Washington State Health Care Authority

Antiasthmatic Monoclonal Antibodies – Anti-IgE Antibodies

Medical policy no. 44.60.30-2 Effective Date: May 1, 2020

Related medical policies:

- **Antiasthmatic Monoclonal Antibodies – IL-5 Antagonists (Medical policy no. 44.60.40)**

Note: New-to-market drugs are non-preferred and subject to this class/category prior authorization (PA) criteria. Non-preferred agents in this class/category, require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class/category documentation of inadequate response to ONE preferred agent is needed.

Background:

Asthma is a common chronic inflammatory disease of the airways. For most patients asthma is well controlled with inhaled therapy but for those with severe asthma it can be associated with substantial morbidity, mortality, and economic effects.

Medical necessity

Drug	*Medical Necessity*
omalizumab (XOLAIR®)	**Omalizumab (XOLAIR®)** may be considered medically necessary when used for : • severe persistent allergic asthma in patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids. • chronic idiopathic urticaria in patients 12 years of age and older who remain symptomatic despite H1 antihistamine treatment. **Omalizumab (XOLAIR®)** is not considered medically necessary when used for: • relief of acute bronchospasm or status asthmaticus • treatment of other allergic conditions • treatment of other forms of urticaria • treatment of atopic dermatitis

Clinical policy:

Clinical Criteria	
Moderate to severe persistent allergic asthma	Omalizumab may be approved when all of the following criteria are met: 1. Severe persistent (allergic) asthma is defined by at least **ONE** of the following: a. FEV_1 less than (<) 80% predicted; **OR** b. Two or more bursts of systemic corticosteroids in the previous 12 months; **OR** c. Frequent (at least twice per year) additional medical treatment such as: emergency department (ED) visits, hospitalizations, mechanical ventilation, or unplanned (sick) office visits; **OR** d. Documentation of functional impairment due to poor asthma control or exacerbations: (e.g. activities of daily living (ADLs), nighttime awakening, or dyspnea); **AND** 2. Poor symptom control (e.g., ACQ score consistently greater than 1.5 or ACT score consistently less than 20); **AND** 3. History of failure (remains symptomatic after 6 weeks), contraindication or intolerance to medium- to high-dose inhaled corticosteroids (ICS); **AND** 4. Positive skin prick test or in-vitro specific IgE test (such as RAST, MAST, FAST, ELISA) to one or more allergens, (or is currently receiving specific immunotherapy like allergy shots) which support the patient's clinical history; **AND** 5. Pre-treatment serum IgE level between 30 and 700 IU/mL; **AND** 6. Combination use with other monoclonal antibodies(e.g. benralizumab, mepolizumab, reslizumab) is considered not medically necessary; **AND** 7. Prescribed by or in consultation with a specialist in allergy, pulmonology, or immunology; **AND** 8. Greater than or equal to (≥) 6 years of age If ALL criteria are met, the request may be approved for 12 months
	Criteria (Reauthorization) Omalizumab may be approved when all of the following criteria are met: 1. Clinical documentation of improved or sustained clinical benefit compared to baseline measures (e.g., reduced missed days from work or school, improved FEV_1, ACQ or ACT scores, decrease in burst of systemic corticosteroids, etc.) or stable asthma control If ALL criteria are met, the request may be approved for 12 months
Chronic idiopathic urticaria	Omalizumab may be approved when all of the following criteria are met:

	1. Diagnosis of chronic idiopathic urticarial **AND** documentation that rules out all other causes of urticaria, including all potential triggers of urticaria; **AND** 2. Patient continues to have spontaneous urticarial flares, in the absence of potential triggers, and while on optimal management of all underlying conditions and potential triggers; **AND** 3. Documentation of functional impairment due to poor urticaria control or exacerbations: (e.g., activities of daily living (ADLs), insomnia, missing school or work); **AND** 4. Patient shows a trial at least 2 weeks minimum with second-generation H1 antihistamines; **AND** 5. Patient has tried at least **ONE** or more of the following: a. Dose increase of second-generation H1 antihistamine at the maximally tolerated dose, unless contraindicated; **OR** b. Addition of another second-generation H1 antihistamine; **OR** c. Addition of H2 antihistamine; **OR** d. Addition of leukotriene-receptor antagonist; **OR** e. Addition of first-generation H1 antihistamine at bedtime; **AND** 6. Patient is not using omalizumab with benralizumab or mepolizumab or reslizumab; **AND** 7. Patient is greater than or equal to (≥) 12 years of age; **AND** 8. Prescribed by or in consultation with a specialist in allergy, dermatology, immunology, or pulmonology If ALL criteria are met, the request may be approved for 12 months
	Criteria (Reauthorization) Omalizumab may be approved when all of the following criteria are met: 1. Clinical documentation of improved or sustained clinical benefit from reduced urticaria symptoms (such as reduced missed days from work or school or insomnia due to itching) If ALL criteria are met, the request may be approved for 12 months

Dosage and quantity limits

Indication	Dose and Quantity Limits
Severe persistent allergic asthma	• Up to 375 mg every 14 days.
Chronic idiopathic urticaria	• Up to 300mg every 28 days; 2 vial per 28-day supply

Coding:

HCPCS Code	*Description*
J2357	Injection, omalizumab, 5 mg

References

1. Product Information: XOLAIR(R) subcutaneous injection, omalizumab subcutaneous injection. Genentech Inc (per FDA), South San Francisco, CA, 2019.

History

Date	Action and Summary of Changes
01/27/2020	General formatting updates and updated footnote date to January 27, 2020
01/13/2020	Changed effective date to May 1, 2020
12/10/2019	General formatting updates
09/24/2019	General formatting updates
08/15/2019	Updated criteria
02/21/2018	New Policy