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Programmes provinciaux de medicaments
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# PEI Pharmacare Bulletin

**Issue (2024 - 14)** **August 13, 2024**

## 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 |
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| **Insulin Aspart** | **Trurapi** | **100 units/mL** | **10mL vial** | **02529254** | **AVN** |
| Criteria | Open Benefit<br>*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 | | | | |

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| **Ustekinumab** | **Jamteki** | **45mg / 0.5mL**<br>**90mg / 1.0mL** | **Prefilled Syringe**<br>**Prefilled Syringe** | **02543036**<br>**02543044** | **JPC** |
| Criteria | For ustekinumab-naïve patients whose ustekinumab therapy is initiated after August 26, 2024, an ustekinumab biosimilar will be the product approved. | | | | |

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| | 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.<br><br><u>Plaque Psoriasis</u><br>For patients with severe, debilitating chronic plaque psoriasis who meet all of the following:<br>• Body surface area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genitals;<br>• 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<br>• Failure to, intolerant of or unable to access phototherapy.<br><br>Continued coverage is dependent on evidence of improvement, specifically:<br>• A >75% reduction (provide baseline and current score) in the Psoriasis Area and Severity Index (PASI) score; or<br>• A >50% reduction (provide baseline and current score) in PASI with a > 5 point improvement in DLQI (Dermatology Life Quality Index); or<br>• Significant reduction in BSA involved, with consideration of important regions such as the face, hands, feet or genitals.<br><br>Clinical Notes:<br>• 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.<br>• Failure is defined as lack of effect at the recommended doses and for duration of treatments specified above.<br>• Treatment should be discontinued if a response has not been demonstrated after 16 weeks.<br>• Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.<br><br>Claim notes:<br>• 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.<br>• Initial approval: 16 weeks.<br>• Renewal approval: 1 year.<br>• Concurrent use of biologics not approved.<br><br><u>Psoriatic Arthritis</u><br>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. |

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| | • For the treatment of predominantly peripheral psoriatic arthritis who are refractory, intolerant or have contraindications to:<br>o Sequential use of at least two NSAIDs for a minimum of two weeks each; AND<br>o 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<br>o Leflunomide for a minimum of 10 weeks or sulfasalazine for a minimum of 3 months<br><br>Clinical Notes:<br>• 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.<br>• Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.<br>• Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.<br><br>Claim Notes:<br>• Must be prescribed by a rheumatologist.<br>• Concurrent use of biologics not approved.<br>• Initial period 6 months.<br>• 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 >100kg, doses of 90mg may be considered.<br>• 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**<br><br>**Wezlana I.V.** | **45mg / 0.5mL**<br>**90mg / 1.0mL**<br>**45mg / 0.5mL**<br>**130mg / 26mL** | **Prefilled Syringe**<br>**Prefilled Syringe**<br>**Single-use Vial**<br>**Single-use Vial** | **02544180**<br>**02544199**<br>**02544202**<br>**02544210** | **AMG** |
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| Criteria | For ustekinumab-naïve patients whose ustekinumab therapy is initiated after August 26, 2024, an ustekinumab biosimilar will be the product approved.<br><br>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.<br><br><u>Crohn's Disease</u><br>For the treatment of patients with moderate to severe Crohn's disease who have active disease and are refractory, intolerant or have contraindications to:<br>• Prednisone 40mg (or equivalent) daily for ≥ 2 weeks, AND<br>• Azathioprine ≥ 2 mg/kg/day for ≥ 3 months, OR<br>• Mercaptopurine ≥ 1 mg/kg/day for ≥ 3 months, OR<br>• Methotrexate (SC or IM) ≥ 15 mg/week for ≥ 3 months | | | | |

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| | Clinical Notes:<br>• Refractory is defined as lack or loss of effect at the recommended doses and for duration of treatments specified above.<br>• Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.<br>• 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.<br><br>Claim Notes:<br>• Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.<br>• Combined use with other biologic drugs or janus kinase (JAK) inhibitors will not be reimbursed.<br>• 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.<br>• Initial Approval: 16 weeks<br>• Renewal Approval: 1 year<br><br><u>Plaque Psoriasis</u><br>For patients with severe, debilitating chronic plaque psoriasis who meet all of the following:<br>• Body surface area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genitals;<br>• 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<br>• Failure to, intolerant of or unable to access phototherapy.<br><br>Continued coverage is dependent on evidence of improvement, specifically:<br>• A >75% reduction (provide baseline and current score) in the Psoriasis Area and Severity Index (PASI) score; or<br>• A >50% reduction (provide baseline and current score) in PASI with a > 5 point improvement in DLQI (Dermatology Life Quality Index); or<br>• Significant reduction in BSA involved, with consideration of important regions such as the face, hands, feet or genitals.<br><br>Clinical Notes:<br>• 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.<br>• Failure is defined as lack of effect at the recommended doses and for duration of treatments specified above. |

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| | • Treatment should be discontinued if a response has not been demonstrated after 16 weeks.<br>• Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.<br><br>Claim notes:<br>• 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.<br>• Initial approval: 16 weeks.<br>• Renewal approval: 1 year.<br>• Concurrent use of biologics not approved.<br><br><u>Psoriatic Arthritis</u><br>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.<br>• For the treatment of predominantly peripheral psoriatic arthritis who are refractory, intolerant or have contraindications to:<br>o Sequential use of at least two NSAIDs for a minimum of two weeks each; AND<br>o 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<br>o Leflunomide for a minimum of 10 weeks or sulfasalazine for a minimum of 3 months<br><br>Clinical Notes:<br>• 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.<br>• Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.<br>• Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.<br><br>Claim Notes:<br>• Must be prescribed by a rheumatologist.<br>• Concurrent use of biologics not approved.<br>• Initial period 6 months.<br>• 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 >100kg, doses of 90mg may be considered.<br>• Renewal approval: 1 year. Confirmation of continued response required.<br><br><u>Ulcerative Colitis</u><br>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:<br>• Refractory or intolerant to conventional therapy (i.e. aminosalicylates for a |

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| | minimum of four weeks AND prednisone ≥ 40mg daily for two weeks or IV equivalent for one week) OR<br>• 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.<br><br>Clinical Notes:<br>• Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.<br>• 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.<br>• Patients with severe disease (partial Mayo > 6) do not require a trial of 5-ASA<br><br>Claim Notes:<br>• Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.<br>• Combined use of more than one biologic DMARD will not be reimbursed.<br>• 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.<br>• Initial Approval: 16 weeks<br>• Renewal Approval: 1 year |
| Program Eligibility | Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program |