| Pharmacy Policy Bulletin: J-0935 Interleukin (IL)-5 Antagonists – Commercial and Healthcare Reform | |
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| **Number:** J-0935 | **Category:** Prior Authorization |
| **Line(s) of Business:**<br>☒ Commercial<br>☒ Healthcare Reform<br>☐ Medicare | **Benefit(s):**<br>**Commercial:**<br>**Prior Authorization (1.):**<br>**1.** Miscellaneous Specialty Injectable= Yes w/ Prior Authorization<br>**Healthcare Reform**: Not Applicable |
| **Region(s):**<br>☒ All<br>☐ Delaware<br>☐ New York<br>☐ Pennsylvania<br>☐ West Virginia | **Additional Restriction(s):**<br>None |
| **Version:** J-0935-016 | **Original Date:** 08/07/2019 |
| **Effective Date: 07/18/2025** | **Review Date:** 06/25/2025 |

| | |
|---|---|
| **Drugs Product(s):** | • Nucala (mepolizumab) prefilled autoinjector and prefilled syringe<br>• Fasenra (benralizumab) pen |
| **FDA-Approved Indication(s):** | • Nucala (mepolizumab)<br>  ○ Add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma and with an eosinophilic phenotype.<br>  ○ Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).<br>  ○ Add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype<br>  ○ Treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause.<br>  ○ Add-on maintenance treatment of adult patients 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP).<br>• Fasenra (benralizumab)<br>  ○ Add-on maintenance treatment of patients 6 years of age and older with severe asthma, and with an eosinophilic phenotype.<br>  ○ Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA). |

| | |
|---|---|
| **Background:** | • Nucala and Fasenra work by binding to and inhibiting interleukin-5 (IL-5), the major cytokine responsible for growth and differentiation, recruitment, activation, and survival of eosinophils. IL-5 inhibition reduces the production and survival of eosinophils, but the exact mechanism of action for the treatment of asthma has not been definitively established.<br>**Asthma**<br>• Appropriate diagnosis of asthma (versus etiology of pulmonary fibrosis, for example, COPD or idiopathic pulmonary fibrosis) may be confirmed by measurement of $FEV_1$ reversibility after administration of albuterol. As a standard guideline, 12% or 200 mL is generally accepted as $FEV_1$ reversibility. |

- The standard of care for moderate to severe asthma is maintenance use of a moderate- or high-dose inhaled corticosteroid (ICS) and long-acting beta agonist (LABA) ± oral corticosteroids taken as daily or alternate-day therapy.
- Eosinophilic phenotype asthma is associated with tissue and sputum eosinophilia, thickening of basement membrane zone, and often by response to corticosteroids.
- According to asthma guidelines, it is recommended to attempt to reduce systemic corticosteroid use when asthma is well controlled.
- Biologic therapy may be considered for moderate to severe asthma once maintenance treatment is optimized.
- The Global Initiative for Asthma (GINA) guidelines recommend biologic therapy in patients with uncontrolled, difficult-to-treat and severe asthma when optimized on a medium- or high-dose ICS with a second controller (usually a long-acting beta-2 agonist [LABA]). The GINA guidelines define uncontrolled asthma as 2 or more asthma exacerbations requiring oral corticosteroids or 1 or more asthma exacerbation requiring hospitalization.

| **Estimated Comparative Daily Inhaled Corticosteroid Dosages for Patients 6 to 11 years old** | | | |
|---|---|---|---|
| **Drug** | **Low Dose** | **Moderate Dose** | **High Dose** |
| Beclomethasone dipropionate (pMDI, standard particle, HFA) | 100-200 mcg | > 200-400 mcg | > 400 mcg |
| Beclomethasone dipropionate (pMDI, extrafine particle, HFA) | 50-100 mcg | > 100-200 mcg | > 200 mcg |
| Budesonide (DPI, or pMDI, standard particle, HFA) | 100-200 mcg | > 200-400 mcg | > 400 mcg |
| Budesonide (nebules) | 250-500 mcg | >500-1000 mcg | >1000 mcg |
| Ciclesonide (pMDI, extrafine particle, HFA) | 80 mcg | >80-160 mcg | >160 mcg |
| Fluticasone Furoate (DPI) | 50 mcg | 50 mcg | n.a. |
| Fluticasone propionate (DPI) | 50-100 mcg | > 100-200 mcg | > 200 mcg |
| Fluticasone propionate (pMDI, standard particle, HFA) | 50-100 mcg | >100-200 mcg | >200 mcg |
| Mometasone furoate (pMDI, standard particle, HFA) | 100 mcg | 100 mcg | 200 mcg |

