding biosimilar insulins and pump compatibility can be found in the [Biosimilar Insulin Resources document](#) on the [Resources for Community Pharmacies](#) webpage or by contacting the insulin pump manufacturer.
- Where compatibility information supports the use of Trurapi® with a patient’s insulin pump, the patient must be switched to the biosimilar version at the time of their next refill.
- Patients accessing NovoRapid® vials and who are not on an insulin pump must be switched to the biosimilar at the time of their next refill.

NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: AUGUST 27, 2024)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Insulin Aspart	Trurapi	100 units/mL	10mL vial	02529254	AVN
Criteria	Open Benefit *Please ensure pump compatibility before switching to a biosimilar insulin				
Program Eligibility	Diabetes Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				
Ustekinumab	Jamteki	45mg / 0.5mL 90mg / 1.0mL	Prefilled Syringe Prefilled Syringe	02543036 02543044	JPC
Criteria	For ustekinumab-naïve patients whose ustekinumab therapy is initiated after August 26, 2024, an ustekinumab biosimilar will be the product approved.				

Patients with existing PEI Pharmacare coverage for Stelara® will need to switch to a biosimilar version before August 31, 2025, or by the renewal date of their current special authorization, whichever is earlier, to maintain coverage through PEI Pharmacare.

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 $\geq 20\text{mg}$ weekly ($\geq 15\text{mg}$ 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:

- Approvals will be for a maximum adult dose of up to 90 mg at 0, 4, and 16 weeks. If response criteria is met at 16 weeks, approval will be continued to a maximum dose of up to 90 mg every 12 weeks up to one year.
- Initial approval: 16 weeks.
- Renewal approval: 1 year.
- Concurrent use of biologics not approved.

Psoriatic Arthritis

For the treatment of patients with 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.

	<ul style="list-style-type: none"> • For the treatment of predominantly peripheral psoriatic arthritis who are refractory, intolerant or have contraindications to: <ul style="list-style-type: none"> o Sequential use of at least two NSAIDs for a minimum of two weeks each; AND o Methotrexate (oral or parenteral) at a dose of $\geq 20\text{mg}$ weekly ($\geq 15\text{mg}$ if patient is ≥ 65 years of age) for a minimum of 8 weeks; AND o Leflunomide for a minimum of 10 weeks or sulfasalazine for a minimum of 3 months <p>Clinical Notes:</p> <ul style="list-style-type: none"> • 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. <p>Claim Notes:</p> <ul style="list-style-type: none"> • Must be prescribed by a rheumatologist. • Concurrent use of biologics not approved. • Initial period 6 months. • Approvals will be for a maximum of 45mg subcutaneously at Weeks 0 and 4, and maintenance dosing of 45mg subcutaneously every 12 weeks. For patients $>100\text{kg}$, doses of 90mg may be considered. • Renewal approval: 1 year. Confirmation of continued response required.
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program

Ustekinumab	Wezlana	45mg / 0.5mL	Prefilled Syringe	02544180	AMG
		90mg / 1.0mL	Prefilled Syringe	02544199	
		45mg / 0.5mL	Single-use Vial	02544202	
	Wezlana I.V.	130mg / 26mL	Single-use Vial	02544210	
Criteria	<p>For ustekinumab-naïve patients whose ustekinumab therapy is initiated after August 26, 2024, an ustekinumab biosimilar will be the product approved.</p> <p>Patients with existing PEI Pharmacare coverage for Stelara® will need to switch to a biosimilar version before August 31, 2025, or by the renewal date of their current special authorization, whichever is earlier, to maintain coverage through PEI Pharmacare.</p> <p><u>Crohn's Disease</u></p> <p>For the treatment of patients with moderate to severe Crohn's disease who have active disease and are refractory, intolerant or have contraindications to:</p> <ul style="list-style-type: none"> • Prednisone 40mg (or equivalent) daily for ≥ 2 weeks, AND • Azathioprine $\geq 2 \text{ mg/kg/day}$ for ≥ 3 months, OR • Mercaptopurine $\geq 1 \text{ mg/kg/day}$ for ≥ 3 months, OR • Methotrexate (SC or IM) $\geq 15 \text{ mg/week}$ 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:

- 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.
- Initial reimbursement will be for a single intravenous dose of up to 520mg at Week 0 and a subcutaneous dose of 90mg at Week 8 and 16. Subsequent reimbursement for maintenance dosing is 90mg subcutaneously every 8 weeks.
- Initial Approval: 16 weeks
- Renewal Approval: 1 year

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 ≥ 20 mg weekly (≥ 15 mg 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:

- Approvals will be for a maximum adult dose of up to 90 mg at 0, 4, and 16 weeks. If response criteria is met at 16 weeks, approval will be continued to a maximum dose of up to 90 mg every 12 weeks up to one year.
- Initial approval: 16 weeks.
- Renewal approval: 1 year.
- Concurrent use of biologics not approved.

Psoriatic Arthritis

For the treatment of patients with 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.

- For the treatment of predominantly peripheral psoriatic arthritis who are refractory, intolerant or have contraindications to:
 - o Sequential use of at least two NSAIDs for a minimum of two weeks each; AND
 - o Methotrexate (oral or parenteral) at a dose of $\geq 20\text{mg}$ weekly ($\geq 15\text{mg}$ if patient is ≥ 65 years of age) for a minimum of 8 weeks; AND
 - o 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.
- Concurrent use of biologics not approved.
- Initial period 6 months.
- Approvals will be for a maximum of 45mg subcutaneously at Weeks 0 and 4, and maintenance dosing of 45mg subcutaneously every 12 weeks. For patients $>100\text{kg}$, doses of 90mg may be considered.
- Renewal approval: 1 year. Confirmation of continued response required.

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. aminosalicylates for a

	<p>minimum of four weeks AND prednisone \geq 40mg daily for two weeks or IV equivalent for one week) OR</p> <ul style="list-style-type: none"> • 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. <p>Clinical Notes:</p> <ul style="list-style-type: none"> • 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 <p>Claim Notes:</p> <ul style="list-style-type: none"> • 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. • Initial reimbursement will be for a single intravenous dose of up to 520mg at Week 0 and a subcutaneous dose of 90mg at Week 8 and 16. Subsequent reimbursement for maintenance dosing is 90mg subcutaneously every 8 weeks. • 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