

## PEI Pharmacare Bulletin

Issue (2023 - 6)

June 12, 2023

### NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: JUNE 26, 2023)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
<b>Alfacalcidol</b>	<b>Sandoz Alfacalcidol</b>	<b>0.25 mcg</b>	<b>Capsule</b>	<b>02533316</b>	<b>SDZ</b>
Criteria	Open benefit				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Generic Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

<b>Bimekizumab</b>	<b>Bimzelx</b>	<b>160 mg/ml</b> <b>160 mg/ml</b>	<b>Prefilled syringe</b> <b>Autoinjector</b>	<b>02525267</b> <b>02525275</b>	<b>UCB</b>
Criteria	<p>For the treatment of patients with chronic moderate to severe plaque psoriasis who meet all of the following criteria:</p> <ul style="list-style-type: none"> <li>• Psoriasis Area Severity Index (PASI) &gt; 10; and Dermatology Life Quality Index (DLQI) &gt; 10; or</li> <li>• Major involvement of visible areas, scalp, genitals, at least two finger nails, presence of itch leading to scratching or the presence of recalcitrant plaques; AND</li> <li>• Refractory, intolerant or have contraindications to: <ul style="list-style-type: none"> <li>- Phototherapy (unless restricted by geographic location); and</li> <li>- 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.</li> </ul> </li> </ul> <p>Clinical notes:</p> <ul style="list-style-type: none"> <li>• 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</li> <li>• Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.</li> <li>• Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.</li> </ul> <p>Claim notes:</p> <ul style="list-style-type: none"> <li>• Combined use of more than one biologic DMARD will not be reimbursed</li> <li>• Approvals will be for 320 mg given every 4 weeks for 16 weeks then 320 mg every 8 weeks thereafter.</li> </ul>				

	<ul style="list-style-type: none"> <li>Initial approval: 16 weeks.</li> </ul> Renewal approval: 1 year. Confirmation of continued response is required
Program Eligibility	Financial Assistance Drug Program, Nursing Home Drug Program, High Cost Drug Program, Catastrophic Drug Program

<b>Estradiol</b>	<b>Estrogel</b>	<b>0.06 %</b>	<b>Topical gel</b>	<b>02238704</b>	<b>ORG</b>
Criteria	Open benefit				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

<b>Heparin</b>	<b>Heparin LEO</b>	<b>1000 IU/ml</b>	<b>Vial</b>	<b>00453811</b>	<b>LEO</b>
Criteria	Open benefit				
Program Eligibility	Nursing Home Drug Program, Catastrophic Drug Program				

<b>Ketorolac</b>	<b>Acuvail</b>	<b>0.45 %</b>	<b>Ophthalmic solution</b>	<b>02369362</b>	<b>ABV</b>
Criteria	Open benefit				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

<b>Leuprolide acetate</b>	<b>Lupron Depot</b>	<b>30 mg</b>	<b>Depot injection</b>	<b>02239833</b>	<b>ABV</b>
Criteria	Open benefit				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

<b>Liothyronine</b>	<b>Teva-Liothyronine</b>	<b>5 mcg</b> <b>25 mcg</b>	<b>Tablet</b> <b>Tablet</b>	<b>02494337</b> <b>02494345</b>	<b>TEV</b>
Criteria	Open benefit				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Generic Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

<b>Mometasone</b>	<b>Asmanex</b>	<b>100 mcg</b>	<b>Dry powder inhaler</b>	<b>02438690</b>	<b>ORG</b>
Criteria	Open benefit				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

<b>Nimodipine</b>	<b>Nimotop</b>	<b>30 mg</b>	<b>Tablet</b>	<b>02325926</b>	<b>BAY</b>
Criteria	Open benefit				
Program Eligibility	Financial Assistance Drug Program, Nursing Home Drug Program, High Cost Drug Program, Catastrophic Drug Program				

<b>Praziquantel</b>	<b>Biltricide</b>	<b>600 mg</b>	<b>Tablet</b>	<b>02230897</b>	<b>BAY</b>
Criteria	Open benefit				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

<b>Tinzaparin</b>	<b>Innohep</b>	<b>8000 IU/0.4 ml</b> <b>12000 IU/0.6 ml</b> <b>16000 IU/0.8 ml</b>	<b>Prefilled syringe</b> <b>Prefilled syringe</b> <b>Prefilled syringe</b>	<b>02429462</b> <b>02429470</b> <b>02429489</b>	<b>LEO</b>
Criteria	See online Formulary for clinical criteria				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

