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Benralizumab

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Disclaimer

Medical policies are a set of written guidelines that support current standards of practice. They are based on current peer-reviewed scientific literature. A requested therapy must be proven effective for the relevant diagnosis or procedure. For drug therapy, the proposed dose, frequency and duration of therapy must be consistent with recommendations in at least one authoritative source. This medical policy is supported by FDA-approved labeling and/or nationally recognized authoritative references to major drug compendia, peer reviewed scientific literature and acceptable standards of medical practice. These references include, but are not limited to: MCG care guidelines, DrugDex (IIa level of evidence or higher), NCCN Guidelines (IIb level of evidence or higher), NCCN Compendia (IIb level of evidence or higher), professional society guidelines, and CMS coverage policy.

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For HCSC members residing in the state of Ohio, § 3923.60 requires any group or individual policy (Small, Mid-Market, Large Groups, Municipalities/Counties/Schools, State Employees, Fully-Insured, PPO, HMO, POS, EPO) that covers prescription drugs to provide for the coverage of any drug approved by the U. S. Food and Drug Administration (FDA) when it is prescribed for a use recognized as safe and effective for the treatment of a given indication in one or more of the standard medical reference compendia adopted by the United States Department of Health and Human Services or in medical literature even if the FDA has not approved the drug for that indication. Medical literature support is only satisfied when safety and efficacy has been confirmed in two articles from major peer-reviewed professional medical journals that present data supporting the proposed off-label use or uses as generally safe and effective. Examples of accepted journals include, but are not limited to, Journal of

American Medical Association (JAMA), New England Journal of Medicine (NEJM), and Lancet. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. Evidence limited to case studies or case series is not sufficient to meet the standard of this criterion. Coverage is never required where the FDA has recognized a use to be contraindicated and coverage is not required for non-formulary drugs.

Coverage

Benralizumab (Fasenra®) **may be considered medically necessary** for the add-on maintenance treatment of severe eosinophilic asthma when the following criteria are met:

- Individual is 12 years of age and older; AND
- There is documented and current use of an inhaled corticosteroid (ICS) in combination with a long acting beta2-agonist (LABA), leukotriene receptor antagonist [LTRA], theophylline or long-acting muscarinic antagonist (LAMA) for at least 3 months; AND
- The individual has uncontrolled asthma while on control therapy as evidenced by 2 or more exacerbations requiring systemic glucocorticoids, frequent ER visits, or hospitalizations (see **NOTE 1**); AND
- Eosinophil count of the following (in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease, and known or suspected parasitic infection):
  - 150 cells/µL or more in peripheral blood at screening; or
  - 300 cells/µL or more during the previous year; AND
- Will not be used in combination with another antiasthmatic monoclonal antibody agent (e.g., reslizumab [Cinqair], omalizumab [Xolair], mepolizumab [Nucala], tezepelumab-ekko [Tezspire], dupilumab [Dupixent]).

NOTE 1: Individuals who do not meet the criteria for uncontrolled asthma, but whose asthma worsens on tapering off corticosteroids, will also meet this definition of severe asthma. For definition of uncontrolled asthma see Description section.

NOTE 2: 1 microliter (µL) is equal to 1 cubic millimeter (mm^3).

Benralizumab (Fasenra®) **is considered experimental, investigational and/or unproven** when the above criteria are not met, and for all other indications, including but not limited to:

- Treatment of other eosinophilic conditions; or
- Relief of acute bronchospasm or status asthmaticus.

Self-Administration

The FDA has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage of a formulation that cannot be self-administered **may be considered medically necessary** when:

- Patient or caregiver is unable to recognize symptoms of anaphylaxis; OR
- Patient or caregiver is unable to treat anaphylaxis appropriately; OR

- Patient or caregiver is unable to perform subcutaneous injections with a prefilled syringe or autoinjector with proper technique according to the prescribed dosing regimen and Instructions for Use; OR
- The patient has a physical or cognitive limitation that makes the utilization of a self-administered formulation unsafe or otherwise not feasible, as demonstrated by BOTH of the following:
  - Inability to self-administer the medication; and
  - Lack of caregiver or support system for assistance with administration of self-administered products

Coverage of a formulation that cannot be self-administered **is considered not medically necessary** if the above criteria are not met.

