Utilization Management Policy Name: Nucala® & Fasenra® subcutaneous injection

Restricted Product(s):

- Nucala (mepolizumab)
- Fasenra (benralizumab)

FDA Approved Use:

Nucala:

- Add-on maintenance treatment of patients with severe asthma aged 12 years and older with an eosinophilic phenotype.
- The treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
- Limitations of use: Not for relief of acute bronchospasm or status asthmaticus

Fasnera:

- Add-on maintenance treatment of patients with severe asthma in adults and children 12 years or older with an eosinophilic phenotype.
- Limitations of use: Not for relief of acute bronchospasm or status asthmaticus

Criteria for Approval of Restricted Product(s):

Initial Criteria for Approval:

For patients that are new to the plan and currently taking the medication, the criteria pertain to when the patient started the medication.

1. The patient has a diagnosis of eosinophilic asthma; **AND**
    a. The patient is 12 years of age or older; **AND**
    b. The patient has one of the following:
        i. Eosinophil counts greater than or equal to 150 cells/microliter at initiation of therapy: **OR**
        ii. Eosinophil counts greater than or equal to 300 cells/microliter in the past 12 months; **AND**
    c. The patient does NOT have a hyper-eosinophilic syndrome, neoplastic disease, or known/suspected parasitic infection; **AND**
    d. The patient has had two or more exacerbations in the past year despite therapy with:
        i. 12 months of high-dose inhaled corticosteroid (ICS) given in combination with a minimum of 3 months of controller medication (either a long-acting beta2-agonist [LABA], or leukotriene receptor antagonist [LTRA], or theophylline), unless the individual is intolerant of, or has a medical contraindication to these agents; **OR**

   ii. 6 months of ICS with daily oral glucocorticoids given in combination with a minimum of 3 months of controller medication (either a LABA, or LTRA, or theophylline), unless the individual is intolerant of, or has a medical contraindication to these agents; **OR**

2. The patient has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA/Churg-Strauss Syndrome); **AND**
   a. The request is for Nucala; **AND**
   b. The patient is 18 years of age or older; **AND**
   c. The patient has been diagnosed for six months or greater; **AND**
   d. The patient is stable on oral corticosteroids; **AND**
   e. The patient has tried and failed or has a clinical intolerance/contraindication to an oral immunosuppressant (e.g. cyclophosphamide, azathioprine, methotrexate, leflunomide); **AND**
3. For formularies that exclude (non-formulary) the requested medication, Non-formulary Exception Criteria applies (outlined below) *

Duration of Approval: 365 days

Continuation Criteria for Approval:

1. The patient was approved through Blue Cross NC initial criteria for approval; **OR**
2. The patient would have met criteria for approval at the time they started therapy; **AND**
3. For patients using Nucala or Fasenra for eosinophilic asthma they demonstrated one or more of the following while taking the medication:
   a. Decreased utilization of rescue medications;
   b. Decreased frequency of exacerbations (defined as worsening of asthma that requires an increase in ICS dose or treatment with systemic corticosteroids);
   c. Increase in predicted FEV1 from pretreatment baseline;
   d. Reduction in reported asthma-related symptoms, such as, asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing.
4. For patients using Nucala for eosinophilic granulomatosis;
   a. The member is stable on oral corticosteroid therapy.

Duration of Approval: 365 days

Quantity Limitations: quantity limitations apply to brand and associated generic products.

Maintenance Therapy – Eosinophilic Asthma - Nucala	
Medication	**Quantity per Day (unless specified)**
Nucala 100mg/mL Prefilled Syringe/ Auto-injector	1 syringe/ autoinjector per 28 days
Maintenance Therapy – Eosinophilic Granulomatosis with Polyangiitis - Nucala	
Medication	**Quantity per Day (unless specified)**
Nucala 100mg/mL Prefilled Syringe/ Auto-injector	3 syringes/ autoinjectors per 28 days

Initial Therapy – Eosinophilic Asthma - Fasenra	
Medication	**Quantity per Day (unless specified)**
Fasenra Pen 30mg/mL	3 pens in the first 12 weeks
Maintenance Therapy – Eosinophilic Asthma - Fasenra	
Medication	**Quantity per Day (unless specified)**
Fasenra Pen 30mg/mL	1 pen per 56 days

Quantity Limit Exception Criteria:

1. The quantity (dose) requested is for documented titration purposes at the initiation of therapy (authorization for a 90 day titration period); **AND**
2. The prescribed dose cannot be achieved using a lesser quantity of a higher strength; **AND**
3. The quantity (dose) requested does not exceed the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer's product insert; **OR**
4. If the quantity (dose) requested exceeds the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer's product insert, then the prescriber must submit documentation in support of therapy with a higher dose for the intended diagnosis (submitted documentation may include medical records OR fax form which reflects medical record documentation that shows the length of time the requested dose has been used, and what other medications and doses have been tried and failed).

***Non-formulary Exception Criteria**

Non-Formulary Exception criteria applies on formularies which exclude requested product(s). Satisfactory completion of criteria points (above) may satisfy some, or all, portions of the Non-Formulary Exception Criteria. This criteria is summarized as:

a) Request must be for an FDA approved indication; **AND**
b) Patient must have a trial and failure of up to **TWO** formulary medications or a clinical contraindication/intolerance to those medications not tried.

References: all information referenced is from FDA package insert unless otherwise noted below.

Policy Implementation/Update Information:

April 2020: Criteria change: Added requirement of a trial and failure of an oral immunosuppressant for diagnosis of EGPA/Churg-Strauss Syndrome prior to Nucala use.
November 2019: Criteria update: Added dosing for Fasenra initial therapy to Quantity Limit.
November 2019: Criteria change: Corrected age requirement of Nucala to 12 years of age.
October 2019: Criteria update: Added new to market Fasenra pen injection to criteria.
September 2019: Criteria update: Updated age criteria for eosinophilic asthma from 12 years of age to 6 years of age.
August 2019: Original utilization management criteria issued.

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  - Qualified interpreters

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- You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, Civil Rights Coordinator - Privacy, Ethics & Corporate Policy Office is available to help you.

- You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at *https://ocrportal.hhs.gov/ocr/portal/lobby.jsf,* or by mail or phone at: U.S. Department of Health and Human Services 200 Independence Avenue, SW Room 509F, HHH Building Washington, D.C. 20201 **1-800-368-1019, 800-537-7697** (TDD). Complaint forms are available at *http://www.hhs.gov/ocr/office/file/index.html*.

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