Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 145.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Cinqair (reslizumab)

I. Policy:
Cinqair (reslizumab)

II. Purpose/Objective:
To provide a policy of coverage regarding Cinqair (reslizumab)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Cinqair (reslizumab) is an interleukin-5 antagonist (IgG4 kappa). IL-5 is the major cytokine responsible for the growth and differentiation, recruitment, activation, and survival of eosinophils (a cell type associated with inflammation and an important component in the pathogenesis of asthma). 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. Nucala is indicated as add-on maintenance therapy for patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Cinqair (reslizumab) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when all of the following criteria are met:

- Documentation of patient age $\geq$ 18 years **AND**
- Patient must have severe persistent eosinophilic asthma **AND**
- Cinqair is being used as add-on maintenance treatment **AND**
- Prescription written by an allergist or pulmonologist **AND**
- Medical record documentation of a blood eosinophil count of $\geq$ 400 cells/mcL since the time of asthma diagnosis **AND**
- Medical record documentation of:
    - Intolerance to or not well controlled or very poorly controlled symptoms* despite at least a 3 month trial of: high-dose inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist **OR**
    - Two or more exacerbations in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite current therapy with high-dose inhaled corticosteroids plus a long-acting beta agonist **AND**
- Insured individual must be adherent with current therapeutic regimen and must demonstrate appropriate inhaler technique **AND**
- Known environmental triggers within the member's control have been eliminated **AND**
- Medical record documentation that the medication will not be used in combination with another biologic medication indicated for asthma treatment (e.g. Fasenra (benralizumab), Nucala (mepolizumab), Dupixent (dupilumab), Xolair (omalizumab), Tezspire (tezepelumab)) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to the use of two preferred biologic agents for severe asthma (Dupixent, Fasenra, Nucala, Tezspire, Xolair).

*****Measures of disease severity

Measure	**Not Well Controlled**	**Very Poorly Controlled**
Symptoms	> 2 days per week	Throughout the day
Nighttime awakenings	1-3x/week	$\geq$ 4x/week
Interference with normal activity	Some limitation	Extremely limited
SABA use for symptom control (not to prevent exercise-induced bronchospasm)	> 2 days/week	Several times per day
FEV1 (% predicted) or peak flow (% personal best)	60-80%	< 60%
Asthma Control Test (ACT) Score	16-19	$\leq$ 15

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Cinqair (reslizumab) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

- Documentation of patient age ≥ 18 years **AND**
- Patient must have severe persistent eosinophilic asthma **AND**
- Cinqair is being used as add-on maintenance treatment **AND**
- Prescription written by an allergist or pulmonologist **AND**
- Medical record documentation of a blood eosinophil count of ≥ 400 cells/mcL since the time of asthma diagnosis **AND**
- Medical record documentation of:
  - Intolerance to or not well controlled or very poorly controlled symptoms* despite at least a 3 month trial of: high-dose inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist **OR**
  - Two or more exacerbations in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite current therapy with high-dose inhaled corticosteroids plus a long-acting beta agonist **AND**
- Medical record documentation that the medication will not be used in combination with another biologic medication indicated for asthma treatment (e.g. Fasenra (benralizumab), Nucala (mepolizumab), Dupixent (dupilumab), Xolair (omalizumab), Tezspire (tezepelumab))

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Cinqair [prescribing information]. West Chester, PA: Teva Respiratory, LLC; June 2020.
2. Global Strategy for Asthma Management and Prevention. Global Initiative for Asthma. 2023 July [cited 2023 Dec 26]. Available from: https://ginasthma.org/2023-gina-main-report/

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 9/20/2016

Revised: 5/15/18 (criteria updated), 5/28/19 (grandfather), 5/17/22 (asthma biologic verbiage), 5/11/23 (Medicaid business segment), 11/7/23 (formulary alternative from July P&T), 12/30/23 (references added), 6/6/24 (LOB carve out)

Reviewed: 7/31/17, 4/22/19, 2/1/20, 1/19/21, 1/18/22

MA UM Committee approval: 12/31/23, 8/30/24