Policy Guidelines

None.

Description

Monoclonal antibodies (mAbs), omalizumab, mepolizumab, reslizumab, tezepelumab-ekko, and dupilumab are currently available for use as add-on treatment for severe asthma. These mAbs either bind or block the offending triggers to reduce allergic cascade and airway inflammation when eosinophils are the causative factor. Benralizumab (Fasenra™), an interleukin-5-receptor alpha directed cytolytic monoclonal antibody, offers a different mechanism of action that delivers rapid, direct, and nearly complete eosinophil depletion, with early and sustained efficacy responses. This treatment offers a different choice among the currently available therapies for severe asthma with an eosinophilic phenotype. (7)

Background
According to the Asthma and Allergy Foundation of America, asthma affects more than 27 million Americans. (1) This is 8 percent of adults and 6.5 percent of children. (2) Asthma has been increasing since the early 1980s in all age, sex, and racial groups. It is a chronic disease that causes the airways to become inflamed, making it hard to breathe. There is no cure for asthma. The best way to manage asthma is to avoid triggers, take medications to prevent symptoms, and prepare to treat asthma episodes if they occur. (1)

Asthma symptoms can appear when the individual is exposed to a trigger. A trigger is something that the individual is sensitive to, which causes swelling, mucous production and narrowing within the airways. Common asthma triggers are pollen, chemicals, extreme weather changes, smoke, dust mites, stress, and exercise.

Asthma comprises a number of distinct phenotypes, mainly eosinophilic and non-eosinophilic asthma, based on the cell-profile of induced sputum samples. Response to asthma treatments may be different based on the different types of inflammation.

Definition of Uncontrolled Asthma

At least one of the following:

- Poor symptom control: Asthma Control Questionnaire (ACQ) score consistently >1.5, Asthma Control Test (ACT) score <20 (or ''not well controlled'' by the National Asthma Education and Prevention Program (NAEPP) /Global Initiative for Asthma (GINA) guidelines);
- Frequent severe exacerbations: ≥2 bursts of systemic corticosteroids (CS) (>3 days each) in the previous year;
- Serious exacerbations: at least 1 hospitalization, intensive care unit (ICU) stay, or mechanical ventilation in the previous year;
- Airflow limitation: after appropriate bronchodilator withhold, forced expiratory volume in 1 second (FEV_1) <80% predicted (in the face of reduced FEV_1/forced vital capacity [FVC] defined as less than the lower limit of normal). (3)

Benralizumab

Benralizumab is a humanized afucosylated, monoclonal antibody (IgG1, kappa) that directly binds to the alpha subunit of the human interleukin-5 receptor (IL-5Rα). The IL-5 receptor is expressed on the surface of eosinophils and basophils. Inflammation is an important component in the pathogenesis of asthma. Multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, cytokines) are involved in inflammation. By binding to the IL-5Rα chain, benralizumab reduces eosinophils through antibody-dependent cell-mediated cytotoxicity. (4)

Regulatory Status

Benralizumab (Fasenra®), manufactured by AstraZeneca Pharmaceuticals, Wilmington, DE, was approved by the U.S. Food and Drug Administration on November 14, 2017. Fasenra® is indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype. Limitations of use include treatment of other eosinophilic conditions or relief of acute bronchospasm or status asthmaticus. (4)

Recommended FDA labeled dosing

For severe asthma, eosinophilic phenotype, 30 mg/mL, administered subcutaneously, every 4 weeks for the first 3 doses, and then once every 8 weeks thereafter. (4)

Rationale

This medical policy was created in 2018 and is based on U.S. Food and Drug Administration (FDA) approved labeled indications. The FDA based their approval on the evidence from 5 clinical trials conducted in the U.S., Canada, South America, Europe, Asia, and/or Africa. These clinical trials include:

- One 52-week dose ranging exacerbation trial (NCT01238861; National Clinical Trial); (5)
- Three confirmatory studies (Trial 1 [NCT01928771], (6) Trial 2 [NCT01914757], (7) Trial 3 [NCT02075255]); (8) and
- One 12-week lung function (clinical development program) trial (NCT02322775). (9)

The following is a summary of the key literature from those clinical trials.

