POLICY AND PROCEDURE

POLICY NAME: Benralizumab (Fasenra)	**POLICY ID:** TX.PHAR.99
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy, Medical Directors, Claims
EFFECTIVE DATE: 10/18/2021	**PRODUCT(S):** CHIP, STAR, STAR PLUS, STAR HEALTH, STAR KIDS
REVIEWED/REVISED DATE: 11/30/2021, 8/10/2022	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

POLICY STATEMENT:
The purpose of this Clinical Policy is to provide a guide to medical necessity reviews for benralizumab (Fasenra).

PURPOSE:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review benralizumab (Fasenra).

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.

SCOPE:
This policy applies to Superior HealthPlan Pharmacy Department, Medical Directors, Claims.

DEFINITIONS:
N/A

POLICY:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review benralizumab (Fasenra).

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.

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 J4550, J4551 and J4552)
2. Age ≥ 12 years
   Note: Exceptions may be considered for patients younger than the FDA approved age on a case-by-case basis by the SHP medical director.

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
    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, Nucala or any other interleukin-5 antagonist.

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/CHIP.

II. Continued Therapy

A. Severe Asthma (must meet all):

1. 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:
        - Asthma attacks
        - Chest tightness or heaviness
        - Coughing or clearing throat
        - Difficulty taking deep breath or difficulty breathing out
        - Shortness of breath
        - Sleep disturbance, night wakening, or symptoms upon awakening
        - Tiredness
        - Wheezing/heavy breathing/fighting for air
2. Documentation stating member has not exhibited symptoms of hypersensitivity or anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema) after administration of Fasenra
3. Fasenra is not prescribed concurrently with Cinqair, Xolair, Nucala or any other interleukin-5 antagonist. Member must be compliant with their Fasenra regimen in order to qualify for additional prior authorizations. The provider must submit a statement documenting compliance with the requests for each renewal

    Note: Requests for clients 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

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

REFERENCES:

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

ATTACHMENTS:

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
Ad Hoc	Added diagnosis codes Removed age exception note	11/30/2021
Ad Hoc	Formatted to new template Added compliance statement requirement for continued approval for asthma Added that treatment must not be used with any other IL-5 antagonist Edited ICD-10 codes, typos from J4450, J4451 to J4550 and J551	8/10/2022

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

The electronic approval retained in RSA Archer, the Company's P&P management software, is considered equivalent to a signature.