Cinqair (reslizumab)
Fasenra (benralizumab)
Nucala (mepolizumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial requests: 6 months Continuation requests: 1 year

Medications	Quantity Limit	Dosing Limit
Cinqair (reslizumab) 100 mg vial		3 mg/kg every 4 weeks
Fasenra (benralizumab) 10 mg/0.5 ml prefilled syringe	10 mg (1 syringe) every 8 weeks	
Fasenra (benralizumab) 30 mg/ml prefilled syringe/autoinjector	30 mg (1 syringe/autoinjector) every 8 weeks	
Nucala (mepolizumab) 40 mg/0.4ml prefilled syringe	40 mg (1 syringe) every 4 weeks	
Nucala (mepolizumab) 100 mg vial, 100 mg/ml prefilled syringe/autoinjector	100 mg (1 vial/syringe/autoinjector) every 4 weeks	

For Fasenra, may approve 1 additional 30 mg prefilled syringe/autoinjector or 10 mg/mL prefilled syringe at week 4 if using for severe eosinophilic asthma. The total allowed quantity for initiation of therapy is 30 mg once every 4 weeks for the first 3 doses for individuals age 12 and older or age 6 – 11 weighing greater than or equal to 35 kg. The total allowed quantity for initiation of therapy is 10 mg once every 4 weeks for the first 3 doses for individuals age 6 – 11 weighing less than 35 kg.

For Fasenra, may approve 30 mg/mL prefilled syringe/autoinjector every 4 weeks if individual is using for eosinophilic granulomatosis with polyangiitis (EGPA).

For Nucala 100 mg vial/prefilled syringe/autoinjector, may approve up to 300 mg every 4 weeks if individual is using for eosinophilic granulomatosis with polyangiitis (EGPA) or hypereosinophilic syndrome (HES).

APPROVAL CRITERIA

Initial requests for Cinqair (reslizumab) may be approved for severe **eosinophilic asthma** when the following criteria are met:

I. Individual is 18 years of age or older; **AND**

II. Individual has a diagnosis of severe eosinophilic asthma; **AND**
III. Evidence of asthma is demonstrated by the following (NAEPP, 2008):
    A. A pretreatment forced expiratory volume in 1 second (FEV_1) less than 80% predicted; **AND**
    B. FEV_1 reversibility of at least 12% and 200 ml after albuterol administration;

AND

IV. Documentation is provided that individual has had a 3 month trial and inadequate response or intolerance to combination controller therapy (high dose inhaled corticosteroids plus long acting $beta_2$ –agonists, leukotriene modifiers, long-acting muscarinic antagonists or oral corticosteroids) (GINA 2024); **AND**
V. Individual has experienced two or more asthma exacerbations in the prior 12 months requiring use of a systemic corticosteroid or temporary increase in the individual's usual maintenance dosage of oral corticosteroids (ERS/ATS, 2013); **AND**
VI. Documentation is provided that individual has blood eosinophil count (in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease, and known or suspected parasitic infection) greater than or equal to 400 cells/microliter (400 cells/mm^3) at initiation of therapy.

Initial requests for Fasenra (benralizumab) for severe **eosinophilic asthma** may be approved if the following criteria are met:

I. Individual is 6 years of age or older; **AND**
II. Individual has a diagnosis of severe eosinophilic asthma; **AND**
III. Evidence of asthma is demonstrated by the following (NAEPP, 2008):
    A. A pretreatment forced expiratory volume in 1 second (FEV_1) less than 80% predicted; **AND**
    B. FEV_1 reversibility of at least 12% and 200 milliliters (ml) after albuterol administration;

AND

IV. Documentation is provided that individual has had a 3 month trial and inadequate response or intolerance to combination controller therapy (high dose inhaled corticosteroids plus long acting $beta_2$ –agonists, leukotriene modifiers, long acting muscarinic antagonists or oral corticosteroids) (GINA 2024);

AND

V. Individual has experienced two or more asthma exacerbations in the prior 12 months requiring use of a systemic corticosteroid or temporary increase in the individual's usual maintenance dosage of oral corticosteroids (ERS/ATS, 2013);

AND

VI. Documentation is provided that individual has a blood eosinophil count (in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease, and known or suspected parasitic infection) greater than or equal to 150 cells/microliter (150 cells/mm^3) at initiation of therapy.