Dose-Ranging Trial

In 2014, Castro et al. published results from a phase 2 randomized, double-blind, placebo-controlled, 52-week dose-ranging trial, which enrolled 609 asthmatic patients 18 years of age and older. (5) Patients were treated with Fasenra® 2 mg, 20 mg, or 100 mg or placebo administered subcutaneously every 4 weeks (Q4W) for 3 doses followed by every 8 weeks (Q8W). The primary endpoint was the annual exacerbation rate, while forced expiratory volume in 1 second (FEV_1) and Asthma Control Questionnaire-6 (ACQ-6) were key secondary endpoints. Patients were required to have a history of 2 or more asthma exacerbations (but no more than 6 exacerbations) requiring systemic corticosteroid (SCS) treatment in the past 12 months, ACQ-6 score of 1.5 at least twice during screening, and reduced morning lung function at screening [pre-bronchodilator FEV_1 below 90%] despite treatment with medium-or high-dose inhaled corticosteroid (ICS) plus long-acting ß- (beta-) agonists (LABA). Patients were stratified by eosinophilic status. The annual exacerbation rate reduction for patients receiving Fasenra® 2 mg, 20 mg, and 100 mg were -12% (80% CI [confidence interval]: -52, 18), 34% (80% CI: 6, 54), 29% (80% CI: 10, 44), respectively, compared to placebo (rate 0.56). The researchers concluded Fasenra® seemed to reduce asthma exacerbations in adults with uncontrolled eosinophilic asthma and baseline blood eosinophils (BEs) of at least 300 cells per uL. They proposed the results were possible due to targeting of the interleukin-5-receptor rather than the interleukin-5-ligand and further study was warranted.

Confirmatory Trials

Trial 1 (SIROCCO trial; Bleecker, et al., 2016) (6) and Trial 2 (CALIMA study; Fitzgerald et al., 2016) (7), were randomized, double-blind, parallel-group, placebo-controlled, exacerbation trials in patients 12 years of age and older, and 48 and 56 weeks in duration, respectively. The trials randomized a total of 2510 patients. Patients were required to have a history of 2 or more asthma exacerbations requiring oral corticosteroid (OCS) or SCS treatment in the past 12 months, ACQ-6 score of 1.5 or more at screening, and reduced lung function at baseline [prebronchodilator FEV_1 below 80% in adults, and below 90% in adolescents] despite regular treatment with high-dose ICS (Trial 1) or with medium- or high-dose ICS (Trial 2) plus a LABA with or without OCS and additional asthma controller medications. Patients were stratified by geography, age, and BEs count (≥300 cells/µL or <300 cells/µL). Fasenra® administered once Q4W for the first 3 doses, and then Q4W/Q8W thereafter as add-on to background treatment was evaluated compared to placebo. All subjects continued their background asthma therapy throughout the duration of the trials. In both trials, the researcher group was the same. Their conclusion was Fasenra® was beneficial to these patient populations by significantly reducing annual asthma exacerbation rates and was generally well-tolerated.

Trial 3 (Nair, et al., 2017) (8) was a randomized, double-blind, parallel-group, OCS reduction trial in 220 asthma patients. Patients were required to have treatment with daily OCS (7.5 to 40 mg per day) in addition to regular use of high-dose ICS and LABA, with or without additional controller(s). The trial included an 8-week run-in period during which the OCS was titrated to the minimum effective dose without losing asthma control. For the purposes of the OCS dose titration, asthma control was assessed by the investigator based on a patient's FEV_1, peak expiratory flow, nighttime awakenings, short-acting bronchodilator rescue medication use or any other symptoms that would require an increase in OCS dose. Baseline median OCS dose was similar across all treatment groups. Patients were required to have BE counts greater than or equal to 150 cells/µL and a history of at least 1 exacerbation in the past 12 months. The baseline median OCS dose was 10 mg (range: 8 to 40 mg) for all 3 treatment groups (placebo, Fasenra® Q4W, and Fasenra® Q4W for the first 3 doses, and then once Q8W.