Abbreviations: DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; pMDI: pressurized metered dose inhaler

| **Estimated Comparative Daily Inhaled Corticosteroid Dosages for Patients ≥ 12 years old** | | | |
|---|---|---|---|
| **Drug** | **Low Dose** | **Moderate Dose** | **High Dose** |

| | | | |
|---|---|---|---|
| Beclomethasone dipropionate (pMDI, standard particle, HFA) | 200-500 mcg | >500-1000 mcg | >1000 mcg |
| Beclomethasone dipropionate (DPI or pMDI, extrafine particle, HFA) | 100-200 mcg | >200-400 mcg | >400 mcg |
| Budesonide (DPI, or pMDI, standard particle, HFA) | 200-400 mcg | >400-800 mcg | >800 mcg |
| Ciclesonide (pMDI, extrafine particle, HFA) | 80-160 mcg | >160-320 mcg | >320 mcg |
| Fluticasone furoate (DPI) | 100 mcg | 100 mcg | 200 mcg |
| Fluticasone propionate (DPI) | 100-250 mcg | >250-500 mcg | >500 mcg |
| Fluticasone propionate (pMDI, standard particle, HFA) | 100-250 mcg | >250-500 mcg | >500 mcg |
| Mometasone furoate (DPI) | 220 mcg | >220-440 mcg | >440-880 mcg |
| Mometasone furoate (pMDI, standard particle, HFA) | 200-400 mcg | 200-400 mcg | >400 mcg |

Abbreviations: DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; pMDI: pressurized metered dose inhaler

**Chronic obstructive pulmonary disease (COPD)**

- COPD is a progressive lung disease that encompasses emphysema, chronic bronchitis, and refractory asthma. The airways in the lungs become inflamed and thicken. Lung tissue is destroyed causing less oxygen to enter the body, while carbon dioxide becomes more difficult to remove. COPD may deteriorate acutely over a period of hours or chronically over several days or longer. When this occurs, a re-evaluation of the COPD treatment should be reviewed immediately.
- The 2024 Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines categorize patients into three different categories (A, B and E), based on COPD symptoms and exacerbation frequency and severity. These categories help to guide treatment for patients. For group A patients, first-line drug therapy is a short- or long-acting bronchodilator. A long-acting bronchodilator is preferred unless the patient has only very occasional dyspnea. For group B patients, first-line drug therapy is combination therapy with a LAMA plus a LABA. For group E patients, first-line drug therapy is LABA/LAMA combination therapy. If the blood eosinophil count ≥ 300 cells/mcL, consider triple therapy with LAMA/LABA plus an ICS (LABA/LAMA/ICS). If the patient has a history of asthma or findings suggestive of comorbid asthma, addition of an ICS is mandatory, as management of these patients should primarily follow asthma guidelines.

| | |
|---|---|
| Exacerbation History: ≥ 2 moderate exacerbations or ≥ 1 leading to hospital admission | E |

| Exacerbation History: 0 or 1 moderate exacerbations (not leading to hospital admission) | A | B |
|---|---|---|
| | Symptoms: mMRC 0 to 1 or CAT < 10 | Symptoms: mMRC ≥ 2 or CAT ≥ 10 |

- The GOLD grades and severity of airflow obstruction (note that this may be different from severity of the disease) in COPD is based on post-bronchodilator $FEV_1$.

| **COPD patients ($FEV_1/FVC < 0.7$)** | | |
|---|---|---|
| GOLD 1 | Mild | $FEV_1 \geq 80\%$ predicted |
| GOLD 2 | Moderate | $50\% \leq FEV_1 \leq 80\%$ predicted |
| GOLD 3 | Severe | $30\% \leq FEV_1 \leq 50\%$ predicted |
| GOLD 4 | Very Severe | $FEV_1 < 30\%$ predicted |

- At an individual patient level, $FEV_1$ by itself is an unreliable marker of the severity of breathlessness, exercise limitation, health status impairment, and risk of exacerbation. Because there is a weak correlation between the severity of airflow obstruction and the symptoms experienced by the patient or the impairment of their health status, formal assessment of symptoms using validated questionnaires is required.
- The mMRC dyspnea scale is used to assess the degree of baseline functional disability due to dyspnea.

**Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)**

- Chronic rhinosinusitis (CRS) is defined as inflammation of the nose and paranasal sinuses that lasts for more than 12 weeks and usually responds incompletely to therapy, which may need to be continued long-term. There are 3 phenotypes of CRS: CRS with nasal polyps (CRSwNP), CRS without nasal polyps (CRSsNP), and allergic fungal rhinosinusitis (AFRS).
- According to the British Society for Allergy and Clinical Immunology (BSACI) guidelines, all patients should have a trial of medical treatment before surgery unless the nature of the polyps is in doubt.
- Smaller polyps may respond to intranasal corticosteroids only, initially betamethasone nasal drops. Larger polyps may respond to a medical polypectomy including prednisolone and betamethasone nasal drops.
- Other treatment options for CRSwNP include nasal saline, anti-leukotrienes, systemic corticosteroids, antibiotics, azelastine, aspirin desensitization, and sinus surgery.
- The Nasal Congestion Score is a patient reported tool used to measure changes in nasal congestion and obstruction. It ranges from 0 – 3, and is the monthly average of the daily morning AM patient-assessed daily symptom severity (0 = no symptoms to 3 = severe symptoms).
- The Nasal Polyp Score (NPS), the sum of right and left nostril scores, is a physician-reported assessment used to characterize the patient's polyps from 0 = no polyps to 4 = severe disease with large polyps causing complete obstruction of the inferior nasal cavity. Each nostril is scored on a scale of 0 to 4, with the total score being the sum of left and right nostril scores (range: 0-8).
- Absolute eosinophil count = % Eosinophil x White blood cell count

**EGPA**

- EPGA is a rare form of vasculitis; it causes inflammation in small and medium sized blood vessels, which can result in damage to organs throughout the body. In most people, blood vessels in the lungs are affected, causing breathing and lung issues.

**HES**

- HES is a rare group of inflammatory disorders that affects approximately 20,000 people world-wide. Patients with HES have persistent and marked overproduction of eosinophils. When eosinophils infiltrate certain tissues, they

can cause inflammation and organ damage. If left untreated, the symptoms of HES become progressively worse; the disease can be life-threatening.

- Nucala is available in three dosage forms – a single-dose prefilled syringe available as either 100 mg/mL or 40 mg/0.4 mL; a 100 mg/mL single-dose prefilled autoinjector; and a 100 mg single-dose vial for reconstitution.
  - The single-dose vial is to be administered by a healthcare provider only and is globally excluded under the pharmacy benefit. For severe asthma, this formulation may be used in patients 6 to 11 years of age at a dose of 40 mg every 4 weeks or at a dose of 100 mg every 4 weeks for patients 12 years of age or older.
  - The 100 mg/mL prefilled autoinjector and prefilled syringe are indicated for use in patients 12 years of age and older, while the 40 mg/0.4 mL single-dose prefilled syringe is only indicated for patients 6 to 11 years of age. These formulations may be administered by a healthcare provider or a caregiver.
- Fasenra prefilled syringe is for administration by a healthcare provider and is globally excluded under the pharmacy benefit. Fasenra pen is intended for administration by patients/caregivers. In patients aged 6 to 11 years weighing ≥ 35 kg, Fasenra pen should only be administered by a caregiver or healthcare provider. Fasenra pen is not able to appropriately dose a patient 6-11 years weighing < 35 kg.
- Prescribing considerations:
  - Fasenra, and Nucala are not intended for relief of acute bronchospasm or status asthmaticus.
  - Fasenra is not indicated for treatment of other eosinophilic conditions nor for relief of acute bronchospasm or status asthmaticus.
  - Patients should not utilize dual therapy with another monoclonal antibody for the treatment of asthma.
  - Systemic or inhaled corticosteroids should not be discontinued abruptly upon initiation of therapy with Nucala or Fasenra, but decreased gradually, if appropriate.
  - Opportunistic infections including herpes zoster may occur during treatment. Patients should consider vaccination prior to treatment, if clinically appropriate.
  - Patients with pre-existing helminth infections should be treated prior to initiating therapy with these agents.
  - 1 microliter (ul or mcL) = 1 cubic millimeter ($mm^3$)
  - 1 Liter = $10^6$ microliter
  - Converting from liter to microliter: Absolute eosinophils (decimal) X $10^9$/Liter = Absolute eosinophils (decimal) X 1,000/microliter

## Approval Criteria

**I. Nucala Prefilled Syringe/Autoinjector**

**A. Severe Asthma**

**1. Initial Authorization**

When a benefit, coverage of Nucala may be approved for severe asthma when all of the following criteria are met **(a. through f.):**