<b>Tafamidis</b>	<b>Vyndamax</b>	<b>61 mg</b>	<b>Tablet</b>	<b>02517841</b>	<b>PFI</b>
Criteria	<p>For the treatment of cardiomyopathy in adult patients with documented hereditary or wildtype transthyretin-mediated amyloidosis (ATTR) who meet all of the following criteria:</p> <ul style="list-style-type: none"> <li>• New York Heart Association (NYHA) class I to III heart failure.</li> <li>• At least one prior hospitalization for heart failure or clinical evidence of heart failure that required treatment with a diuretic.</li> <li>• Has not previously undergone a heart or liver transplant.</li> <li>• Does not have an implanted cardiac mechanical assist device (CMAD).</li> </ul> <p>Discontinuation Criteria: The patient has:</p> <ul style="list-style-type: none"> <li>• NYHA class IV heart failure, or</li> <li>• received an implanted CMAD, or</li> <li>• received a heart or liver transplant.</li> </ul> <p>Clinical Notes:</p> <ol style="list-style-type: none"> <li>1. Wild-type ATTR-cardiomyopathy (CM) consists of all of the following: <ul style="list-style-type: none"> <li>• absence of a variant transthyretin (TTR) genotype</li> <li>• evidence of cardiac involvement by echocardiography with end-diastolic interventricular septal wall thickness greater than 12mm</li> <li>• positive findings on technetium-99mm pyrophosphate (Tc-99m-PYP) scintigraphy with single-photon emission computerized tomography (SPECT) scanning OR presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connection tissue sheath, or cardiac tissue); and TTR precursor protein identification by immunohistochemistry, scintigraphy, or mass spectrometer</li> </ul> </li> <li>2. Hereditary ATTR-CM consists of all of the following: <ul style="list-style-type: none"> <li>• presence of a variant TTR genotype associated with CM and presenting with a CM phenotype</li> <li>• evidence of cardiac involvement by echocardiography with end-diastolic interventricular septal wall thickness greater than 12mm</li> <li>• positive findings on technetium-99mm pyrophosphate (Tc-99m-PYP) scintigraphy with single-photon emission computerized tomography (SPECT) scanning OR presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connective tissue sheath, or cardiac tissue)</li> </ul> </li> </ol> <p>Claim Notes:</p> <ul style="list-style-type: none"> <li>• The patient must be under the care of a physician with experience in the diagnosis and treatment of ATTR-CM.</li> <li>• Combination therapy with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat ATTR-CM will not be reimbursed.</li> <li>• Initial approval period: 9 months.</li> <li>• Renewal approval period: 1 year.</li> </ul>				
Program Eligibility	Financial Assistance Drug Program, Nursing Home Drug Program, High Cost Drug Program, Catastrophic Drug Program				

<b>Upadacitinib</b>	<b>Rinvoq</b>	<b>15 mg</b>	<b>Tablet</b>	<b>02495155</b>	<b>ABV</b>
Criteria	For the treatment of moderately to severely active rheumatoid arthritis, alone or in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant or have contraindications to:				

- Methotrexate (oral or parenteral) at a dose of  $\geq 20$  mg weekly ( $\geq 15$ mg if patient is  $\geq 65$  years of age), (or use in combination with another DMARD) for a minimum of 12 weeks AND
- Methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

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.
- Optimal treatment response to DMARDs may take up to 24 weeks, however coverage of a biologic therapy can be considered if no improvement is seen after 12 weeks of triple DMARD use.
- If patient factors (e.g. intolerance) prevent the use of triple DMARD therapy, these must be described and dual therapy with DMARDs must be tried.
- 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.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Approvals will be for a maximum of 15 mg daily.
- Initial Approval: 6 months
- Renewal Approval: 1 year. Confirmation of continued response is required.

For the treatment of predominantly axial psoriatic arthritis who are refractory, intolerant or have contraindications to the sequential use of at least two NSAIDs at a maximum tolerated dose for a minimum of two weeks each.

For the treatment of predominantly peripheral psoriatic arthritis who are refractory or intolerant or have contraindications to:

- Sequential use of at least two NSAIDs at a maximum tolerated dose for a minimum of two weeks each; and
- Methotrexate (oral or parenteral) at a dose of  $\geq 20$ mg weekly ( $\geq 15$ mg if patient is  $\geq 65$  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 with other biologic drugs will not be reimbursed.
  - Approvals will be for a maximum of 15 mg daily.
  - Initial approval 16 weeks.
- Renewal approval: 1 year. Confirmation of continued response is required.

Program Eligibility	Financial Assistance Drug Program, Nursing Home Drug Program, High Cost Drug Program, Catastrophic Drug Program
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**CRITERIA UPDATE**

Effective June 26, 2023, currently listed criteria for Vyndaqel 20 mg DIN 02495732 will be updated to the same criteria for Vyndamax.