Exacerbations

The primary endpoint for Trials 1 and 2 was the rate of asthma exacerbations in patients with baseline BE counts of greater than or equal to 300 cells/µL who were taking high-dose ICS and LABA. (6, 7) Asthma exacerbation was defined as a worsening of asthma requiring use of OCS/SCS for at least 3 days, and/or emergency department (ED) visits requiring use of OCS/SCS and/or hospitalization. For patients on maintenance OCS, an asthma exacerbation requiring OCS was defined as a temporary increase in stable OCS/SCS for at least 3 days or a single depo-injectable dose of corticosteroids. In Trial 1, 35% of patients receiving Fasenra® experienced an asthma exacerbation compared to 51% on placebo. In Trial 2, 40% of patients receiving Fasenra® experienced an asthma exacerbation compared to 51% on placebo (Table 1).

Table 1. Rate of Exacerbations, Trials 1 and 2 (ITT Population) [a] (6, 7)

Trial	Treatment	Exacerbations per Year		
		Rate	Difference	Rate Ratio (95% CI)
All Exacerbations				
Trial 1	Fasenra® [b] (n=267)	0.74	-0.78	0.49 (0.37, 0.64)
	Placebo (n=267)	1.52	--	--
Trial 2	Fasenra® [b] (n=239)	0.73	-0.29	0.72 (0.54, 0.95)
	Placebo (n=248)	1.01	--	--
Exacerbations Requiring Hospitalization or Emergency Department Visits				
Trial 1	Fasenra® [b] (n=267)	0.09	-0.16	0.37 (0.20, 0.67)
	Placebo (n=267)	0.25	--	--
Trial 2	Fasenra® [b] (n=239)	0.12	0.02	1.23 (0.64, 2.35)
	Placebo (n=248)	0.10	--	--
Exacerbations Requiring Hospitalizations				
Trial 1	Fasenra® [b] (n=267)	0.07	-0.07	0.48 (0.22, 1.03)
	Placebo (n=267)	0.14	--	--
Trial 2	Fasenra® [b] (n=239)	0.07	0.02	1.48 (0.65, 3.37)
	Placebo (n=248)	0.05	--	--

Table Key:

ITT: intention-to-treat;
CI: confidence interval;
n: number;
[a] baseline blood eosinophil counts of greater than or equal to 300 cells/µL and taking high-dose inhaled corticosteroids;
[b] Fasenra® 30mg administered every 4 weeks for the first 3 doses, and every 8 weeks thereafter.

Subgroup analyses from Trials 1 and 2 identified patients with a higher prior exacerbation history and baseline BE count as potential predictors of improved treatment response. (6, 7) Reductions in exacerbation rates were observed irrespective of baseline peripheral eosinophil counts; however, patients with a baseline BE count ≥ 300 cells/µL showed a numerically greater response than those with counts < 300 cells/µL. In both trials patients with a history of 3 or more exacerbations within the 12 months prior to Fasenra® randomization showed a numerically greater exacerbation response than those with fewer prior exacerbations.

Oral Corticosteroid Reduction

Trial 3 evaluated the effect of Fasenra® on reducing the use of maintenance OCS. (8) The primary endpoint was percent reduction from baseline of the final OCS dose during weeks 24 to 28, while maintaining asthma control. Compared to placebo, patients receiving Fasenra® achieved greater reductions in daily maintenance OCS dose, while maintaining asthma control. The median percent reduction in daily OCS dose from baseline was 75% in patients receiving Fasenra® (95% CI: 60, 88) compared to 25% in patients receiving placebo (95% CI: 0, 33). Reductions of 50% or higher in the OCS dose were observed in 48 (66%) patients receiving Fasenra® compared to those receiving placebo 28 (37%). The proportion of patients with a mean final dose less than or equal to 5 mg at weeks 24 to 28 was 59% for Fasenra® and 33% for placebo (odds ratio 2.74, 95% CI: 1.41, 5.31). Only patients with an optimized baseline OCS dose of 12.5 mg or less were eligible to achieve a 100% reduction in OCS dose during the study. Of those patients, 52% (22 of 42) receiving Fasenra® and 19% (8 of 42) on placebo achieved a 100% reduction in OCS dose. Exacerbations resulting in hospitalization and/or emergency department (ED) visit were also assessed as a secondary endpoint. In this 28-week trial, patients receiving Fasenra® had 1 event while those on placebo had 14 events (annualized rate 0.02 and 0.32 respectively; rate ratio of 0.07, 95% CI: 0.01, 0.63). Overall, Fasenra® showed significant benefits to the tested population group when compared to placebo on OCS use and exacerbation rates.

