Policy and Procedure

DEPARTMENT: Pharmacy, Medical Directors	**DOCUMENT NAME:** Benralizumab (Fasenra)
PAGE: 1 of 5	**REPLACES DOCUMENT:**
APPROVED DATE:	**RETIRED:**
EFFECTIVE DATE: 10/18/2021	**REVIEWED/REVISED: 11/30/2021**
PRODUCT TYPE: STAR, STAR Health, STAR Kids, STAR Plus, CHIP, CHIP Perinate	**REFERENCE NUMBER:** TX.PHAR.99

SCOPE:
Superior HealthPlan Pharmacy Department, Medical Directors

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan.

While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria, but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical policy and prior authorization requirements.

BACKGROUND:
Description:
Benralizumab (Fasenra™) is an interleukin-5 receptor alpha-directed cytolytic monoclonal antibody (IgG1 kappa).

FDA Approved Indication(s)
Fasenra is indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

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PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria

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

1. Diagnosis of severe asthma with eosinophilic phenotype (as defined by the National Heart, Lung, and Blood Institute's Guidelines for the Diagnosis and management of Asthma) (diagnosis codes J4450, J4451, J4452).
2. Age ≥ 12 years
3. Documentation showing symptoms are inadequately controlled with use of one of the following combination therapies (a or b):
    a. 12 months of high-dose inhaled corticosteroid (ICS) given in combination with a minimum of 3 months of controller medication (either a long-acting beta2-agonist [LABA], leukotriene receptor antagonist [LTRA], or theophylline), unless the individual is intolerant of, or has a medical contraindication to these agents
    b. 6 months of ICS with daily oral glucocorticoids given in combination with a minimum of 3 months of controller medication (a LABA, LTRA, or theophylline), unless the individual is intolerant of, or has a medical contraindication to these agents

    Note: Exceptions to the criteria above will be considered on a case-by-case basis, which will require a letter from the prescribing provider stating the medical necessity for benralizumab, the member's asthma severity level, and the duration of current and past therapies and lack of asthma control. Consideration for these exceptions will be reviewed by the SHP medical director.
4. Pulmonary function tests must have been performed within a three-month period and be documented for all members.
    Note: Exceptions may be considered with documentation of medical reasons explaining why pulmonary function tests cannot be performed.

5. Blood eosinophil count greater than or equal to 150 cells/microliter before the initiation of therapy, in the absence of other potential causes of eosinophilia including hypereosinophilic syndromes, neoplastic disease, and known or suspected parasitic infection
   Note: 1 microliter (ul) is equal to 1 cubic millimeter (mm3).
6. Documentation member is not currently smoking
7. Fasenra is not prescribed concurrently with Cinqair®, Xolair®, or Nucala®

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Documentation of compliance with the medication for 6 continuous months
2. Member has a satisfactory clinical response to therapy (Documentation of clinical improvement must include one or more of the following (a, b, or c):
   a. Decreased utilization of rescue medications
   b. Increase in predicted FEV1 (forced expiratory volume) from pretreatment baseline
   c. Reduction in reported asthma-related symptoms, as evidenced by decreases in frequency or magnitude of one or more of the following symptoms:
      i. Asthma attacks
      ii. Chest tightness or heaviness
      iii. Coughing or clearing throat
      iv. Difficulty taking deep breath or difficulty breathing out
      v. Shortness of breath
      vi. Sleep disturbance, night wakening, or symptoms upon awakening
      vii. Tiredness

viii. Wheezing/heavy breathing/fighting for air

3. Documentation stating member has not exhibited symptoms of hypersensitivity or anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema) after administration of benralizumab
4. Fasenra is not prescribed concurrently with Cinqair®, Xolair®, or Nucala®

   Note: Requests for members who do not meet the above criteria will be reviewed for medical necessity by the SHP medical director. After lapses in treatment of 3 months or greater, prior authorization requests submitted with documentation will be reviewed by a SHP medical director.

Approval duration: 6 months

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

1. Refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ICS: inhaled corticosteroids
LABA: long-acting beta-agonist
LTRA: leukotriene modifier

REFERENCES:

1. Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual, Accessed December 2021

ATTACHMENTS:

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REVISION LOG

REVISION	DATE
Added diagnosis codes Removed age exception note	11.30.2021

POLICY AND PROCEDURE APPROVAL

Karen Tadlock, V.P., Pharmacy Operations — Approval on file

Dr. David Harmon, Sr. V.P., Chief Medical Officer — Approval on file

Pharmacy & Therapeutics Committee: — Approval on file

NOTE: The electronic approval retained in RSA Archer, Centene's P&P management software, is considered equivalent to a physical signature.