Initial requests for Nucala (mepolizumab) for severe **eosinophilic asthma** may be approved if the following criteria are met:

I. Individual is 6 years of age or older; **AND**
II. Individual has a diagnosis of severe eosinophilic asthma; **AND**
III. Evidence of asthma is demonstrated by the following (NAEPP, 2008):
    A. A pretreatment forced expiratory volume in 1 second (FEV_1) less than 80% predicted; **AND**
    B. FEV_1 reversibility of at least 12% and 200 milliliters (ml) after albuterol administration;

AND

IV. Documentation is provided that individual has had a 3 month trial and inadequate response or intolerance to combination controller therapy (high dose inhaled corticosteroids plus long acting $beta_2$ –agonists, leukotriene modifiers, long-acting muscarinic antagonists or oral corticosteroids) (GINA 2024); **AND**
V. Individual has experienced two or more asthma exacerbations in the prior 12 months requiring use of a systemic corticosteroid or temporary increase in the individual's usual maintenance dosage of oral corticosteroids (ERS/ATS, 2013); **AND**
VI. Documentation is provided that individual has a blood eosinophil counts (in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease, and known or suspected parasitic infection) greater than or equal to 150 cells/microliter (150 cells/mm^3) at initiation of therapy.

Continuation requests for Cinqair (reslizumab), Fasenra (benralizumab), or Nucala (mepolizumab) for severe **eosinophilic asthma** may be approved if the following criteria are met:

I. Treatment with Cinqair (reslizumab), Fasenra (benralizumab), or Nucala (mepolizumab) has resulted in clinical improvement in one or more of the following:
    A. Decreased utilization of reliever medication; **OR**
    B. Decreased frequency of exacerbations (defined as worsening of asthma that requires an increase in inhaled corticosteroid dose or treatment with systemic corticosteroids); **OR**
    C. Increase in percent predicted FEV_1 from pretreatment baseline; **OR**
    D. Reduction in reported asthma-related symptoms, such as, asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing;

AND

II. Individual continues to use Cinqair (reslizumab), Fasenra (benralizumab), or Nucala (mepolizumab) in combination with inhaled corticosteroid-based controller therapy.

Initial requests for Fasenra (benralizumab) for **eosinophilic granulomatosis with polyangiitis** may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**

II. Individual has a diagnosis of relapsing or refractory eosinophilic granulomatosis with polyangiitis (EGPA) defined as (Wechsler 2024):
    A. A history or presence of asthma; **AND**
    B. A blood eosinophil level of greater than 10% of leukocytes or an absolute eosinophil count of greater than 1000 cells per microliter (in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease and known or suspected parasitic infection), and documentation is provided; **AND**
    C. The presence of two or more features of eosinophilic granulomatosis with polyangiitis (including, a biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatosis inflammation; neuropathy, mono or poly [motor deficit or nerve conduction abnormality]; pulmonary infiltrates, non-fixed; sinonasal abnormality; cardiomyopathy; glomerulonephritis; alveolar hemorrhage; palpable purpura; antineutrophil cytoplasmic antibody [ANCA] positive status; MPO or PR3 antibody positive status); **AND**
III. Individual is using in combination with oral corticosteroid therapy (Wechsler 2024).

Initial requests for Nucala (mepolizumab) for **eosinophilic granulomatosis with polyangiitis** when the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual has been diagnosed with relapsing or refractory eosinophilic granulomatosis with polyangiitis (EGPA) defined as (Wechsler, 2017):
    A. A history or presence of asthma; **AND**
    B. A blood eosinophil level of greater than 10% of leucocytes or an absolute eosinophil count of greater than 1000 cells per microliter (in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease, and known or suspected parasitic infection), and documentation is provided; **AND**
    C. The presence of two or more features of eosinophilic granulomatosis with polyangiitis (such as, a biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatosis inflammation; neuropathy, mono or poly [motor deficit or nerve conduction abnormality]; pulmonary infiltrates, non-fixed; sinonasal abnormality; cardiomyopathy; glomerulonephritis; alveolar hemorrhage; palpable purpura, or antineutrophil cytoplasmic antibody [ANCA] positive status; MPO or PR3 antibody positive status); **AND**
III. Individual is using in combination with oral corticosteroid therapy (Wechsler, 2017).

