Generic Name: Benralizumab

Therapeutic Class or Brand Name: Fasenra®

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 3/6/2020

Date Last Reviewed / Revised: 9/27/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I and IV are met)

I. Documented diagnosis of one of the following conditions, and must meet all criteria under applicable diagnosis:

A. Severe asthma and must meet criteria 1 AND 2:

1. Documentation of one of the following (a or b):

a) Documented blood eosinophilia count ≥150 cells/mcL at baseline.

b) Documentation that the patient has been on a minimum of a six-month trial of a high-dose inhaled corticosteroid (ICS) used in combination with a long-acting inhaled beta-2 agonist (LABA).

2. Documentation that the patient's asthma symptoms are poorly controlled despite therapy AND patient meets at least one of the following criteria (a through e):

a) Poor symptom control (eg, Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20)

b) Two or more asthma exacerbations requiring systemic corticosteroids within the past 12 months.

c) One or more asthma exacerbations requiring emergency treatment (ie, hospitalization, mechanical ventilation, emergency room visit) within the past 12 months.

d) Worsening asthma when oral corticosteroids are tapered.

e) Baseline forced expiratory volume in one second (FEV1) less than 80% predicted.

3. Minimum age requirement: 6 years old

B. Eosinophilic granulomatosis with polyangiitis (EGPA, formerly Churg-Strauss Syndrome):

1. Documentation of active, non-severe disease (vasculitis without life- or- organ-threatening manifestations [eg, rhinosinusitis, asthma, mild systemic symptoms, uncomplicated cutaneous disease, mild inflammatory arthritis]).

2. Documentation of blood eosinophils ≥1000 cells/mL and/or ≥10% of leukocytes

3. Documented history or presence of asthma and at least two of the following disease characteristics a through i:
    a) Histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
    b) Neuropathy
    c) Non-fixed pulmonary infiltrates
    d) Sinonasal abnormality
    e) Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
    f) Glomerulonephritis (hematuria, red cell casts, and proteinuria)
    g) Alveolar hemorrhage
    h) Palpable purpura
    i) Anti-neutrophil cytoplasmic antibody [ANCA] positivity
4. Documentation that the patient is stable on daily corticosteroid therapy or has a contraindication to corticosteroid therapy.
5. Documented treatment failure to one or contraindication to all systemic immunosuppressant(s) (ie, azathioprine, cyclophosphamide, methotrexate, mycophenolate mofetil). Minimum age requirement: 18 years old.

II.

III. Treatment must be prescribed by or in consultation with an allergist, immunologist, or pulmonologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Treatment of other eosinophilic conditions.
- Treatment of acute bronchospasm or status asthmaticus.
- Concurrent use with other anti-asthma monoclonal antibodies (ie, Cinqair (reslizumab), Dupixent(dupilumab), Nucala (mepolizumab), Tezspire (tezepelumab), Xolair (omalizumab)).

OTHER CRITERIA

- N/A

Quantity / Days Supply Restrictions

- Severe asthma: one 30 mg pen or syringe every 28 days for the first 3 doses, then one 30 mg pen or syringe every 8 weeks.
- EGPA: one 30 mg pen or syringe every 4 weeks.

Approval Length

- **Authorization:** 6 months
- **Re-Authorization:** 12 months, with an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

Appendix

- N/A

References

1. Fasenra®. Prescribing Information. AstraZeneca Pharmaceuticals; 09/2024. Accessed September 27, 2024. https://den8dhaj6zs0e.cloudfront.net/50fd68b9-106b-4550-b5d0-12b045f8b184/3647bed4-ce91-4fe7-9bc5-32dbee73f80a/3647bed4-ce91-4fe7-9bc5-32dbee73f80a_viewable_rendition__v.pdf
2. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma [published correction appears in *Eur Respir J*. 2014 Apr;43(4):1216. Dosage error in article text] [published correction appears in *Eur Respir J*. 2018 Jul 27;52(1):] [published correction appears in *Eur Respir J*. 2022 Jun 9;59(6):]. *Eur Respir J*. 2014;43(2):343-373. doi:10.1183/09031936.00202013
3. Global Initiative for Asthma. Difficult-to-treat & severe asthma in adolescent and adult patients: diagnosis and management V4.0. August 2023. Accessed October 15, 2023. https://ginasthma.org/severeasthma/