

Protocol for Biologics Used in Moderate to Severe Asthma

DURB Approval Date	10/2022; 10/2025
Commissioners Approval Date	7/2023; 2/2026

Preferred Agents:

Xolair (omalizumab)

Non-Preferred Agents:

Cinqair (reslizumab)

Fasenra (benralizumab)

Nucala (mepolizumab)

Tezspire (tezepelumab-ekko)

The patient is unable to take the required number of preferred products for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

Protocol applies to FDA approved biosimilars and related indications and dosages.

For Dupixent requests please refer to the Dupixent Protocol

Addendum:

The specific criteria for biologic drugs were updated to reflect the Food and Drug Administration (FDA) labeling and GINA (Global Initiative for Asthma) 2024 guidelines. In addition, since there is an existing separate Dupixent protocol, Dupixent has been removed from this protocol.

Background:

Severe asthma is present, by definition, when adequate control of asthma cannot be achieved by high-dose treatment with inhaled corticosteroids and additional controllers (long-acting inhaled beta 2 agonists, montelukast, and/or theophylline) or by oral corticosteroid treatment (for at least six months per year) or is lost when the treatment is reduced.

General Criteria for Approval (must meet all of the following):

1. Confirmed diagnosis of one of the following (a. or b.):
 - a. Severe asthma with eosinophilic phenotype (blood eosinophil counts ≥ 150 cells/microliter) (**Fasenra, Cinqair, Nucala**) or severe asthma (**Tezspire**)
 - b. Moderate to severe persistent allergic asthma not adequately controlled with inhaled corticosteroids accompanied by one of the following (**Xolair**):
 - i. A positive skin test
 - ii. In-vitro reactivity to a perennial aeroallergen
2. The patient has been treated with one of the following maximally tolerated conventional regimens for at least the past 3 months
 - a. Patients 12 years and older must receive one of the following:
 - i. An inhaled corticosteroid (ICS) plus formoterol (or another long-acting beta agonist (LABA) with an as-needed short-acting beta agonist (SABA)) plus long-acting muscarinic antagonist (LAMA)
 - ii. ICS plus LABA with or without a leukotriene receptor antagonist (LTRA)
 - iii. ICS plus LABA plus theophylline

- b. Patients 6 to 11 years of age must receive an ICS plus formoterol (or another LABA with an as needed SABA) or ICS plus LABA plus LTRA or ICS plus LABA plus tiotropium
3. Patient is of the FDA-labeled or compendial approved age
2. Medication is prescribed by or in consultation with a pulmonologist, allergist, or immunologist
3. The patient is continuing to utilize maximally tolerated conventional asthma treatment with the requested medication, where indicated
4. Patient has experienced one of the following despite regular use of conventional therapies within the past 12 months (must meet a. b. or c.):
 - a. Two or more exacerbations requiring systemic corticosteroids (steroid bursts)
 - b. At least one asthma exacerbation requiring hospitalization or emergency medical care visits
 - c. Poor symptom control defined by one of the following:
 - a. Frequent asthma symptoms
 - b. Frequent rescue medication use
 - c. Limited activity due to asthma
 - d. Night waking due to asthma
5. The patient will not concomitantly be using another biologic immunomodulator for the same diagnosis
6. Weight will be monitored and provided for drugs that have weight-based dosing
7. Tezspire vial and Cinqair are administered by a healthcare provider
8. The medication requested is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence
9. Patient does not have any contraindications to therapy

Criteria for Continuation of Therapy:

1. Documentation of positive clinical response to therapy by at least one of the following:
 - a. Decreased asthma symptoms and frequency of exacerbations from baseline
 - b. Improved lung function, defined as FEV1 increase from baseline
 - c. Reduction in number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to asthma exacerbations
 - d. Reduction in the dose of inhaled/oral corticosteroids required to control the patient's asthma
 - e. Decreased utilization of rescue medications
2. The patient will not concomitantly be using another biologic immunomodulator for the same diagnosis
3. The patient is continuing to utilize maximally tolerated conventional asthma treatment with the requested medication, where indicated

Approval Duration: Initial – 6 months; Renewal – 12 months

Quantity Level Limits:

- Cinqair 100 mg/10 mL (10 mg/mL) single use vial: 3 vials per 30 days
- Xolair 150 mg vial: 8 vials per 30 days
- Xolair 75 mg single-dose prefilled syringe: 2 syringes per 30 days
- Xolair 150 mg single-dose prefilled syringe: 8 syringes per 30 days
- Xolair (omalizumab) 300 mg/2 mL single-dose prefilled syringe/autoinjector: 4 syringes/autoinjectors per 30 days
- Tezspire 210mg/1.91mL prefilled pen or syringe: 1 syringe or pen per 30 days
- Fasenra 30mg/mL single-dose prefilled syringe/autoinjector: 1 syringe/autoinjector per 30 days
- Fasenra 10mg/0.5mL single-dose prefilled syringe: 1 syringe per 60 days
- Nucala 100 mg single-dose vial: 3 vials per 28 days
- Nucala 100 mg/mL single-dose prefilled safety syringe: 3 syringes per 28 days
- Nucala 100 mg/mL single-dose prefilled autoinjector: 3 autoinjector's per 28 days
- Nucala 40mg/0.4mL, single-dose prefilled syringe: 1 syringe per 28 days

References:

1. Cinqair [package insert]. Teva Respiratory, LLC. West Chester, PA. February 2020
2. Dupixent [package insert]. Regeneron Pharmaceuticals, Inc. Tarrytown, NY. June 2025
3. Frasenra [package insert]. AstraZeneca Pharmaceuticals LP. Wilmington, DE. September 2024
4. Nucala [package insert]. GlaxoSmithKline LLC. Philadelphia, PA. May 2025
5. Tezspire [package insert]. Amgen Inc. and AstraZeneca. Thousand Oaks, CA. May 2023
6. Xolair [package insert]. Genentech Inc. San Francisco, CA. February 2024
7. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2024 Updated May 2024. Available from: www.ginasthma.org
8. Clinical Pharmacology Gold Standard Series [Internet database]. Tampa FL. Elsevier 2016. Updated periodically
9. Holguin F, Cardet JC, Chung KF, et al. Management of severe asthma: A European Respiratory Society/American Thoracic Society Guideline. European Res J 2020;55(1):1-21
<https://pubmed.ncbi.nlm.nih.gov/31558662/> Accessed October 4, 2022
10. McGregor MC, Krings JG, et al. Role of Biologics in Asthma. American Journal Respiratory and Critical Care Medicine. December 2018;199(4):433-445
11. Gupta SK, Mitra K. Criteria for Steroid Dependence. Chest. 1998;93(4):896
12. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2022. Available from: www.ginasthma.org