Field Name	Field Description
Prior Authorization Group Description	**Pulmonary Biologics for Asthma and Eosinophilic Conditions**
Drugs	Nucala (mepolizumab), Fasenra (benralizumab), Cinqair (reslizumab), Tezspire (tezepelumab) or any newly marketed agents
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• When being used for relief of acute bronchospasm or status asthmaticus • When used in combination with another monoclonal antibody for the treatment of asthma or eosinophilic conditions
Required Medical Information	See "other criteria"
Age Restrictions	Per Package Insert
Prescriber Restrictions	Prescriber must be an allergist, pulmonologist, immunologist, rheumatologist, other provider who specializes in the treatment of asthma or eosinophilic conditions, or in consultation with one of these specialists
Coverage Duration	If the above conditions are met, the initial request will be approved with a 4 month duration. All subsequent requests will be approved with a 6 month duration. If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	**Initial Authorization:** Asthma: • Confirmed diagnosis of one of the following: o Nucala, Fasenra, and Cinqair: Severe Eosinophilic Asthma o Tezspire: Severe Asthma • Documentation has been provided of blood eosinophil count within ONE of the following ranges: o Nucala: ≥ 150 cells/mcL (within 6 weeks of request) OR ≥ 300 cells/mcL (within the past 12 months) o Fasenra: ≥ 150 cells/mcL (within the past 12 months) o Cinqair: ≥ 400 cells/mcL (within the past 12 months) o Tezspire: No baseline blood eosinophil counts are required • The member has a documented baseline FEV_1 < 80% of predicted with evidence of reversibility by bronchodilator response. o Tezspire ONLY: If age is < 18 years, the member has a documented baseline FEV_1 < 90% of predicted with evidence of reversibility by bronchodilator response • Documentation has been provided indicating that that the member continues to experience significant symptoms while compliant on a

	maximally tolerated inhaled corticosteroid with long-acting beta2 agonist (ICS/LABA) AND long-acting muscarinic antagonist (LAMA) (or a documented medical reason must be provided why the member is unable to use these therapies) and ONE of the following: o Nucala: ≥ 2 exacerbations in the past 12 months o Fasenra: ≥ 1 exacerbation in the past 12 months o Cinqair: ≥ 1 exacerbation in the past 12 months requiring systemic corticosteroids o Tezspire: ≥ 2 exacerbations requiring systemic corticosteroids OR ≥ 1 exacerbation in the past 12 months requiring hospitalization • The prescribed dose is within FDA approved dosing guidelines <u>Eosinophilic granulomatosis with polyangiitis (EGPA) (*Nucala only*):</u> • Confirmed diagnosis of EGPA and eosinophilic asthma lasting for ≥6 months • Member has a history of relapsing disease defined as at least one EGPA relapse requiring additional corticosteroids or immunosuppressant or hospitalization within the past 2 years OR member has a history of refractory disease defined as failure to attain remission in the prior 6 months following induction treatment with standard therapy • Member must be on a stable dose of oral corticosteroids for at least 4 weeks prior to request • Member has a blood eosinophil count ≥1,000 cells/mcL OR > 10% of total leukocyte count • Documented trial and failure, intolerance, or contraindication to cyclophosphamide, azathioprine, methotrexate, rituximab, OR mycophenolate mofetil • The prescribed dose is within FDA approved dosing guidelines <u>Hypereosinophilic Syndrome (HES) (*Nucala only*):</u> • Confirmed diagnosis of FIP1 like 1-platelet derived growth factor receptor alpha (FIP1L1-PDGFRA)-negative HES lasting for ≥6 months without an identifiable non-hematologic secondary cause • Member has a history of two or more HES flares (worsening of HES-related symptoms necessitating therapy escalation or ≥2 courses of rescue oral corticosteroids) within the past 12 months • Member has a blood eosinophil count ≥1,000 cells/mcL • Documented trial and failure, intolerance, or contraindication to oral corticosteroids AND at least one second-line agent (e.g. hydroxyurea, interferon, imatinib, methotrexate, cyclophosphamide, cyclosporine, azathioprine) (member must be on stable dose of at least one agent for at least 4 weeks prior to request)

Revision/Review Date 1/2023	**<u>Re-Authorization:</u>** 1. Documentation submitted indicates the member has clinically benefited from the medication (e.g. Asthma: improved FEV_1, reduced exacerbations; HES: symptomatic improvement, reduced oral corticosteroid dose; EGPA: reduction in relapse frequency or severity, disease remission, symptomatic improvement, reduced oral corticosteroid dose) 2. The prescribed dose is within FDA approved dosing guidelines **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**