**a.** The member meets one (1) of the following **(i. or ii.)**:

**i.** If the request is for the 40 mg/0.4 mL prefilled syringe, the member is 6 to 11 years of age.

**ii.** If the request is for the 100 mg/mL prefilled syringe or autoinjector, the member is 12 years of age or older.

**b.** The member has a diagnosis of severe asthma with an eosinophilic phenotype (ICD 10: J45.5, J82.83).

**c.** The member meets one (1) of the following criteria **(i. or ii.)**:

**i.** The member has history of ≥ 2 asthma exacerbations requiring oral or injectable corticosteroid treatment in the previous 12 months.

**ii.** The member has a history of ≥ 1 asthma exacerbation requiring hospitalization in the previous 12 months.

**d.** The member meets one (1) of the following blood eosinophil counts (in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease, and known suspected parasitic infection) **(i. or ii.)**:

**i.** Baseline (pre-treatment) levels greater than or equal to 150 cells/microliter within the past 6 weeks.

**ii.** Greater than or equal to 300 cells/microliter within the past 12 months.

**e.** The member has inadequate symptom control despite regular treatment with medium- or high-dose inhaled corticosteroids (ICS) and at least one (1) additional asthma controller (e.g., long-acting beta-2 agonist [LABA], leukotriene receptor antagonist [LTRA], or theophylline), with or without oral corticosteroids (OCS).

**f.** The member will continue treatment with medium- or high-dose ICS and at least one (1) additional asthma controller (e.g., LABA, LTRA, or theophylline), with or without OCS, while using Nucala.

**2. Reauthorization**

When a benefit, reauthorization of Nucala may be approved when all of the following criteria are met **(a. and b.)**:

**a.** The member meets one (1) of the following criteria **(i. or ii.)**:

**i.** If the request is for the 40 mg/0.4 mL prefilled syringe, the member is 6 to 11 years of age.

**ii.** If the request is for the 100 mg/mL prefilled syringe or autoinjector, the member is 12 years of age or older.

**b.** The member meets one (1) of the following criteria **(i. through iv.)**:

**i.** The prescriber attests that the member has decreased rescue medication or OCS use.

**ii.** The prescriber attests that the member has had a decrease in frequency of severe asthma exacerbations.

**iii.** The prescriber attests that the member experienced an increase in pulmonary function from baseline (e.g., FEV1).

**iv.** The prescriber attests that the member has experienced a reduction in reported asthma-related symptoms (e.g., asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing).

**B. Chronic Obstructive Pulmonary Disease (COPD)**

**1. Initial Authorization**

When a benefit, coverage of Nucala may be approved when all of the following criteria are met **(a. through g.)**:

**a.** The member is 18 years of age and older.

**b.** The member has a diagnosis of COPD (ICD-10: J41-J44).

**c.** The member has a post-bronchodilator $FEV_1$ ≤ 80% predicted.

**d.** The member meets one (1) of the following criteria **(i. or ii.)**:

**i.** The member has a blood eosinophilic count of ≥ 300 cells/mcL.

**ii.** The member is currently taking daily or alternate-day oral corticosteroids.

**e.** The member has a modified Medical Research Council dyspnea scale score of ≥ 2.

**f.** The member meets one (1) of the following criteria **(i., ii., or iii.)**:

i. An exacerbation history of at least two (2) moderate exacerbations resulting in treatment with systemic corticosteroids and/or antibiotics in the previous year.
ii. One (1) severe exacerbation resulting in hospitalization or observation in the emergency department for over 24 hours in the previous year.
iii. GOLD group E.

**g.** The member has inadequate symptom control despite regular treatment for at least 3 months with triple therapy consisting of a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (LAMA/LABA/ICS), unless intolerant of, or has contraindications to these agents.

**2. Reauthorization**

When a benefit, reauthorization of Nucala may be approved when one (1) of the following criteria is met **(a. through d.):**

**a.** The prescriber attests that the member has experienced a reduction in symptoms of COPD.
**b.** The prescriber attests that the member has experienced an improvement in exercise tolerance.
**c.** The prescriber attests that the member has experienced delayed disease progression.
**d.** The prescriber attests that the member has experienced a reduction in the number of exacerbations.

