

SENTARA COMMUNITY PLAN (MEDICAID)

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; fax to 1-844-305-2331. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. If information provided is not complete, correct, or legible, authorization can be delayed.

Drug Requested: Fasenra® SQ (benralizumab) (J0517) (Medical)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight (if applicable): _____ Date weight obtained: _____

☐ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

- Fasenra® 10mg/0.5ml single prefilled syringe and pen= 10 billable units
- Fasenra® 30mg/ml single prefilled syringe and pen= 30 billable units

Recommended Dosing:

☐ **Asthma, severe eosinophilic:**

Adult and Adolescent Patients 12 Years of Age and Older:

- 30 mg every 4 weeks for the first 3 doses followed by once every 8 weeks thereafter

Pediatric Patients 6 Years to 11 Years of Age:

- Weighing Less Than 35 kg: the recommended dosage is 10 mg every 4 weeks for first 3 doses followed by once every 8 weeks thereafter
- Weighing 35 kg or More: the recommended dosage is 30 mg every 4 weeks for first 3 doses followed by once every 8 weeks thereafter

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☐ **Eosinophilic granulomatosis with polyangiitis (EGPA):** 30 mg every 4 weeks

***The Health Plan considers the use of concomitant therapy with Cinqair[®], Dupixent[®], Nucala[®], Tezspire[™] and Xolair[®] to be experimental and investigational. Safety and efficacy of these combinations have **NOT** been established and will **NOT** be permitted. In the event a member has an active Cinqair[®], Dupixent[®], Nucala[®], Tezspire[™] or Xolair[®] authorization on file, all subsequent requests for Fasenra[®] will **NOT** be approved.**

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

☐ **Diagnosis: Asthma, severe eosinophilic**

Initial Authorization: 6 months

1. Has the member been approved for Fasenra[®] previously through the Sentara pharmacy department?
☐ Yes ☐ No
2. Is the member 6 years of age or older?
☐ Yes ☐ No
3. Does the member have a diagnosis of severe* asthma?
☐ Yes ☐ No
4. Does the member have asthma with an eosinophilic phenotype defined as blood eosinophils ≥ 150 cells/ μ L?
☐ Yes ☐ No
5. Will coadministration with another monoclonal antibody be avoided (i.e. omalizumab, mepolizumab, reslizumab, dupilumab, tezepelumab-ekko)?
☐ Yes ☐ No
6. Will Fasenra[®] be used for add-on maintenance treatment in members regularly receiving both (unless otherwise contraindicated) of the following:
 - Medium to high dose inhaled corticosteroids **AND**
 - An additional controller medication (i.e. long-acting beta agonist, leukotriene modifiers)?☐ Yes ☐ No
7. Has the member had two or more exacerbations in the previous year requiring oral or injectable corticosteroid treatment (in addition to the regular maintenance therapy defined above) **or** one exacerbation resulting in hospitalization?
☐ Yes ☐ No

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8. Does the member have at least one of the following for assessment of clinical status:
- Use of systemic corticosteroids
 - Use of inhaled corticosteroids
 - Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition forced expiratory volume in 1 second (FEV₁)?
- ☐ Yes ☐ No

☐ **Diagnosis: Asthma, severe eosinophilic**

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

1. Has the member been assessed for toxicity?
☐ Yes ☐ No
2. Does the member have improvement in asthma symptoms or asthma exacerbations as evidenced by a decrease in one or more of the following:
 - Use of systemic corticosteroids
 - Hospitalizations
 - ER visits
 - Unscheduled visits to healthcare provider
 - Improvement from baseline in forced expiratory volume in 1 second (FEV₁)?☐ Yes ☐ No

☐ **Diagnosis: Eosinophilic Granulomatosis Polyangiitis (EGPA)**

Initial Authorization : 6 months

1. Has the member been approved for Fasenra[®] previously through the Sentara pharmacy department?
☐ Yes ☐ No
2. Is the member 18 years of age and older?
☐ Yes ☐ No
3. Does the member have a confirmed diagnosis of EGPA (aka Churg-Strauss Syndrome)?
☐ Yes ☐ No
4. Does the member have blood eosinophils ≥ 1000 cells/ μ L or $>10\%$ of leukocytes?
☐ Yes ☐ No
5. Is the member currently on maximally tolerated oral corticosteroid therapy or have an intolerance, hypersensitivity or contraindication to oral corticosteroid therapy?
☐ Yes ☐ No

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6. Has the physician assessed baseline disease severity utilizing an objective measure/tool (e.g., Birmingham Vasculitis Activity Score [BVAS], history of asthma symptoms and/or exacerbations, duration of remission, rate of relapses)?

☐ Yes ☐ No

☐ Diagnosis: Eosinophilic Granulomatosis Polyangiitis (EGPA)

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

1. Has the member been assessed for toxicity?
☐ Yes ☐ No
2. Does the member have disease response as indicated by improvement in signs and symptoms compared to baseline as evidenced in one or more of the following:
 - Member is in remission [defined as a Birmingham Vasculitis Activity Score (BVAS) score=0 and a prednisone/prednisolone daily dose of ≤ 4 mg]
 - Decrease in maintenance dose of systemic corticosteroids
 - Improvement in BVAS score compared to baseline
 - Improvement in asthma symptoms or asthma exacerbations
 - Improvement in duration of remission or decrease in the rate of relapses?☐ Yes ☐ No

***Components of severity for classifying asthma as *severe* may include any of the following (not all inclusive):**

- Asthma that remains uncontrolled despite optimized treatment with high-dose ICS-LABA
- Asthma that requires high-dose ICS-LABA to prevent it from being uncontrolled
- Symptoms throughout the day
- Nighttime awakenings, often 7 times per week
- SABA use for symptom control occurs several times per day
- Extremely limited normal activities
- Lung function (percent predicted FEV₁) < 60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

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Eosinophilic Granulomatosis Polyangiitis (EGPA) is defined as all of the following:

- History or presence of asthma
- Blood eosinophil level > 10% or an absolute count > 1000 cells/mm³
- Two or more of the following criteria:
 - Histopathologic evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil rich granulomatous inflammation
 - Neuropathy
 - Pulmonary infiltrates
 - Sinonasal abnormalities
 - Cardiomyopathy
 - Glomerulonephritis
 - Alveolar hemorrhage
 - Palpable purpura
 - Antineutrophil Cytoplasmic Antibody (ANCA) positivity

Medication being provided by: Please check applicable box below.

☐ Location/site of drug administration: _____

NPI or DEA # of administering location: _____

OR

☐ Specialty Pharmacy – PropriumRx

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****