Patient Reported Outcomes

The ACQ-6 and Standardized Asthma Quality of Life Questionnaire for 12 Years and Older (AQLQ(S)+12) were assessed in Trials 1, 2 and 3. (6-8) The responder rate for both measures were defined as improvement in score of 0.5 or more as threshold at the end of Trials 1, 2, and 3 (48, 56, and 28 weeks, respectively). In Trial 1, the ACQ-6 responder rate for Fasenra® was 60% versus 50% placebo (odds ratio 1.55; 95% CI: 1.10, 2.19). (6) In Trial 2, the ACQ-6 responder rate for the Fasenra® was 63% versus 59% placebo (odds ratio 1.16; 95% CI: 0.80, 1.68). (7) In Trial 1, the responder rate for AQLQ(S)+12 for Fasenra® was 57% versus 49%

placebo (odds ratio 1.42; 95% CI: 0.99, 2.02), and in Trial 2, 60% Fasenra® versus 59% placebo (odds ratio of 1.03; 95% CI: 0.70,1.51). (6, 7) Similar results were seen in Trial 3. (8)

Lung Function Study

Change from baseline in mean FEV_1 was assessed in Trials 1, 2, and 3 as a secondary endpoint. (6-8) Compared with placebo, Fasenra® provided consistent improvements over time in the mean change from baseline in FEV_1 (Table 2).

Table 2. Change from Baseline in Mean Pre-Bronchodilator FEV_1 at End of Trial [a] (6-8)

Trial	Difference from Placebo in Mean Change from Pre-Bronchodilator Baseline FEV_1 (95% CI)
1	0.159 (0.068, 0.249)
2	0.116 (0.028, 0.204)
3	0.112 (-0.033, 0.258)

Table Key: FEV_1: forced expiratory volume in 1 second; CI: confidence interval;
[a] Week 48 in Trial 1 (6), Week 56 in Trial 2 (7), Week 28 in Trial 3. (8)

Clinical Development Program

A final study was completed prior to the FDA-approval for clinical development program for Fasenra®. Ferguson et al., (BISE trial; 2017) evaluated the lung function of patients with mild- to moderate-persistent asthma. (9). This study was a 12-week, randomized, double-blind, placebo-controlled lung function trial conducted in 211 patients. Patients were treated with placebo (n=105) or Fasenra® (n=106) 30 mg subcutaneously Q4W for 3 doses. Lung function, as measured by the change from baseline in FEV_1 at week 12, was improved in the Fasenra® treatment group compared to placebo. Table 3 provides the FEV_1 results at baseline and at 12 weeks. The authors concluded that the active and modifiable disease processes might be ongoing in patients with mild- to moderate-persistent asthma receiving ICS. Although the lung function improvement does not warrant the use of Fasenra® in this patient population, further study is needed.

Table 3. Comparison of Baseline in Pre-Bronchodilator FEV_1 to End of Trial at 12 Weeks Measured in Liters (9)

	Fasenra™ (n=106)	**Placebo** (n=105)
Baseline	2.248 mL (0.6062)	2.246 mL (0.7677)
Week 12	2.310 mL (0.6702)	2.261 mL (0.7959)
Difference	0.057mL (0.2734)	-0.016 mL (0.2350)

Table Key: FEV_1: forced expiratory volume in 1 second; mL: milliliters; n: number.

