Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	N/A

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

DRUG.00080

Override(s)	Approval Duration
Prior Authorization	Initial Therapy: 1 year Continuation Therapy: 1 year

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

APPROVAL CRITERIA

Eosinophilic asthma

Cinqair (reslizumab) may be approved for the treatment of severe eosinophilic asthma when the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Symptoms are inadequately controlled with a minimum of 12 months of maintenance inhaled corticosteroid (for example, daily fluticasone at a dosage of 440 micrograms [or equivalent]), unless the individual is intolerant of, or has a medical contraindication to these agents; **AND**
III. Individual has experienced at least one asthma exacerbation in the prior 12 months requiring uninterrupted oral, intramuscular, or intravenous corticosteroid administration for 3 or more days; **AND**
IV. Individual has 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 400 cells/microliter* in the prior 12 months; **AND**
V. Evidence of asthma is demonstrated by **all** of the following:
    A. A pretreatment FEV_1 less than 80% predicted; **AND**
    B. FEV_1 reversibility of at least 12% and 200 ml after albuterol (salbutamol) administration; **AND**
    C. A baseline Asthma Control Questionnaire-7 score of greater than or equal to 1.5.

Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	N/A

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Fasenra (benralizumab) may be approved for the treatment of severe eosinophilic asthma when the following criteria are met:

I. Individual is 12 years of age or older; **AND**
II. Symptoms are inadequately controlled with use of **either** combination therapy:
    A. 12 months of medium- or high-dose inhaled corticosteroid (for example, daily fluticasone at a medium dosage of 250 micrograms or greater [or equivalent] **or** high dosage of greater than or equal to 500 micrograms [or equivalent]) given in combination with a minimum of 3 months of controller medication (either a long-acting beta2-agonist, **or** leukotriene receptor antagonist, **or** theophylline), unless the individual is intolerant of, **or** has a medical contraindication to these agents; **OR**
    B. 6 months of inhaled corticosteroid with daily oral glucocorticoids given in combination with a minimum of 3 months of controller medication (either a long-acting beta2-agonist, **or** leukotriene receptor antagonist, **or** theophylline), unless the individual is intolerant of, **or** has a medical contraindication to these agents; **AND**
III. 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; **AND**
IV. 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* at initiation of therapy; **AND**
V. Evidence of asthma is demonstrated by all of the following:
    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 (salbutamol) administration; **AND**
    C. A baseline Asthma Control Questionnaire-6 score of greater than or equal to 1.5.

Nucala (mepolizumab) may be approved for the treatment of severe eosinophilic asthma when the following criteria are met:

I. Individual is 12 years of age or older; **AND**
II. Symptoms are inadequately controlled with use of **either** combination therapy:
    A. 12 months of high-dose inhaled corticosteroid given in combination with a minimum of 3 months of controller medication (either a long-acting beta2-agonist , **or** leukotriene receptor antagonist , **or** theophylline), unless the individual is intolerant of, **or** has a medical contraindication to these agents; **OR**
    B. 6 months of inhaled corticosteroid with daily oral glucocorticoids given in combination with a minimum of 3 months of controller medication (either a long-

Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	N/A

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acting beta2-agonist, **or** leukotriene receptor antagonist, **or** theophylline), unless the individual is intolerant of, **or** has a medical contraindication to these agents;

AND

III. 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* at initiation of therapy; **OR**
   B. Greater than or equal to 300 cells/microliter* in the prior 12 months;

AND

IV. Evidence of asthma is demonstrated by **both** of the following:
   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 (salbutamol) administration.

Continuation of therapy with either Cinqair (reslizumab), Fasenra (benralizumab), or Nucala (mepolizumab) or after 12 months may be approved for the treatment of an individual with documented severe eosinophilic asthma when the following criteria are met:

I. Treatment with Cinqair (reslizumab), Fasenra (benralizumab), or Nucala (mepolizumab) has resulted in clinical improvement as documented 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 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.

Cinqair (reslizumab), Fasenra (benralizumab), or Nucala (mepolizumab) may **not** be approved when criteria are not met and for **all** other conditions, including but not limited to:

I. Aspirin-exacerbated respiratory disease; **OR**
II. Atopic dermatitis; **OR**
III. Eosinophilic esophagitis; **OR**
IV. Eosinophilic granulomatosis with polyangiitis ; **OR**
V. Nasal polyposis; **OR**
VI. Hypereosinophilic syndromes (other than severe eosinophilic asthma).

Eosinophilic granulomatosis with polyangiitis

Nucala (mepolizumab) may be approved for the treatment of severe eosinophilic granulomatosis with polyangiitis when the following criteria are met:

Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	N/A

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I. Individual is 18 years of age or older; **AND**
II. Individual is diagnosed with eosinophilic granulomatosis with polyangiitis for 6 months or greater, defined as:
    A. A history or presence of asthma; **AND**
    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 cubic millimeter (mm3) (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; sino-nasal abnormality; cardiomyopathy; glomerulonephritis; alveolar hemorrhage; palpable purpura, or antineutrophil cytoplasmic antibody [ANCA] positive status).

Continuation of therapy with Nucala (mepolizumab) after 12 months may be approved for an individual with documented relapsing or refractory eosinophilic granulomatosis with polyangiitis when treatment has resulted in clinical improvement as documented by the achievement of remission at some point during treatment, defined as the following:

I. Birmingham Vasculitis Activity Score (BVAS), version 3, of 0 (on a scale from 0 to 63); **AND**
II. Receipt of prednisolone or prednisone at a dose of 4.0 mg or less per day.

Nucala (mepolizumab) may **not** be approved when criteria are not met and for **all** other conditions, including but not limited to:

I. Aspirin-exacerbated respiratory disease; **OR**
II. Atopic dermatitis; **OR**
III. Eosinophilic esophagitis; **OR**
IV. Eosinophilic granulomatosis with polyangiitis ; **OR**
V. Nasal polyposis; **OR**
VI. Hypereosinophilic syndromes (other than severe eosinophilic asthma or eosinophilic granulomatosis with polyangiitis).

****Note*:** 1 microliter (ul) is equal to 1 cubic millimeter (mm^3)

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	N/A

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.