Updated: 01/2019
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Gateway Health
Prior Authorization Criteria
Interleukin-5 Inhibitors

Interluekin-5 Inhibitors addressed in this policy include: Nucala (mepolizumab), Cinqair (reslizumab), and Fasenra (benralizumab)

All initial requests for Interleukin-5 Inhibitors require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Interleukin-5 Inhibitors Prior Authorization Criteria:

For all requests for Interleukin-5 Inhibitors all of the following criteria must be met:

- Must be prescribed by, or in consultation with, an allergist, immunologist, pulmonologist, or rheumatologist
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines

Coverage may be provided with a diagnosis of severe asthma and the following criteria is met:

- The member is at least 12 years of age for Nucala/Fasenra **OR** the member is at least 18 years of age for Cinqair
- Documentation of bronchodilator reversibility demonstrated either by an increase in FEV1 of ≥ 12 percent from baseline or an increase of ≥ 10 percent of predicted FEV1
- The member has one of the following blood eosinophil counts:
    - For Nucala:
        - Blood eosinophil count > 150 cells/microliter within 6 weeks of treatment initiation; **OR**
        - Blood eosinophil count > 300 cells/microliter in the past 12 months
    - For Cinqair:
        - Blood eosinophil count > 400 cells/microliter within 4 weeks of treatment initiation
    - For Fasenra:
        - Blood eosinophil count > 150 cells/microliter within 4 weeks of treatment initiation
- Failure of controller medications defined as:
    - Symptoms have been uncontrolled despite adherence with at least a three month trial of controller medications, which includes at least a high-dosed inhaled corticosteroid plus another agent
- The requested medication will be used in conjunction with one of the following:
    - A maximally-dosed combination inhaled corticosteroid/long-acting-beta-agonist product **OR**
    - Combination therapy defined as:
        - A maximally-dosed inhaled corticosteroid; **AND**

        - An additional standard asthma controller medication (e.g., long-acting beta agonist, leukotriene receptor antagonist, etc.)
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
    - Documentation the member had a positive clinical response or stabilization as demonstrated by one of the following:
        - An increase in the member's FEV_1
        - A decreased need for systemic corticosteroids
        - A decrease in the number of asthma related hospitalizations
        - A reduction in reported asthma-related symptoms
    - Adjunctive therapies (inhaled corticosteroids, long-acting beta-2 agonist, leukotriene receptor antagonist, theophylline) must be consistently filled per pharmacy claims history
        - If pharmacy claims do not confirm fills within the previous 2 months, the request will be denied
- **Reauthorization Duration of approval:**12 months

Coverage may be provided with a diagnosis of eosinophilic granulomatosis with polyangiitis and the following criteria is met:

- Request must be for Nucala
- The member is at least 18 years of age or older
- Member has a documented diagnosis of eosinophilic granulomatosis with polyangiitis based on the presence of at least four of the following diagnostic criteria:
    - Asthma
    - Eosinophilia (>10% eosinophils on the differential leukocyte count)
    - Mononeuropathy or polyneuropathy
    - Migratory or transient pulmonary infiltrates on chest x-rays
    - Paranasal sinus abnormalities
    - Biopsy containing a blood vessel with extravascular eosinophils
- The member has been stable on corticosteroids for at least 4 weeks or the prescriber has indicated clinical inappropriateness of corticosteroid therapy
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
    - Must provide documentation of at least one of the following:
        - Reduction in the frequency or severity of relapses
        - Reduction or discontinuation of doses of corticosteroids or immunosuppressant
        - Reduction in severity or frequency of symptoms
- **Reauthorization Duration of approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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INTERLEUKIN-5 INHIBITORS
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health[SM] Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis: _____ **ICD-10 Code**: _____

Please list the therapies and dates tried in the "Current or Previous Pharmacologic Therapy" Section on page 2.

For diagnosis of severe asthma:
Has the member been uncontrolled despite adherence with at least a three month trial of controller medications, which includes at least a high-dosed inhaled corticosteroid? ☐ Yes ☐ No
Will the requested medication be used in conjunction with one of the following?
☐ Maximally-dosed combination inhaled corticosteroid/ long-acting-beta2-agonist product
Please document what combination agent will be prescribed: _____
☐ Combination therapy defined as a high-dose inhaled corticosteroid **AND** an additional standard asthma controller medication (e.g., long-acting beta agonist, leukotriene receptor antagonist, etc.)
Please document what inhaled corticosteroid will be prescribed: _____
Please document what standard asthma controlled medication will be prescribed: _____

For diagnosis of eosinophilic granulomatosis with polyangiitis:
Please select all the diagnostic criteria that are applicable to the member:
- ☐ Asthma
- ☐ Mononeuropathy or polyneuropathy
- ☐ Migratory or transient pulmonary infiltrates on chest x-rays
- ☐ Eosinophilia (>10% eosinophils on the differential leukocyte count)
- ☐ Paranasal sinus abnormalities
- ☐ Biopsy containing a blood vessel with extravascular eosinophils

Has the member been stable on corticosteroids for at least four weeks? ☐ Yes ☐ No

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MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Is there documentation of clinical benefit and tolerance to therapy? ☐ Yes ☐ No

For diagnosis of severe asthma:
Which of the following has the member experienced?: *Please select all that apply*
☐ Reduced asthma exacerbations
☐ Reduced asthma-related hospitalizations
☐ Reduced asthma-related emergency room visits
☐ Reduced requirement for oral corticosteroid therapy
☐ Reduction in reported asthma-related symptoms
☐ Other: _____

For diagnosis of eosinophilic granulomatosis with polyangiitis:
☐ Reduction in the frequency or severity of relapses
☐ Reduction or discontinuation of doses of corticosteroids or immunosuppressant
☐ Reduction in severity or frequency of symptoms
☐ Other: _____

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date