Original Effective Date: 07/01/2010
Current Effective Date: 01/21/2023
Last P&T Approval/Version: 10/26/2022
Next Review Due By: 10/2023
Policy Number: C13643-A

Fasenra (benralizumab)

PRODUCTS AFFECTED

Fasenra (benralizumab)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Severe asthma with an eosinophilic phenotype or predominantly eosinophil-driven disease also described as “airway eosinophilia”

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review.

A. SEVERE ASTHMA WITH EOSINOPHILIC PHENOTYPE:
1. Documented diagnosis of moderate to severe asthma AND
2. Prescriber attests or clinical reviewer has found that Fasenra (benralizumab) is NOT being prescribed as:

Molina Healthcare, Inc. confidential and proprietary © 2022
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

(a) Monotherapy for asthma (must be prescribed as add-on maintenance to be used in combination with other medications for long-term control of asthma)
AND
(b) Concurrent therapy with other monoclonal antibodies used to treat asthma [i.e., Xolair (omalizumab) OR other IL-5 inhibitors [Cinqair (reslizumab), Nucala (mepolizumab)] OR IL-2 agonist Dupixent (dupilumab) OR Anti-TSLP Tezspire (Tezepelumab-ekko)]
AND

3. Documentation of one of the following [DOCUMENTATION REQUIRED]:
(a) Member has eosinophilic phenotype or predominantly eosinophil-driven disease with blood eosinophil counts: >150 cells/microliter at initiation of therapy (within 6 weeks of request) Or >300cells/microliter in the prior 12 months
OR
(b) Member has experienced exacerbation(s) or hospitalization(s), within the last 12 months documented by ANY of the following:
    i. TWO (2) or more exacerbations requiring treatment with systemic corticosteroid (intramuscular, intravenous, or oral) despite the use of high-dose inhaled corticosteroids in the past 12 months OR
    ii. Two-fold increase or greater in the dose of systemic corticosteroid treatment for asthma exacerbations OR
    iii. Asthma worsens upon tapering of oral corticosteroid therapy OR
    iv. Mechanical ventilation in the past 12 months OR
    v. Poor symptom control indicated by Asthma Control Questionnaire (ACQ) score consistently greater than 1.5 or Asthma Control Test (ACT) score consistently less than 20 OR
    vi. Forced expiratory volume in 1 second (FEV1) < 80% predicted OR
    vii. FEV1/forced vital capacity (FVC) < 0.80

AND

4. Symptoms inadequately controlled (as documented in criteria above) by the following adherent regimen of **at least 3 months** (within the past 90 days): (a) OR (b)
(a) COMBINATION THERAPY of high-dose inhaled corticosteroid (ICS) AND an asthma controller medication with or without oral corticosteroid:
    i) Maximally tolerated dose of inhaled ICS (appropriately adjusted for age), OR Documented serious side effects, FDA labeled contraindication, or hypersensitivity to ICS [Appendix 2: Suggested total daily dosages for inhaled corticosteroids (ICS) in adults and adolescents (12 years and older) AND
    ii) ONE of the following ASTHMA CONTROLLER MEDICATION (LABA, LTRA, LAMA, AND theophylline), OR documented serious side effects, FDA labeled contraindication, or hypersensitivity to all these medications (LABA, LTRA, LAMA, AND theophylline)
        - Long-acting beta-2 agonist (LABA) [e.g., salmeterol products (Serevent) formoterol (Foradil)], OR
        - Leukotriene receptor antagonist (LTRA) [e.g., montelukast (Singulair); zafirlukast (Accolate);zileuton (Zyflo)], OR
        - Long-acting muscarinic antagonist (LAMA) [e.g., tiotropium bromide inhalation spray (Spiriva, Respimat)], OR
        - Theophylline (Theo-24, Uniphyl, TheoChron ER, generics)

