Clinical Policy: Reslizumab (Cinqair)

Reference Number: CP.PHAR.223
Effective Date: 05/16
Last Review Date: 04/17

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for use of reslizumab (Cinqair®).

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® that Cinqair is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria:

A. Severe Asthma (must meet all):

1. Prescribed by or in consultation with an allergist or pulmonologist;
2. Age ≥ 18 years;
3. Diagnosis of asthma with absolute blood eosinophil count ≥ 400 cells/mcL;
4. If current smoking history, engaged in smoking cessation effort;
5. Member has experienced at least two exacerbations requiring oral/systemic corticosteroid treatment, urgent care visit or hospital admission, within the last 12 months, despite adherent use of controller therapy (i.e., high dose inhaled corticosteroid [ICS] plus either a long acting beta-2 agonist [LABA] or leukotriene modifier [LTRA] if LABA contraindication/intolerance);
6. Cinqair is prescribed concomitantly with an ICS plus either an LABA or LTRA;
7. Prescribed dose does not exceed 3mg/kg once every 4 weeks.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval

A. Severe Asthma (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Demonstrated adherence to asthma controller therapy that includes an ICS plus either an LABA or LTRA;
3. Member is responding positively to therapy (e.g.: reduction in exacerbations or corticosteroid dose, improvement in forced expiratory volume$_1$ over one second) since baseline; reduction in the use of rescue therapy);
4. Prescribed dose does not exceed 3mg/kg once every 4 weeks.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:

Reslizumab is a humanized interleukin-5 (IL-5) antagonist monoclonal antibody (IgG4k) produced by recombinant DNA technology in murine myeloma non-secreting 0 (NS0) cells. IL-5 is the major cytokine responsible for the growth and differentiation, recruitment, activation, and survival of eosinophils. Reslizumab binds to and inhibits the bioactivity of IL-5 by blocking its binding to the alpha chain of the IL-5 receptor complex expressed on the eosinophil surface. Inflammation is an important component in the pathogenesis of asthma. Multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, and cytokines) are involved in inflammation. Reslizumab, by inhibiting IL-5 signaling, reduces the production and survival of eosinophils; however, the mechanism of reslizumab action in asthma has not been definitively established.

Formulations:

Cinqair (reslizumab) injection is supplied in a 100 mg/10 mL (10 mg/mL) single-use vial.

FDA Approved Indications:

Reslizumab is an interleukin-5 antagonist/intravenous formulation indicated for:

- Add-on maintenance treatment of patients with severe asthma aged 18 years and older with an eosinophilic phenotype:

Limitations of use:

- Cinqair is not indicated for treatment of other eosinophilic conditions.
- Cinqair is not indicated for the relief of acute bronchospasm or status asthmaticus.

Appendices

Appendix A: Abbreviation Key

ICS: inhaled corticosteroid
IL: interleukin
LABA: long acting beta-2 agonist
LTRA: leukotriene modifier

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2786	Injection, reslizumab, 1 mg

Reviews, Revisions, and Approvals	Date	Approval Date
Policy developed.	05/16	05/16
An absolute blood eosinophil count ≥400 cells/mcL is added. Controller trial requirements are edited in the initial and renewal criteria and a smoking cessation line item is added. The contraindication/hypersensitivity black box warning of anaphylaxis is not included. Efficacy statement is added to renewal criteria. Approval durations changed to 6 and 12 months.	03/17	04/17

References

1. Cinqair prescribing information. Frazer, PA: Teva Pharmaceutical Industries Ltd.; May 2016. Available at http://www.cinqair.com/pdf/PrescribingInformation.pdf. Accessed March 22, 2017.
2. National Asthma Education and Prevention Program: Expert panel report III: Guidelines for the diagnosis and management of asthma. Bethesda, MD: National Heart, Lung, and Blood Institute, 2007. (NIH publication no. 08-4051). Available at http://www.nhlbi.nih.gov/health-pro/guidelines/current/asthma-guidelines. Accessed March 22, 2017.
3. Wenzel S. Treatment of severe asthma in adolescents and adults. In: UpToDate, Waltham, MA: Wolters Kluwer Health; 2017. Available at uptodate.com. Accessed March 22, 2017.
4. Corren J, Weinstein S, Janka L, Zangrilli J, Garin M. Phase 3 study of reslizumab in patients with poorly controlled asthma: effects across a broad range of eosinophil counts. *Chest.* 2016; 150(4): 799-810.
5. Maselli DJ, Velez MI, Rogers L. Reslizumab in the management of poorly controlled asthma: The data so far. *Journal of Asthma and Allergy.* August 31, 2016; 9: 155-162.

Important reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs and Medicare Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.