Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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

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

Medications	Dosing Limit
Cinqair (reslizumab) 100 mg vial	3 mg/kg every 4 weeks
Fasenra (benralizumab) 30 mg/ml prefilled syringe/autoinjector	30 mg (1 syringe/autoinjector) every 8 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 at week 4. The total allowed quantity for initiation of therapy is 30 mg once every 4 weeks for the first 3 doses.

For Nucala, may approve up to 300 mg every 4 weeks if individual is using for eosinophilic granulomatosis with polyangitis.

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. 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, theophylline or oral corticosteroids) (ERS/ATS, 2013; GINA 2019)); **AND**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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. 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 12 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. 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, theophylline or oral corticosteroids) (ERS/ATS, 2013; GINA 2019);

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. 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 300 cells/microliter (300 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):

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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. 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, theophylline or oral corticosteroids) (ERS/ATS, 2013; GINA 2019); **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. Individual has one of the following blood eosinophil counts (in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease, and known or suspected parasitic infection):
    A. Greater than or equal to 150 cells/microliter (150 cells/mm^3) at initiation of therapy; **OR**
    B. Greater than or equal to 300 cells/microliter (300 cells/mm^3) in the prior 12 months.

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 as confirmed by one or more of the following:
    A. Decreased utilization of rescue medications; **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.

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 for 6 months defined as (Wechsler, 2017):
    A. A history or presence of asthma; **AND**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

B. A blood eosinophil level of greater than or equal to 10% of leucocytes or an absolute eosinophil count of greater than 1000 cells per mm^3 (in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease, and known or suspected parasitic infection); **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); **AND**

III. Individual is on concurrent oral corticosteroid therapy (Wechsler, 2017).

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

I. Treatment with Nucala has resulted in clinical improvement as confirmed by the achievement of remission at some point during treatment defined as(Wechsler, 2017):
   A. Birmingham Vasculitis Activity Score (BVAS), version 3, of 0 (on a scale from 0 to 63); **AND**
   B. Receipt of prednisolone or prednisone at a dose of 4.0 mg or less per day.

Cinqair (reslizumab), Fasenra (benralizumab), or Nucala (mepolizumab) 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:

1. Bradding P. Asthma: eosinophil disease, mast cell disease, or both? *Allergy Asthma Clin Immunol*. 2008; (4)2:84-90.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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10. Wenzel S. Treatment of severe asthma in adolescents and adults. Last updated: November 13, 2019. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: January 30, 2020.