

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
 - 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 beta2 agonist
 - ii. Inhaled corticosteroids & long acting muscarinic antagonist
 - c. Patient has **ONE** of the following:
 - 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
 - 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
 - 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:
 - Eosinophil count greater than 1000 cells/mcL



IL-5 ANTAGONISTS

Fasenra (benralizumab) Nucala (mepolizumab)

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
 - 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
 - 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
 - NO identifiable non-hematologic secondary cause (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, nonhematologic 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:
 - 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 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:



IL-5 ANTAGONISTS

Fasenra (benralizumab) Nucala (mepolizumab)

- Long acting beta₂ agonist & long acting muscarinic antagonist
 & inhaled corticosteroid
- ii. Long acting beta₂ agonist & long acting muscarinic antagonist if inhaled corticosteroids are contraindicated
- e. **NOT** used for the emergency relief of acute bronchospasm
- 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	Indication	Drug/Strength	Quantity
(years)			
6-11	Asthma	Fasenra 10 mg	5 injections per 180 days OR
		Fasenra 30 mg	
12+	Asthma	Fasenra 30 mg	5 injections per 180 days OR
6-11	Asthma	Nucala 40 mg	3 injections per 84 days OR
		Nucala 100 mg vial	
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.,



IL-5 ANTAGONISTS

Fasenra (benralizumab) Nucala (mepolizumab)

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



IL-5 ANTAGONISTS

Fasenra (benralizumab) Nucala (mepolizumab)

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	Indication	Drug/Strength	Quantity
(years)			
6-11	Asthma	Fasenra 10 mg	3 injections per 168 days OR
		Fasenra 30 mg	
12+	Asthma	Fasenra 30 mg	3 injections per 168 days OR
6-11	Asthma	Nucala 40 mg	3 injections per 84 days OR
		Nucala 100 mg <u>vial</u>	
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



IL-5 ANTAGONISTS

Fasenra (benralizumab) Nucala (mepolizumab)

Generic Name	Brand Name
dupilumab	Dupixent
mepolizumab	Nucala
omalizumab	Xolair