**C. EGPA**

**1. Initial Authorization**

When a benefit, coverage of Nucala may be approved for EGPA when all of the following criteria are met **(a. through d.):**

**a.** The member is 18 years of age or older.
**b.** The request is for the 100 mg/mL prefilled syringe or autoinjector.
**c.** The member has a history of relapsing or refractory EGPA. (ICD-10: M30.1)
**d.** The member will be receiving standard of care while on therapy with glucocorticoid treatment (e.g. prednisone or prednisolone), with or without immunosuppressive therapy (e.g. cyclosporine, leflunomide, azathioprine etc.).

**2. Reauthorization**

When a benefit, reauthorization of Nucala may be approved when all of the following criteria are met **(a. and b.):**

**a.** The request is for the 100 mg/mL prefilled syringe or autoinjector.
**b.** The member meets one (1) of the following **(i. through iv.)**:
**i.** The prescriber attests that the member has experienced reduction in the frequency and/or severity of relapses.
**ii.** The prescriber attests that the member has experienced a reduction or discontinuation of doses of corticosteroids and/or immunosuppressant.
**iii.** The prescriber attests that the member has experienced disease remission.
**iv.** The prescriber attests that the member has experienced a reduction in severity or frequency of EGPA-related symptoms.

**3. Quantity Level Limits for EGPA**

When prior authorization is approved, Nucala may be authorized for the following quantity **(a.)**:

**a.** Three (3) 100 mg prefilled syringes or auto-injectors every 4 weeks

**D. HES**

**1. Initial Authorization**

When a benefit, coverage of Nucala may be approved for HES when all of the following criteria are met **(a. through f.):**

**a.** The member is 12 years of age or older.
**b.** The request is for the 100 mg/mL prefilled syringe or autoinjector.

**c.** The member has HES (ICD-10: D72.11) without an identifiable non-hematologic secondary cause for ≥ 6 months.
**d.** The member has experienced at least 2 HES flares (HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy) within the past 12 months.
**e.** The member has a blood eosinophil count of ≥ 1,000 cells per mcL.
**f.** The member has been stable on HES therapy for at least 4 weeks (chronic or episodic oral corticosteroids, immunosuppressive, or cytotoxic therapy).

**2. Reauthorization**
When a benefit, reauthorization of Nucala may be approved when the following criteria are met **(a. and b.):**
**a.** The request is for the 100 mg/mL prefilled syringe or autoinjector.
**b.** The member meets one (1) of the following **(i. or ii.)**:
**i.** The prescriber attests that the member has experienced a reduction in frequency of HES flares.
**ii.** The prescriber attests that the member has experienced a maintenance or reduction in background HES therapy requirements.

**3. Quantity Level Limits for HES**
When prior authorization is approved, Nucala may be authorized for the following quantity **(a.)**:
**a.** Three (3) 100 mg prefilled syringes or auto-injectors every 4 weeks

**E. CRSwNP**
**1. Initial Authorization**
When a benefit, coverage of Nucala may be approved for CRSwNP when all of the following criteria are met **(a. through f.):**
**a.** The member is 18 years of age or older.
**b.** The request is for the 100 mg/mL prefilled syringe or autoinjector.
**c.** The member has a diagnosis of recurrent or symptomatic CRSwNP. (ICD-10: J32.9, J33.9)
**d.** The prescriber submits documentation that the patient's baseline bilateral nasal polyp score (NPS) is ≥ 5.
**e.** The prescriber submits documentation of the patient's baseline nasal congestion score.
**f.** The member has experienced therapeutic failure, contraindication, or intolerance to a generic intranasal corticosteroid.

**2. Reauthorization**
When a benefit, reauthorization of Nucala may be approved when all of the following criteria are met **(a. and b.):**
**a.** The request is for the 100 mg/mL prefilled syringe or autoinjector.
**b.** The member meets one (1) of the following criteria **(i. or ii.)**:
**i.** The prescriber submits attestation that the member has a decrease in their nasal polyp score.
**ii.** The prescriber submits attestation that the member has a reduction in their nasal congestion/obstruction severity score.

**II. Fasenra Pen**
**A. Severe Asthma**
**1. Initial Authorization**
When a benefit, coverage of Fasenra pen may be approved for severe asthma when all of the following criteria are met **(a. through f.)**:
**a.** The member is 6 years of age or older.

