

omalizumab (XOLAIR)

Diagnoses Considered for Coverage:

- Chronic spontaneous urticaria (or chronic idiopathic urticaria)
- Nasal polyps
- Moderate to severe persistent allergic asthma

Coverage Criteria:

For diagnosis of nasal polyps:

INITIAL AUTHORIZATION:

- Patient has been on Xolair via office administration and requests to self-administer, **and**
- Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist, **and**
- Provider attestation that patient has nasal polyps, **and**
- Age is consistent with FDA-approved indication, **and**
- Inadequate response, intolerable side effect, or contraindication to intranasal glucocorticoid, **and**
- Dose does not exceed FDA label maximum.

Coverage Duration: 6 months

REAUTHORIZATION:

- Dose does not exceed FDA label maximum, **and**
- Patient responded to therapy.

For diagnosis of chronic spontaneous urticaria (or chronic idiopathic urticaria):

INITIAL AUTHORIZATION:

- Patient has been on Xolair via office administration and requests to self-administer, **and**
- Dose does not exceed FDA label maximum, **and**
- Diagnosis of moderate to severe chronic idiopathic urticaria, **and**
- Prescribed by or in consultation with an allergist or immunologist, **and**
- Age is consistent with FDA-approved indication, **and**
- A history of (a) or (b) or (c):
 - a. Inadequate response to a one-week trial of hydroxyzine or doxepin, or
 - b. Inadequate response to maximally tolerated second-generation antihistamine (see below), or
 - c. Intolerance or contraindication to hydroxyzine, doxepin and second-generation antihistamines.

Coverage Duration: 6 months

REAUTHORIZATION:

- Dose does not exceed FDA label maximum, **and**
- Patient responded to therapy.

For diagnosis of allergic asthma:

INITIAL AUTHORIZATION:

- Patient has been on Xolair via office administration and requests to self-administer, **and**
- Dose does not exceed FDA label maximum, **and**
- Age is consistent with FDA-approved indication, **and**
- Prescribed by or in consultation with a pulmonologist, allergist, or immunologist, **and**
- Total serum IgE level is ≥ 30 IU/ml and the pre-treatment IgE levels do not exceed manufacturer's dosing recommendations, **and**
- Asthma symptoms remain uncontrolled despite 3 months of treatment with a high-dose inhaled corticosteroid in combination with long-acting beta agonist [LABA] or leukotriene receptor antagonists [LTRA], **and**
- Patient is not receiving this medication in combination with another biologic medication indicated for asthma treatment, **and**
- Meets ONE of the following within the past year:
 - One or more acute asthma attacks requiring emergency care, or
 - One or more acute inpatient visits where asthma was the principal diagnosis, or
 - Use of chronic systemic steroids due to severe asthma OR two or more acute asthma exacerbations requiring oral systemic steroids.

Coverage Duration: 6 months

REAUTHORIZATION:

- Patient is not receiving this medication in combination with another biologic medication indicated for asthma treatment, **and**
- Provider attestation that asthma symptoms have improved and/or controlled while on Xolair
- Dose does not exceed FDA label maximum.

Coverage Duration: one year

Effective Date: 3/29/2023