Continuation requests for Fasenra (benralizumab) or Nucala (mepolizumab) for **eosinophilic granulomatosis with polyangiitis** may be approved if the following criteria are met:

I. Treatment with Fasenra or Nucala has resulted in the achievement of remission at some point during treatment defined as (Wechsler, 2017, 2024):
    A. Birmingham Vasculitis Activity Score (BVAS) of 0 (on a scale from 0 to 63), and documentation is provided; **AND**

B. Receipt of prednisolone or prednisone at a dose of 4 mg or less per day.

Initial requests for Nucala (mepolizumab) for **hypereosinophilic syndrome (HES)** may be approved if the following criteria are met:

I. Individual is 12 years of age or older; **AND**
II. Individual has been diagnosed with hypereosinophilic syndrome (HES) for at least six months; **AND**
III. Individual has had a trial and inadequate response to oral corticosteroids (WHO 2022); **AND**
IV. Documentation is provided that individual has experienced two or more HES flares within the past 12 months requiring escalation in therapy (increase in oral corticosteroid dose or increase/addition of immunosuppressive or cytotoxic therapy); **AND**
V. Documentation is provided that individual has a blood eosinophil count greater than or equal to 1,000 cells/microliter.

Continuation requests for Nucala (mepolizumab) for **hypereosinophilic syndrome (HES)** may be approved if the following criteria are met:

I. Treatment with Nucala has resulted in confirmed clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to decrease or absence of HES flares, improvement in fatigue).

Nucala (mepolizumab) for **hypereosinophilic syndrome (HES)** may not be approved for the following:

I. Individuals with non-hematologic secondary HES (including but not limited to drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy); **OR**
II. Individuals with FIP1L1-PDGFRα kinase-positive HES.

Initial requests for Nucala (mepolizumab) for **chronic rhinosinusitis with nasal polyps (CRSwNP)** may be if approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP); **AND**
III. Documentation is provided that there is presence of nasal polyps demonstrated on one of the following (AAO-HNS 2015):
    A. Anterior rhinoscopy; **OR**
    B. Nasal endoscopy; **OR**
    C. Computed tomography (CT); **AND**
IV. Individual has had a trial and inadequate response to maintenance intranasal corticosteroids; **AND**

V. Individual is refractory to or is ineligible or intolerant to the following (AAAAI/ACAAI 2014, JTFPP 2022):
   A. Systemic corticosteroids; **OR**
   B. Sinonasal surgery; **AND**
VI. Individual is requesting Nucala as add-on therapy to maintenance intranasal corticosteroids.

Continuation requests for Nucala (mepolizumab) for **chronic rhinosinusitis with nasal polyps (CRSwNP)** may be if approved if the following criteria are met:

I. Treatment with Nucala has resulted in confirmed clinically significant improvement in clinical signs and symptoms of disease (including but not limited to improvement in nasal congestion or reduced nasal polyp size); **AND**
II. Individual continues to use Nucala in combination with maintenance intranasal corticosteroids.

Cinqair (reslizumab) may not be approved for the following:

I. In combination with Dupixent, Fasenra, Nucala, Tezspire or Xolair; **OR**
II. May not be approved when the above criteria are not met and for all other indications.

Fasenra (benralizumab) may not be approved for the following:

I. In combination with Cinqair, Dupixent, Nucala, Tezspire or Xolair; **OR**
II. May not be approved when the above criteria are not met and for all other indications.

Nucala (mepolizumab) may not be approved for the following:

I. In combination with Cinqair, Dupixent, Fasenra, Tezspire or Xolair; **OR**
II. May not be approved when the above criteria are not met and for all other indications.

Note:
Cinqair has a black box warning for anaphylaxis. Anaphylaxis occurred with Cinqair infusion in 0.3% of participants in placebo-controlled studies. Individuals should be observed after Cinqair administration for an appropriate period of time by a healthcare professional prepared to manage anaphylaxis that can be life-threatening. Discontinue Cinqair immediately if the patient experiences signs or symptoms of anaphylaxis.

Key References:

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.