Policy Title:	Fasenra (benralizumab) Subcutaneous		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	11/27/2019, 12/18/19		
Revision Date:	11/27/2019		

Purpose: To support safe, effective and appropriate use of Fasenra (benralizumab).

Scope: Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

Policy Statement:

Fasenra (benralizumab) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Fasenra (benralizumab) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

- Clinically documented severe asthma with an eosinophilic phenotype: Peak expiratory flow and/or FEV1 less than 60% of normal predicted values; AND
- Must be prescribed by a Pulmonologist or Allergist/Immunologist; AND
- Must be 12 years of age or older; AND
- Evidence of severe asthma in accordance with national asthma guidelines (such as, symptoms throughout the day, nighttime awakenings(often 7 times a week), SABA use for symptom control occurs several times daily, extremely limited in normal activities, lung function (percent predicted FEV1) less than 60% or exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma; AND
- Must be used as add-on maintenance treatment in patients regularly receiving ONE of the following combinations of therapy: High-dose inhaled corticosteroids plus a long-acting beta agonist (LABA) plus Spiriva OR high-dose inhaled corticosteroids plus a long acting beta agonist (LABA) plus a leukotriene receptor antagonists (LTRA) OR the member is intolerant/contraindication to one of these; AND
- Patient is not using in combination with omalizumab (Xolair) or reslizumab (Cinqair) or Mepolizumab (Nucala) or dupilumab(Dupixent)

Continuation of Therapy Criteria:

- Patient is tolerating treatment; AND
- Patient has clinical documentation of disease stabilization or improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in at least one of the following: Use of systemic corticosteroids, decrease in inhaled corticosteroid use, hospitalizations, ER visits, unscheduled visits to healthcare provider OR Improvement from baseline in forced expiratory volume in 1 second (FEV1); AND
- Patient is not using in combination with omalizumab (Xolair) or reslizumab (Cinqair) or Mepolizumab (Nucala) or dupilumab(Dupixent)

Coverage durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 12 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.***

Dosage/Administration:

Indication	**Dose**	**Maximum dose (1 billable unit = *1* mg)**
Severe Asthma with eosinophilic phenotype	30 mg administered subcutaneously, by a healthcare professional, every 4 weeks for the first three doses and then once every 8 weeks thereafter	Loading: 30 mg (30 units) every 28 days x 3 doses Maintenance: 30 mg (30 units) every 56 days

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J0517	Injection, benralizumab, 1mg

References:

1. Fasenra [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals; November 2017. Accessed August 2018.
2. National Asthma Education and Prevention Program (NAEPP). Guidelines for the diagnosis and management of asthma. Expert Panel Report
3. Bethesda, MD: National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI); August 2007. 3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2018 Update. Available from: http://www.ginasthma.org. Accessed August 2018.
4. Walford HH, Doherty TA. Diagnosis and management of eosinophilic asthma: a US perspective. J Asthma Allergy. 2014; 7: 53–65.
5. Goldman M, Hirsch I, Zangrilli JG, et al. The association between blood eosinophil count and benralizumab efficacy for patients with severe, uncontrolled asthma: subanalyses of the Phase III SIROCCO and CALIMA studies. Curr Med Res Opin. 2017 Sep;33(9):1605- 1613. doi: 10.1080/03007995.2017.1347091. Epub 2017 Jul 19.
6. The Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention, 2017. Available from: www.ginasthma.org.
7. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS Guidelines on Definition, Evaluation, and Treatment of Severe Asthma. Eur Respir J 2014; 43: 343-373.