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PEI Pharmacare Bulletin

Issue (2025-26) **December 19, 2025**

NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: JANUARY 6, 2026)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Omalizumab	**Omlyclo**	**75mg/0.5mL 150mg/1.0mL**	**Pre-filled syringe**	**02553805 02553813**	**CLT**
Criteria	For omalizumab-naïve patients whose omalizumab therapy is initiated after January 6, 2026, the omalizumab biosimilar will be the product approved. Patients with existing PEI Pharmacare coverage for Xolair will need to switch to the biosimilar version before January 6, 2027, or by the renewal date of their current special authorization, whichever is earlier, to maintain coverage through PEI Pharmacare. **Chronic Idiopathic Urticaria (CIU)** For the treatment of patients ≥ 12 years of age with moderate to severe chronic idiopathic urticaria (CIU) who remain symptomatic (presence of hives and/or associated itching) despite optimum management with H1 antihistamines. Initiation Criteria: • Documentation of the most recent Urticaria Activity Score over 7 days (UAS7) to be provided on the submitted request. • Approvals will be for a maximum dose of 300mg every four weeks. • Initial Approval Period: 24 weeks. Renewal Criteria: • Requests for renewal will be considered if the patient has achieved: o Complete symptom control for less than 12 consecutive weeks; or o Partial response to treatment, defined as at least a ≥ 9.5 point reduction in baseline UAS7 Clinical Notes: 1. Moderate to severe CIU is defined as UAS7 ≥16. 2. Treatment cessation could be considered for patients who experience complete symptom control for at least 12 consecutive weeks at the end of a 24-week treatment period. 3. In patients who discontinue treatment due to temporary symptom control,				

	reinitiation can be considered if CIU symptoms reappear. Claim Notes: • Prescribed by a specialist (allergist, immunologist, dermatologist, etc.) or other authorized prescriber with knowledge of CIU treatment. • Combined use of omalizumab with other biologics used to treat CIU will not be reimbursed. **<u>Allergic Asthma</u>** Initiation Criteria: • For the treatment of moderate to severe asthma in patients 6 years or older who meet all of the following criteria: o Asthma remains inadequately controlled despite the use of a high-dose inhaled corticosteroid (ICS) and a long-acting inhaled beta2-agonist (LABA). o Has within the past 12 months required: ▪ hospitalization for asthma; OR ▪ two or more urgent visits for asthma to a physician or an emergency department; OR ▪ two or more courses of high-dose oral corticosteroids. o The patient has a documented positive skin test or in vitro reactivity to a perennial aeroallergen. Discontinuation Criteria: • Baseline asthma control questionnaire score has not improved since the initiation of treatment, OR • Number of clinically significant asthma exacerbations has increased since the initiation of treatment. Clinical Notes: • High-dose inhaled corticosteroids is defined as greater than or equal to 500 mcg of fluticasone propionate or equivalent daily dose. • For patients 6 to 11 years old, medium dose ICS is defined as between 200 mcg and 400 mcg of fluticasone propionate or equivalent daily dose and high-dose ICS is defined as greater than 400 mcg of fluticasone propionate or equivalent daily dose. • A baseline and a re-assessment of asthma symptom control using an asthma control questionnaire score must be provided. • A baseline and a re-assessment of the number of clinically significant asthma exacerbations must be provided. Claim Notes: • Should be prescribed by a respirologist, clinical immunologist or allergist. Individual consideration may be given for extenuating circumstances where access to these specialists is not possible. • Combined use of omalizumab with other biologics used to treat asthma will not be reimbursed. • Approvals will be for a maximum dose of 375 mg every 2 weeks. • Initial approval duration: 6 months • Renewal approval duration: Long-term
Program Eligibility	High Cost Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Catastrophic Drug Program

Ustekinumab	Steqeyma	45mg/0.5mL	Vial	02558270	CLT
Criteria	See online Formulary for Ustekinumab criteria. **Effective January 6, 2026, special authorization criteria for currently listed Ustekinumab products have been amended to include the following indication:** <u>Ulcerative Colitis</u> 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 minimum of four weeks AND prednisone ≥ 40mg daily for two weeks or IV equivalent for one week) OR • 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. Clinical Notes: • 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. Claim Notes: • 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: Long term. Confirmation of continued response is required.				
Program Eligibility	High Cost Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

CRITERIA UPDATE

Effective immediately, special authorization criteria for currently listed aripiprazole (Abilify Maintena) long acting injectables have been amended to the following:

For the treatment of patients who are:

- not adherent to an oral antipsychotic, OR
- currently receiving a long-acting injectable antipsychotic and require an alternative long-acting injectable antipsychotic.

Claim Notes:

- Requests will not be considered for the treatment of psychotic symptoms related to dementia.
- Must be requested and prescribed by a psychiatrist.
- Only doses up to 400 mg every 4 weeks will be considered.
- For Community Mental Health Drug Program, no Special Authorization is required.