Protocol for Biologics Used in Moderate to Severe Asthma

Approved October 2022

Cinqair (reslizumab) ≥ 18 years
Dupixent (dupilumab) ≥ 6 years
Fasenra (benralizumab) ≥ 12 years
Nucala (mepolizumab) ≥ 6 years
Tezspire (tezepelumab-ekko) ≥ 12 years
Xolair (omalizumab) ≥ 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 ≥ 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 ≥ 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

Initial Approval: 6 months

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

Renewal Approval: 12 months

Quantity Level Limits:

<u>Cinqair</u>

- Initial QLL: 100 mg/10 mL (10 mg/mL) single use vial / 3 vials per 28 days

- Renewal QLL: Cinqair 100 mg/10 mL (10 mg/mL) single use vial / 6 vials per 28 days

Dupixent

- Dupixent 200 mg/ 1.14 mL pre-filled syringe/pen:2 syringes/pens per 28 days
- Dupixent 300 mg/ 2 mL pre-filled syringe/pen: 4 syringes/pens per 28 days
- Dupixent 100 mg/ 0.67 mL pre-filled syringe: 2 syringes per 28 days

Tezspire

- QLL, 1 vial, syringe or pen per 28 days

Fasenra

- Initial QLL: 3 syringes for first 84 days
- Renewal QLL: 1 syringe per 56 days

Nucala

- 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

Xolair

- Xolair 150 mg vial: 8 vials per 28 days
- Xolair 75 mg single-dose prefilled syringe: 2 syringes per 28 days
- Xolair 150 mg single-dose prefilled syringe: 8 syringes per 28 days

References:

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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]. AstraZenaca AB; Sodertalie, 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
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11. Global Initiative for Asthma (GINA). Global Strategy For Asthma Management and Prevention, Global Initiative for Asthma (GINA) 2022. Available at www.ginasthma.org