BlueCross BlueShield
Federal Employee Program

IL-5 ANTAGONISTS

Fasenra (benralizumab) Nucala (mepolizumab)

Pre - PA Allowance

None

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following **AND** submission of medical records (e.g., chart notes, laboratory values) documenting the following:

Fasenra and Nucala

1. Severe asthma with an eosinophilic phenotype
    a. 6 years of age or older
    b. Inadequate control of asthma symptoms after a minimum of 3 months of compliant use with greater than or equal to 50% adherence with **ONE** of the following within the past 6 months:
        i. Inhaled corticosteroids & long acting $beta_2$ agonist
        ii. Inhaled corticosteroids & long acting muscarinic antagonist
    c. Patient has **ONE** of the following:
        a. Eosinophil count greater than or equal 150 cells/mcL in the past 90 days
        b. Eosinophil count greater than or equal 300 cells/mcL in the past 12 months
    d. **NOT** used for the relief of acute bronchospasm or status asthmaticus
    e. Used as add-on maintenance treatment
    f. **NO** dual therapy with another monoclonal antibody for the treatment of asthma or COPD (see Appendix 1)

2. Eosinophilic granulomatosis with polyangiitis (EGPA)
    a. 18 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to **TWO** of the following medications:
        i. Systemic glucocorticoids
        ii. Cyclophosphamide
        iii. Azathioprine
        iv. **Methotrexate**
        v. Leflunomide
    c. Patient has **ONE** of the following:
        i. Eosinophil count greater than 1000 cells/mcL

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ii. Eosinophil count greater than 10% of the total leukocyte count

Nucala only

1. Chronic rhinosinusitis with nasal polyps (CRSwNP)
    a. 18 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of **TWO** nasal corticosteroid sprays (e.g., mometasone, fluticasone, budesonide, or triamcinolone)
    c. Used as add-on maintenance treatment
    d. **NO** dual therapy with another monoclonal antibody for the treatment of CRSwNP (see Appendix 2)

2. Hypereosinophilic syndrome (HES)
    a. 12 years of age or older
    b. Patient has had HES for at least 6 months
    c. **NO** identifiable non-hematologic secondary cause (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy)
    d. Patient has had HES flares while on stable HES therapy (such as chronic or episodic oral corticosteroids, immunosuppressive, or cytotoxic therapy)
    e. Eosinophil count greater than or equal to 1000 cells/mcL

3. Chronic obstructive pulmonary disease (COPD)
    a. 18 years of age or older
    b. Patient has **ONE** of the following:
        i. Eosinophil count greater than or equal to 150 cells/mcL in the past 90 days **OR** 300 cells/mcL in the past 12 months
        ii. Oral corticosteroid dependent COPD with **ONE** of the following:
            1. 1 month of daily oral corticosteroid use within the last 3 months
            2. Patient currently requires oral corticosteroids
    c. Exacerbation history in the past year of **ONE** of the following:
        i. ≥ 2 moderate COPD exacerbations
        ii. ≥ 1 severe COPD exacerbation leading to hospitalization
    d. Inadequate control of COPD symptoms after a minimum of 3 months of compliant use with greater than or equal to 50% adherence with **ONE** of the following within the past 6 months:

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i. Long acting beta$_2$ agonist & long acting muscarinic antagonist & inhaled corticosteroid
ii. Long acting beta$_2$ agonist & long acting muscarinic antagonist if inhaled corticosteroids are contraindicated

e. **NOT** used for the emergency relief of acute bronchospasm
f. **NO** dual therapy with another monoclonal antibody for the treatment of asthma or COPD (see Appendix 1)

AND the following for **ALL** indications and **ALL** medications:

1. Prescriber will assess the medical appropriateness for a varicella vaccination prior to therapy

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Prior - Approval Limits

Quantity

Age (years)	Indication	Drug/Strength	Quantity
6-11	Asthma	Fasenra 10 mg Fasenra 30 mg	5 injections per 180 days **OR**
12+	Asthma	Fasenra 30 mg	5 injections per 180 days **OR**
6-11	Asthma	Nucala 40 mg Nucala 100 mg vial	3 injections per 84 days **OR**
12+	Asthma	Nucala 100 mg	3 injections per 84 days **OR**
18+	COPD	Nucala 100 mg	3 injections per 84 days **OR**
18+	CRSwNP	Nucala 100 mg	3 injections per 84 days **OR**
18+	EGPA	Fasenra 30 mg	3 injections per 84 days **OR**
18+	EGPA	Nucala 100 mg	9 injections per 84 days **OR**
12+	HES	Nucala 100 mg	9 injections per 84 days

Duration 6 months

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following **AND** submission of medical records (e.g.,

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chart notes, laboratory values) documenting the following:

Fasenra and Nucala

1. Asthma with an eosinophilic phenotype
    a. 6 years of age or older
    b. Decreased exacerbations **OR** improvement in symptoms
    c. Decreased utilization of rescue medications
    d. Patient has been compliant on Fasenra/Nucala therapy
    e. **NOT** used for the relief of acute bronchospasm or status asthmaticus
    f. Used as add-on maintenance treatment
    g. **NO** dual therapy with another monoclonal antibody for the treatment of asthma or COPD (see Appendix 1)

2. Eosinophilic granulomatosis with polyangiitis (EGPA)
    a. 18 years of age or older
    b. Improvement in symptoms
    c. Patient has been compliant on Fasenra/Nucala therapy

Nucala only

1. Chronic rhinosinusitis with nasal polyps (CRSwNP)
    a. 18 years of age or older
    b. Improvement in sino-nasal symptoms
    c. Used as add-on maintenance treatment
    d. Patient has been compliant on Nucala therapy
    e. **NO** dual therapy with another monoclonal antibody for the treatment of CRSwNP (see Appendix 2)

2. Hypereosinophilic syndrome (HES)
    a. 12 years of age or older
    b. Improvement in symptoms and/or reduction in the number of flares
    c. Patient has been compliant on Nucala therapy

3. Chronic obstructive pulmonary disease (COPD)
    a. 18 years of age or older
    b. Decreased exacerbations **OR** improvement in symptoms
    c. Patient has been compliant on Nucala therapy
    d. **NOT** used for the emergency relief of acute bronchospasm

e. **NO** dual therapy with another monoclonal antibody for the treatment of asthma or COPD (see Appendix 1)

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Prior - Approval *Renewal* Limits

Quantity

Age (years)	Indication	Drug/Strength	Quantity
6-11	Asthma	Fasenra 10 mg Fasenra 30 mg	3 injections per 168 days **OR**
12+	Asthma	Fasenra 30 mg	3 injections per 168 days **OR**
6-11	Asthma	Nucala 40 mg Nucala 100 mg vial	3 injections per 84 days **OR**
12+	Asthma	Nucala 100 mg	3 injections per 84 days **OR**
18+	COPD	Nucala 100 mg	3 injections per 84 days **OR**
18+	CRSwNP	Nucala 100 mg	3 injections per 84 days **OR**
18+	EGPA	Fasenra 30 mg	3 injections per 84 days **OR**
18+	EGPA	Nucala 100 mg	9 injections per 84 days **OR**
12+	HES	Nucala 100 mg	9 injections per 84 days

Duration 12 months

Appendix 1 - List of Monoclonal Antibodies for Asthma or COPD

Generic Name	Brand Name
benralizumab	Fasenra
dupilumab	Dupixent
mepolizumab	Nucala
omalizumab	Xolair
reslizumab	Cinqair
tezepelumab-ekko	Tezspire

Appendix 2 - List of Monoclonal Antibodies for CRSwNP

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Generic Name	Brand Name
dupilumab	Dupixent
mepolizumab	Nucala
omalizumab	Xolair