Montana Healthcare Programs
Physician Administered Drug Coverage Criteria

XOLAIR® (omalizumab)

I. Medication Description

Xolair® is an anti-IgE antibody indicated for:

- Moderate to severe persistent 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 adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.

II. Position Statement

Coverage is determined through a prior authorization process **that must include** supporting clinical documentation for each request.

III. Initial Coverage Criteria

Allergic Asthma:

Member must meet all the following criteria:

- Member must be 6 years of age or older**.**
- Member must have moderate/severe asthma and allergies**.**
- Prescriber must practice in an appropriate specialty clinic (Pulmonology/Allergy/Immunology) or have an annual consult on file.
- Member must be adherent to ICS**.**
- Please include pretreatment serum total IgE level and current body weight for dose calculation/verification.

Chronic Idiopathic Urticaria (CIU):

Member must meet all the following criteria:

- Member must be 12 years of age or older.
- Member must have a diagnosis of chronic idiopathic urticaria**.**
- Prescriber must practice in an appropriate specialty clinic (Allergy/Immunology/Dermatology) or have an annual consult on file**.**
- Member must have had an inadequate response to 2 different antihistamine trials of 4 weeks each.

IV. Renewal Coverage Criteria

Allergic Asthma:

Member must meet all the following criteria:

- Member has been adherent to Xolair®.
- Member has experienced a positive clinical response (reduction in the frequency and/or severity of symptoms and exacerbations).
- Annual specialist consult provided if prescriber not a specialist**.**

CIU:

Member must meet all the following criteria:

- Member has been adherent to Xolair®.
- Member has experienced a positive clinical response (reduction in the frequency and/or severity of symptoms and exacerbations).
    - If there is insufficient control after initial 3 months, no further authorization will be approved.
- Annual specialist consult provided if prescriber not a specialist**.**

V. Quantity Limitations

Allergic Asthma: Max 375mg SQ every 2 weeks (refer to dosage chart in package insert).
CIU: Max 300mg SQ every 4 weeks.

VI. Coverage Duration

Allergic Asthma:

Initial approval duration: 1 year
Renewal approval duration: 1 year

CIU:

Initial approval duration: 3 months
Renewal approval duration: 6 months