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 spontaneous urticaria (CSU) in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.
- Nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance 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 Spontaneous Urticaria (CSU):
Member must meet all the following criteria:

- Member must be 12 years of age or older.
- Member must have a diagnosis of chronic spontaneous 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.

Nasal Polyps
Member must meet all the following criteria:

- Member must be 18 years of age or older.
- Prescriber must practice in an appropriate specialty clinic (Allergy/Immunology/Otolaryngology) or have an annual consult on file.
- Member has clinical documentation of chronic rhinosinusitis WITH nasal polyps as evidenced by CT scan or endoscopy.

- Member must have had an inadequate treatment response, intolerance or contraindication to **BOTH** of the following:
    - **TWO** different intranasal corticosteroids (must have been adherent to therapy at optimized doses for at least three months).
    - Systemic corticosteroid trial (must be within last year) **and/or** sino-nasal surgery.
- Member must concurrently be using an intranasal corticosteroid, unless contraindicated.
- Please include pretreatment serum total IgE level and current body weight for dose calculation/verification.

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**.**

CSU
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**.**

Nasal Polyps
Member must meet all the following criteria:

- Member has been adherent to Xolair®.
- Member has been adherent to intranasal corticosteroid.
- Member has experienced a positive clinical response (reduction in polyp size, decreased congestion, improved sense of smell, post-nasal drip, runny nose).
- 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).

CSU
Max 300mg SQ every 4 weeks.

Nasal Polyps
Max 600mg SQ every 2 weeks (refer to dosage chart in package insert).

VI. Coverage Duration

Allergic Asthma
Initial approval duration: 1 year
Renewal approval duration: 1 year

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

Nasal Polyps
Initial approval duration: 6 months
Renewal approval duration: 1 year