**b.** The member has a diagnosis of severe asthma with an eosinophilic phenotype (ICD 10: J45.5, J82.83).
**c.** The member meets one (1) of the following criteria **(i. or ii.):**
  **i.** The member has a history of ≥ 2 asthma exacerbations requiring oral or injectable corticosteroid treatment in the previous 12 months.
  **ii.** The member has a history of ≥ 1 asthma exacerbation requiring hospitalization in the previous 12 months.
**d.** The member meets one (1) of the following blood eosinophil counts (in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease, and known suspected parasitic infection) **(i. or ii.)**:
  **i.** Baseline (pre-treatment) levels greater than or equal to 150 cells/microliter within the past 6 weeks.
  **ii.** Greater than or equal to 300 cells/microliter within the past 12 months.
**e.** The member has inadequate symptom control despite regular treatment with medium- or high-dose inhaled corticosteroids (ICS) and at least one (1) additional asthma controller (e.g., long-acting beta-2 agonist [LABA], leukotriene receptor antagonist [LTRA], or theophylline), with or without oral corticosteroids (OCS).
**f.** The member will continue treatment with medium- or high-dose ICS and at least one (1) additional asthma controller (e.g., LABA, LTRA, or theophylline), with or without OCS, while using Fasenra.

**2. Reauthorization**
When a benefit, reauthorization of Fasenra pen may be approved when one (1) of the following criteria are met **(a. through d.):**
**a.** The prescriber attests that the member has decreased rescue medication or OCS use.
**b.** The prescriber attests that the member has had a decrease in frequency of severe asthma exacerbations.
**c.** The prescriber attests that the member experienced an increase in pulmonary function from baseline (e.g. FEV1).
**d.** The prescriber attests that the member has experienced a reduction in reported asthma-related symptoms (e.g. asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing).

**3. Quantity Level Limits**
When prior authorization is approved, Fasenra pen may be authorized in quantities as follows:

| Diagnosis | Induction Therapy | Maintenance Therapy |
|---|---|---|
| **Severe asthma with eosinophilic phenotype in pediatric patients 6 to 11 years of age (≥ 35 kg)** | One (30 mg) auto-injector every 4 weeks for 3 doses | One (30 mg) auto-injector every 8 weeks |
| **Severe asthma with eosinophilic phenotype in adult and adolescent patients 12 years of age and older** | One (30 mg) auto-injector every 4 weeks for 3 doses | One (30 mg) auto-injector every 8 weeks |

**B. EGPA**
**1. Initial Authorization**
When a benefit, coverage of Fasenra may be approved for EGPA when all of the following criteria are met **(a. through d.):**
**a.** The member is 18 years of age or older.
**b.** The request is for the 30 mg/mL autoinjector.
**c.** The member has a history of relapsing or refractory EGPA. (ICD-10: M30.1)

**d.** The member will be receiving standard of care while on therapy with glucocorticoid treatment (e.g. prednisone or prednisolone), with or without immunosuppressive therapy (e.g. cyclosporine, leflunomide, azathioprine etc.).

**2. Reauthorization**

When a benefit, reauthorization of Fasenra may be approved when all of the following criteria are met **(a. and b.):**

**a.** The request is for the 30 mg/mL autoinjector.

**b.** The member meets one (1) of the following **(i. through iv.)**:

**i.** The prescriber attests that the member has experienced reduction in the frequency and/or severity of relapses.

**ii.** The prescriber attests that the member has experienced a reduction or discontinuation of doses of corticosteroids and/or immunosuppressant.

**iii.** The prescriber attests that the member has experienced disease remission.

**iv.** The prescriber attests that the member has experienced a reduction in severity or frequency of EGPA-related symptoms.

**3. Quantity Level Limits for EGPA**

When prior authorization is approved, Fasenra may be authorized for the following quantity **(a.)**: One (1) 30 mg auto-injector every 4 weeks

**III.** An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

## Limitations of Coverage

**I.** Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

**II.** For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

## Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization will be granted.

## Automatic Approval Criteria

None

**References:**


1. Nucala [package insert]. Research Triangle Park, NC: GlaxoSmithKline; May 2025.
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3. Global Initiative for Asthma. Global Strategy for Astha Management and Prevention. Available at: https://ginasthma.org/2025-report/. Accessed May 28, 2025.
4. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2024.
5. Eosinophilic Granulomatosis with Polyangiitis (EGPA). Available at: https://www.lung.org/lung-health-diseases/lung-disease-lookup/egpa?gclid. Accessed October 5, 2020.

6. GSK's Nucala Hits the Mark in Phase III HES Trial, Setting Up Potential Approval. Available at: https://www.biospace.com/article/gsk-plans-for-another-nucala-approval-following-positive-phase-iii-hes-study/. Accessed October 2, 2020.