



Montana Healthcare Programs Drug Prior Authorization (PA) or Physicians Administered Drugs (PAD) Criteria **Fasenra® (benralizumab)**

I. Medication Description

Fasenra® is an interleukin-5 receptor alpha-directed cytolytic monoclonal antibody (IgG1, kappa) indicated for the add-on maintenance treatment of patients with severe asthma aged 6 years and older and with an eosinophilic phenotype.

II. Position Statement

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

III. Initial Coverage Criteria

Member must meet all the following criteria:

- Be 6 years of age or older.
- Have a diagnosis of severe uncontrolled asthma with an eosinophilic phenotype.
 - Have baseline peripheral blood eosinophil count of ≥ 150 cells/ μ L.
 - Have a history of severe asthma attacks despite treatment with, and adherence to, an optimized dose of inhaled corticosteroid in combination with a long-acting beta2-agonist (ICS/LABA) for three consecutive months.

Prescriber requirements:

- Must be prescribed by or in consult with a pulmonology, allergy or immunology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests member **will not** use Fasenra® concomitantly with other biologics.

Limitations:

- Fasenra® is not indicated for treatment of other eosinophilic conditions or for the relief of acute bronchospasm or status asthmaticus.
- Dosed per package labeling.

IV. Renewal Coverage Criteria

Member must meet all the following criteria:

- Have documentation of positive clinical response to therapy such as a reduction in frequency and/or severity of symptoms and exacerbations or medication dose reduction.
- Be compliant with Fasenra® and ICS/LABA therapy.

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Verification of compliance will be made via Medicaid paid claims data. If non-compliance is determined, the reauthorization time frame may be reduced to allow time for the provider to address member compliance.
- Attests member **will not** use Fasenra® concomitantly with other biologics.

V. Quantity Limits

Maximum dose:

- Adults and adolescents 12 years of age and older: 30mg SQ every 4 weeks for 3 doses, then 30mg SQ every 8 weeks.
- Children 6 to 11 years of age and older:
 - Weighing less than 35kg: 10mg SQ every 4 weeks for the first 3 doses, then 10mg SQ once every 8 weeks.
 - Weighing 35kg or more: 30mg SQ every 4 weeks for the first 3 doses, then 30mg SQ once every 8 weeks.

VI. Coverage Duration

Initial approval: 6 months

Renewal approval duration: 12 months