

## Proposed Protocol for Biologics Used in Moderate to Severe Asthma

October 2022

**Cinqair** (reslizumab)  $\geq$  18 years

**Dupixent** (dupilumab)  $\geq$  6 years

**Fasenra** (benralizumab)  $\geq$  12 years

**Nucala** (mepolizumab)  $\geq$  6 years

**Tezspire** (tezepelumab-ekko)  $\geq$  12 years

**Xolair** (omalizumab)  $\geq$  6 years

### 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.*

### Criteria for approval:

1. Confirmed Diagnosis of one of the following:
  - a. Asthma with eosinophilic phenotype with blood eosinophil counts  $\geq$  150 cells/microliter while on high-dose inhaled corticosteroids or oral corticosteroids **AND**
    - i. Severe asthma (**Fasenra, Cinqair, Nucala, Tezspire**)
  - b. Moderate to severe asthma (**Dupixent**) **OR**
  - c. Moderate to severe persistent allergic asthma with one of the following: (**Xolair**)
    - i. A positive skin test **OR**
    - ii. In-vitro reactivity to a perennial aeroallergen
2. Medication is used as add on therapy for patients on conventional asthma treatment (e.g., inhaled corticosteroid (ICS), long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline).
3. Medication and dosage is used for the appropriate age
4. Medication is prescribed by or in consultation with a pulmonologist, allergist, or immunologist
5. Patient must have experienced  $\geq$  2 exacerbations within the last 12 months despite meeting all of the following (exacerbation is defined as requiring the use of oral/systemic corticosteroids, urgent care/hospital admission, or intubation):
  - a. Adherence to a maximally tolerated inhaled corticosteroid for the past 3 months or has intolerance, contraindication, or hypersensitivity to all inhaled corticosteroids; **AND**

- b. Adherence to at least ONE of the afore mentioned therapies (LABA, LTRA, or LAMA) for 90 consecutive days) unless there is documented intolerance, contraindication, or hypersensitivity.
6. The patient will not be concomitantly using another biologic drug for the same indication [e.g., omalizumab (Xolair), reslizumab (Cinqair), mepolizumab (Nucala), or benralizumab (Fasenra)].
7. Weight will be monitored for drugs that have weight-based dosing
8. Tezspire and Cinqair will be administered by a healthcare professional
9. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with 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

**Continuation of therapy:**

1. Documentation of positive clinical response to therapy by at least one of the following:
  - a. A decrease asthma symptoms and frequency of exacerbation from baseline
  - b. Improved lung function, defined as FEV1 increase from baseline
  - c. Reduction of 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. For Xolair requests:  
Medication will be administered by a healthcare provider unless the patient has already received at least 3 doses under the guidance of a healthcare provider with no hypersensitivity reactions

References:

1. Cinqair [package insert]. Teva Respiratory, LLC; West Chester, PA: June 2020
2. Dupixent [package insert]. Regeneron Pharmaceuticals, Inc. Tarrytown, NY: October 2021
3. Fasenra [package insert] AstraZeneca Pharmaceuticals, LP; Wilmington, DE: February 2021
4. Nucala [package insert]. GlaxoSmithKline LLC; Philadelphia, PA: October 2021.
5. Tezspire [package insert]. AstraZeneca AB; Sodertalje, Sweden SE; December 2021
6. Xolair [package insert]. Genentech, Inc.; South San Francisco, CA; July 2021
7. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2016. Updated periodically
8. 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 on October 4, 2022
9. McGregor MC, Krings JG, et al. Role of Biologics in Asthma. *American Journal of Respiratory and Critical Care Medicine*. December 2018; 199 (4):433-445.
10. Gupta SK, Mitra K. Criteria for Steroid Dependence. *Chest Journal*.1988; 93 (4):896
11. Global Initiative for Asthma (GINA). Global Strategy For Asthma Management and Prevention, Global Initiative for Asthma (GINA) 2022. Available at [www.ginasthma.org](http://www.ginasthma.org)