Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Cinqair® (Reslizumab) and Fasenra (benralizumab)***
DEPARTMENT: **Clinical Pharmacy Services – Utilization Management**
ORIGINAL DATE: ***April 2016***

Last P & T Committee Approval Date: *December 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Cinqair® (reslizumab) and Fasenra (benralizumab).

Cinqair® (reslizumab) is indicated for add-on maintenance treatment of patients with severe asthma aged 18 years and older, and with an eosinophilic phenotype.

Fasenra® (benralizumab) is indicated for add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drugs, Cinqair® (reslizumab) and Fasenra® (benralizumab), are subject to the prior authorization process.

PROCEDURE
Initial Authorization Criteria:

I. PLAN DESIGN SUMMARY

Requests for Cinqair® and Fasenra® are subject to the preferred medical drug list program. Coverage for these products (those which are non-preferred and not covered for the prescribed indication) is provided based on clinical circumstances that would exclude the use of the preferred product(s) for the indication. Coverage for non-preferred products will continue in situations where the patient is currently receiving treatment.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Asthma Products

	Products*
Preferred	• Nucala® **(mepolizumab)**
Non-preferred	• Cinqair® **(reslizumab)** • Fasenra® **(benralizumab)**

Requests for Cinqair® and Fasenra® on the Medical Benefit must meet one of the following exception criteria in addition to clinical criteria:

II. EXCEPTION CRITERIA (*Use for Cinqair and Fasenra Requests Only*)

This program applies to members requesting treatment for an indication that is FDA approved for the preferred product.

Coverage for a non-preferred product is provided when the member has a documented inadequate response or intolerable adverse event with the preferred product.

III. CLINICAL CRITERIA (*Use for Cinqair and Fasenra Drug Requests Only – Refer to Nucala policy for drug specific clinical criteria*)

Must meet all of the criteria listed below:

- Must be prescribed by or in consultation with an allergist, immunologist, or pulmonologist
- Must be 18 years or older for Cinqair® or 12 years or older for Fasenra®
- Must have a diagnosis of severe persistent asthma (chart documentation must be provided)
- Must have weight of patient at each visit to ensure appropriate dosing
- Must have an eosinophilic phenotype
    - Must have a blood eosinophil count of at least 400/mcL within 3 to 4 weeks of dosing (test date must be provided)
- Must have asthma symptoms that have not been adequately controlled despite adherence to an optimized medication therapy regimen, defined by ONE of the following:
    - Hospitalization for asthma in the past year
    - Requirement for systemic (oral, parenteral) corticosteroids to control exacerbations of asthma on 2 occurrences in the past year
    - On daily corticosteroid with inability to taper off
- Must have tried other add-on maintenance treatment with a high dose inhaled corticosteroid and TWO of the following:
    - Inhaled long-acting beta agonist
    - Inhaled long-acting muscarinic antagonist
    - Leukotriene receptor antagonist
    - Theophylline

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber of the following:

- The member's condition has improved based upon the prescriber's assessment while on therapy
- Reduction in exacerbations, hospitalizations, emergency department visits, or requirement for oral corticosteroid therapy

Limitations:

Length of Authorization (if above criteria met)

Initial Authorization	Up to 6 months
Reauthorization	Up to 1 year

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Cinqair [Prescribing Information]. Frazer, PA: Teva Respiratory LLC; March 2016.
2. Fasenra [Prescribing Information]. Wilmington, DE: AstraZeneca; November 2017

RECORD RETENTION
Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New policy	*4/16*
Annual Review	*02/17, 02/18*
Preferred Product Update	*12/18*