Ongoing and Unpublished Clinical Trials

Currently, there are multiple ongoing, published and/or unpublished trials which focus on Fasenra® for the treatment of numerous conditions. These conditions include both FDA-approved indications, and non-FDA approved indications such as eosinophilic gastritis, nasal polyposis, exercise-induced bronchospasm, chronic obstructive pulmonary disease, eosinophilic

polyposis, uncontrolled asthma, mild asthma, moderate asthma, atopic asthmaticus, eosinophilic granulomatosis, eosinophilic chronic rhinosinusitis, and chronic urticaria.

Summary of Evidence
For individuals 12 years and older who have eosinophilic phenotype (severe) asthma, whose asthma is not well controlled while on current medications/therapy, the evidence includes 5 clinical trials. Relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. The clinical trials have shown that patients who received benralizumab (Fasenra®) had fewer asthma attacks that required a stay in the hospital and/or a visit to the emergency department (ED) and had greater reduction in their daily maintenance dose of oral corticosteroids (OCS) or inhaled corticosteroids (ICS). The evidence is sufficient to support the use of Fasenra® for its U.S. Food and Drug Administration (FDA) approved indications, which is based on clinical trials outcomes documented in the published labeling.

For individuals who have conditions beyond the approved FDA indications, there is no published literature to support the use of benralizumab (Fasenra®) as a treatment or therapy. The lack of studies does not permit conclusions on the health benefits of Fasenra® for those patient populations. The evidence is insufficient to determine the impact of the technology on health outcomes and to support the use of Fasenra® beyond its FDA approved indications.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	None
HCPCS Codes	J0517

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
04/15/2025	Document updated. The following change was made to Coverage: Added "The FDA has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage of a formulation that cannot be self-administered is considered not medically necessary unless the patient has a physical or cognitive limitation that makes the utilization of a self-administered formulation unsafe or otherwise not feasible, as demonstrated by BOTH of the following: Inability to self-administer the medication, AND lack of caregiver or support system for

	assistance with administration of self-administered products." No new references added.
03/15/2024	Document updated with literature review. The following change was made to Coverage: Modified medically necessary coverage criteria. No new references added; other(s) updated.
07/01/2023	Reviewed. No changes.
12/01/2022	Document updated with literature review. The following change was made to Coverage: Added tezepelumab-ekko [Tezspire] and dupilumab [Dupixent]) to this statement: Will not be used in combination with another antiasthmatic monoclonal antibody agent (e.g., reslizumab [Cinqair], omalizumab [Xolair], mepolizumab [Nucala]. References revised; none added.
09/01/2021	Reviewed. No changes.
10/01/2020	Document updated with literature review. The following changes were made to Coverage: 1) Modified medically necessary conditional criteria; 2) Removed documentation requirements; and 3) Modified NOTE 1 to read: "Patients who do not meet the criteria for uncontrolled asthma, but whose asthma worsens on tapering off corticosteroids, will also meet this definition of severe asthma. For definition of uncontrolled asthma see Description section." The following references were added/updated: 1-4. Title changed from "Benralizumab (Fasenra)".
12/01/2018	New medical document. Benralizumab (Fasenra™) may be considered medically necessary for the add-on maintenance treatment of eosinophilic phenotype (severe) asthma when the patient meets ALL of the following criteria (see NOTE 1 for documentation required): 12 years of age or older; and Blood eosinophilic count is 150 cells/µL or higher prior to initiation of this therapy; and Reduced lung function at baseline (pre-bronchodilator FEV_1 below 80% for all age groups); and History of 2 or more severe asthmatic exacerbations requiring systemic corticosteroid treatment within the past 12 months; and History of current and regular treatments with high-dose inhaled corticosteroids AND long-acting ß- (beta-) agonists, with or without oral corticosteroid therapy and additional asthma-controlled medications. NOTE 1: Documentation should include ALL of the following information: Eosinophil count, and Lung function (FEV_1), and History of asthmatic exacerbations, and Current medications (specifically inhaled corticosteroids and long-acting ß- [beta-] agonists). Benralizumab (Fasenra™) is considered experimental, investigational and/or unproven when the above criteria are not met, and for all other indications, including but not limited to: Treatment of other eosinophilic conditions, or Relief of acute bronchospasm or status asthmaticus.