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PEI Pharmacare Bulletin

Issue (2025-15) **July 29, 2025**

NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: AUGUST 12, 2025)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Tocilizumab	**Tyenne**	**80mg / 4mL** **200mg / 10mL** **400mg / 20mL** **162mg / 0.9mL** **162mg / 0.9mL**	**Vial** **Vial** **Vial** **Prefilled Syringe** **Auto Injector**	**02552450** **02552469** **02552477** **02552493** **02552485**	**FKB**
Criteria	Patients with existing PEI Pharmacare coverage for Actemra® will need to switch to a biosimilar version before **July 31, 2026,** or by the renewal date of their current special authorization, whichever is earlier, to maintain coverage through PEI Pharmacare. <u>Giant Cell Arteritis</u> For the treatment of adult patients with new onset or relapsed giant cell arteritis (GCA) in combination with glucocorticoids (at initiation of therapy, or with relapse). Initial coverage will be for 16 weeks. • Reassessment should occur between 12 weeks and 16 weeks of therapy to determine response. Renewal requests: • Confirmation of response to treatment (i.e absence of flares AND normalization of C-reactive protein (CRP) to <1mg/dL) Clinical Note: • Flare is defined as the recurrence of signs or symptoms of GCA and/or erythrocyte sedimentation rate (ESR) greater or equal to 30 mm/hr attributable to GCA. Claim Notes: • Must be prescribed by, or in consultation with, a rheumatologist or other physician experienced in the treatment of GCA. • Combined use of more than one biologic DMARD will not be reimbursed. • Subcutaneous injection: Approvals will be for 162 mg every week.				

- Duration of therapy will be limited to 52 weeks per treatment course.

Authorization may be granted following any new episode of the disease, according to the treatment terms and conditions previously mentioned for the initial episode.

Juvenile Idiopathic Arthritis

For the treatment of active systemic juvenile idiopathic arthritis (sJIA), in patients 2 years of age or older, who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids (with or without methotrexate) due to intolerance or lack of efficacy.

- Must be prescribed by, or in consultation with, a pediatric rheumatologist.
- Coverage will be approved for an IV dose of 12 mg/kg for patients weighing less than 30kg or 8 mg/kg for patients weighing greater than or equal to 30kg to a maximum of 800mg, administered every two weeks.
- Initial Approval Period: 16 weeks
- Renewal Approval: Long term. Continued coverage will be dependent on a positive patient response as determined by a pediatric rheumatologist.

Polyarticular Juvenile Idiopathic Arthritis

For patients who have had an inadequate response to one or more disease modifying antirheumatic drugs (DMARDs).

- Must be prescribed by, or in consultation with, a pediatric rheumatologist.
- Coverage will be approved for an IV dose of 10 mg/kg for patients weighing less than 30kg or 8 mg/kg for patients weighing greater than or equal to 30kg to a maximum of 800mg, administered every four weeks.
- Initial Approval Period: 16 weeks
- Renewal Approval: Long term. Continued coverage will be dependent on a positive patient response as determined by a pediatric rheumatologist.

Rheumatoid Arthritis

For the treatment of severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:

- Methotrexate (oral or parenteral), alone or in combination with another DMARD, at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age), 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.

IV formulation: Approval for adults is 4mg/kg/dose every four weeks, with a maximum maintenance dose escalation up to 8mg/kg, to a maximum of 800mg per infusion.

SC formulation: Approval for adults is 162mg every other week for patients less than 100kg, with a maximum maintenance dose escalation to weekly dosing permitted. Patients equal to or greater than 100kg will be approved for 162mg every week, with no dose escalation permitted.

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 of more than one biologic DMARD will not be reimbursed. • Initial Approval: 6 months • Renewal Approval: Long term. Confirmation of continued response is required.
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program