PHARMACY PRE-AUTHORIZATION CRITERIA

ConnectiCare

DRUG (S)	**Xolair (omalizumab)**
POLICY #	**24113, J-2357**
INDICATIONS	Xolair is indicated for adults and adolescents 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 aeroallergan and those symptoms are inadequately controlled with inhaled corticosteroids. Xolair is indicated for the treatment of chronic idiopathic urticaria in adults and adolescents 12 years and older who remain symptomatic despite H1 antihistamine treatment.
CRITERIA	**Criteria for use in Asthma:** 1. Patients must have a diagnosis of moderate to severe persistent asthma and must meet all (a, b, c, d,e,f and g) of the following criteria. a. Prescribed by an allergist, immunologist, or pulmonologist b. Patient has a positive skin test or *in vitro* testing (ie, a blood test for allergen-specific IgE antibodies such as the radioallergosorbent test (RAST)) for one or more perennial aeroallergens (eg, house dust mite [*Dermatophagoides farinae, D. pteronyssinus*], animal dander (dog, cat), cockroach, feathers, mold spores), AND/OR for one or more seasonal aeroallergens (grass, pollen, weeds) c. Patient's asthma symptoms have not been adequately controlled by inhaled corticosteroids after at least 3 months of therapy. Inadequate control on inhaled corticosteroids is demonstrated by one or more of the following: • hospitalization for asthma, • requirement for systemic (oral, parenteral) corticosteroids to control exacerbations of asthma, or • increasing need (usually > one time a day) for short-acting inhaled $beta_2$ agonists for symptoms (excluding preventive use for exercise-induced asthma) d. Patient is currently using a long acting beta-agonist in combination with a high dose inhaled corticosteroids at maximum doses for a minimum of 3 months. There is evidence of reversible airway disease (12% or greater improvement in FEV1 with at least a 200ml increase or 20% or greater improvement in PEF) Spirometry required. e. Patient is ≥ 6 years of age. **Criteria for use in Urticaria:** a. Prescribed by an allergist, immunologist, or dermatologist b. Patient must have a diagnosis of chronic idiopathic urticaria (at least a 6 week history) c. Patient must have tried, for a minimum of 2 weeks and failed 3 of the following antihistamines: cetirizine, levocetirizine, desloratadine, fexofenadine, loratadine **AND** d. A trial of a high-dose antihistamine with a leukotriene antagonist

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LIMITATIONS	Initial authorization is limited to a 3 month trial. Subsequent authorization up to 1 year will be granted with documented efficacy.
REFERENCES	1. Xolair® subcutaneous injection [package insert]. South San Francisco, CA and East Hanover, NJ: Genentech, Inc. and Novartis Pharmaceuticals Corporation 2. The Joint Task Force on Practice Parameters (JTFPP) represented the American Academy of Allergy, Asthma and Immunology (AAAAI); the American College of Allergy, Asthma and Immunology (ACAAI); and the Joint Council of Allergy, Asthma and Immunology (JCAAI) in developing the parameters of these guidelines. Bernstein J, et al. JACI 2014; 133, 1270-1277.
P&T REVIEW HISTORY	6/05, 6/07, 6/08, 9/09, 9/10, 12/11, 10/12, 10/13, 10/14, 11/15, 11/16, 11/17, 11/18
REVISION RECORD	11/12, 3/14, 2/15, 8/16, 11/16