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DRUG POLICY

Cinqair (reslizumab)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Cinqair (reslizumab) drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines, and clinical studies. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy. For this program, Dupixent, Fasenra, Nucala, and Xolair are the preferred products and applies to members requesting treatment for an indication that is FDA-approved for the preferred products. Coverage for non-preferred product, Cinqair, is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made.

FDA-Approved Indication

Cinqair is indicated for the add-on maintenance treatment of patients with severe asthma aged 18 years and older with an eosinophilic phenotype.

Limitations of Use:

- Not for treatment of other eosinophilic conditions
- Not for the relief of acute bronchospasm or status asthmaticus

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Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. For initial requests:

1. Member's chart or medical record showing pretreatment blood eosinophil count, dependence on systemic corticosteroids if applicable.
 2. Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.
- B. For continuation requests: Chart notes or medical record documentation supporting improvement in asthma control.

Must meet BOTH the Preferred Drug Plan Design and Criteria for Initial Approval/Continuation of Therapy when both are applicable.

Preferred Drug Plan Design

Coverage for a non-preferred product is provided when the following criteria is met:

- The member has had a documented inadequate response or intolerable adverse event with at least three of the preferred products.

Table. Asthma Products

	Product(s)
Preferred	<ul style="list-style-type: none"> • Dupixent (dupilumab) • Fasenra (benralizumab) • Nucala (mepolizumab) • Tezspire (Tezepelumab-ekko) • Xolair (omalizumab)
Targeted	<ul style="list-style-type: none"> • Cinqair (reslizumab) • Exdensur (depemokimab)

Prescriber Specialty

This medication must be prescribed by or in consultation with an allergist/immunologist or pulmonologist.

Criteria for Initial Approval

Authorization of 6 months may be granted for treatment of severe asthma when ALL of the following criteria are met:

1. Member is 18 years of age or older
2. Member meets either of the following criteria:
 - a. Member has baseline blood eosinophil count of at least 400 cells per microliter; OR
 - b. Member is dependent on systemic corticosteroids
3. Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
 - a. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment
 - b. One or more asthma exacerbation resulting in hospitalization or emergency medical care visit
 - c. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)
4. Member has inadequate asthma control despite current treatment with both of the following medications at maximally tolerated doses:
 - a. Medium-to-high dose inhaled corticosteroid
 - b. Additional controller (i.e., long-acting beta₂-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
5. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Cinqair
6. Member will not use Cinqair concomitantly with other biologics indicated for asthma (e.g., Dupixent, Fasenra, Nucala, Tezspire, Xolair)

Continuation of Therapy

Authorization of 12 months may be granted for treatment of severe asthma when ALL of the following criteria are met:

1. Member is 18 years of age or older
2. Asthma control has improved on Cinqair treatment as demonstrated by at least one of the following:
 - a. A reduction in the frequency and/or severity of symptoms and exacerbations
 - b. A reduction in the daily maintenance oral corticosteroid dose
3. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Cinqair
4. Member will not use Cinqair concomitantly with other biologics indicated for asthma (e.g., Dupixent, Fasenra, Nucala, Tezspire, Xolair)

Other

Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Note: If the member is a current smoker or vaper, they should be counseled on the harmful effects of smoking on pulmonary conditions and available smoking and vaping cessation options.

Cinqair is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J2786 Injection, reslizumab, 1mg

REFERENCES

- Cinqair [package insert]. West Chester, PA: Teva Respiratory, LLC; February 2020.
- Castro M, Zangrilli J, Wechsler ME, et al. Reslizumab for inadequately controlled asthma with elevated blood eosinophil counts: results from two multicentre, parallel, double-blind, randomised, placebo-controlled, phase 3 trials. *Lancet Respir Med*. 2015;3(5):355-366.
- Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention, 2021 update. Available at: <https://ginasthma.org/wp-content/uploads/2021/05/GINA-Main-Report-2021-V2-WMS.pdf>. Accessed March 11, 2022.
- American Academy of Allergy, Asthma & Immunology (AAAAI) 2020 Virtual Annual Meeting. Available at: <https://annualmeeting.aaaai.org/>. Accessed March 14, 2022.
- Cloutier MM, Dixon AE, Krishnan JA, et al. Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program. *JAMA*. 2020;324(22):2301-2317.

*Some content reprinted from CVSHealth

POLICY HISTORY

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