



Medicaid Coverage Policies for Xolair (omalizumab) injection

Xolair (omalizumab) injection	
Indication	<ul style="list-style-type: none"> For patients 6 years of age and older with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and who symptoms are inadequately controlled with inhaled corticosteroids Treatment of adults and adolescents 12 years of age and older with chronic idiopathic urticaria who remain symptomatic despite H1 antihistamine treatment
ICD10 Diagnosis Codes	J45.40, J45.50
Availability NDC	Single dose vial sterile powder without preservatives 150 mg/5 mL NDC 50242-0040-62 75 mg prefilled syringe NDC 50242-0214-01 150 mg prefilled syringe NDC 50242-0215-01
HCSPCS Code	J2357
Prior Authorization Status	Requires a prior authorization
Clinical Criteria for approval	<p>For Severe Persistent Allergic Asthma</p> <ul style="list-style-type: none"> Children and adults (≥ 6 years of age) 6 to <12 years of age IgE level: ≥ 30 and $\leq 1,300$ IU/mL ≥ 12 years of age IgE level: ≥ 30 and < 700 IU/mL Positive skin test or in vitro reactivity (≥ 0.35 kUA/L) to perennial aeroallergen (examples: dust mites, pet dander, cockroach) Symptoms must be inadequately controlled while adherent to high dose ICS with LABA for a period of three months or require use of oral systemic steroid to maintain control Must be prescribed by allergist/immunologist or pulmonologist <p>For Chronic Idiopathic Urticaria</p> <ul style="list-style-type: none"> Children and adults (≥ 6 years of age) History of chronic idiopathic urticaria for at least six months Presence of wheals and itching despite documented trial of therapy with H1 with or without H2 antihistamines. Doses of agent trials should be titrated to a 4x dose maximum from the starting dose unless intolerant or contraindicated to such titration. Therapy trial must be for at least 3 months in duration Must be prescribed by allergist/immunologist or pulmonologist