OR

(b) Combination ICS/LABA at maximum recommended doses or maximally tolerated dose [i.e., fluticasone/salmeterol (Advair), mometasone/formoterol (Dulera), budesonide/formoterol (Symbicort); fluticasone/vilanterol (Breo Ellipta)]
MOLINA REVIEWER: Verify pharmacy claims for compliance with the combination therapy above within the last 90 days. For new members to Molina Healthcare, confirm medication use in medical chart history. Non-compliance, which can be documented by review of the prescription fill history, would not constitute therapeutic failure.
AND

Molina Healthcare, Inc. confidential and proprietary © 2022
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

5. Prescriber attestation that IF member is a smoker, the member has been counseled regarding the benefits of smoking cessation and/or connected with a program to support smoking cessation
AND
6. Prescriber attestation that the member's underlying conditions or triggers for asthma or pulmonary disease are being maximally managed
AND
7. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or intolerance to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s) [DOCUMENTATION REQUIRED]

CONTINUATION OF THERAPY:

A. SEVERE ASTHMA WITH EOSINOPHILIC PHENOTYPE:

1. Member compliance with therapy as verified by Prescriber and member's medication fill history (review Rx history for compliance)
AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or unacceptable toxicity from the drug [e.g. symptoms of anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema), malignancy, symptoms similar to serum sickness (fever, arthralgia, and rash); parasitic (helminth) infection, eosinophilic conditions (e.g. vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy, especially upon reduction of oral corticosteroids];
AND
3. Documentation that Fasenra (benralizumab) therapy has resulted in clinical improvement as documented by ONE or more of the following from baseline [DOCUMENATION REQUIRED]:
    a) Improvement in lung function (increase in percent predicted FEV1 or PEF) from pre-treatment baseline
    OR
    b) Decreased utilization of rescue medications, decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids)
    OR
    c) Decreased frequency of unscheduled clinic, urgent care or emergency department visits OR
    d) Reduction in reported symptoms: chest tightness, coughing, shortness of breath, nocturnal wakening wheezing, sustained improvement in Asthma Control Test (ACT) scores
    OR
    e) Decreased or stopped oral treatments (including oral corticosteroids and other add on medications, if applicable), or reduced ICS-LABA dose (to at least moderate)
    MOLINA REVIEWER NOTE: For members with unclear response after initial use, see Background (GINA 2022).

AND
4. Member is currently treated and is compliant with standard therapy (e.g., inhaled corticosteroids, long- acting beta-2 agonist (LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline) within the past 90 days
AND
5. Prescriber attests or clinical reviewer has found that requested therapy is NOT prescribed for, or intended for, combination therapy or concurrent therapy with other monoclonal antibodies used to treat asthma [i.e., Xolair (omalizumab) OR other IL-5 inhibitors [Cinqair (reslizumab), Nucala (mepolizumab)] OR IL-4 agonist Dupixent (dupilumab) OR Anti-TSLP Tezspire (Tezepelumab-ekko)]

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of therapy: 12 months

Molina Healthcare, Inc. confidential and proprietary © 2022
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

PRESCRIBER REQUIREMENTS:
Prescribed by, or in consultation with, a board-certified asthma specialist (allergist, immunologist, pulmonologist) or physician experienced in the management of asthma. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
12 years of age or older

QUANTITY:
30 mg (1 syringe) every 4 weeks for the first 3 doses, then 30 mg (1 syringe) every 8 weeks

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable products administered in a place of service that is a non-hospital facility-based location as per the Molina Health Care Site of Care program.

Note: Site of Care Utilization Management Policy applies for Fasenra (benralizumab). For information on site of care, see
Specialty Medication Administration Site of Care Coverage Criteria (molinamarketplace.com)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
Interleukin-5 Antagonists (IgG1 kappa)

FDA-APPROVED USES:
Add-on maintenance treatment of patients with severe asthma aged 12 years of age and older with an eosinophilic phenotype
Limitations of use: Not indicated for treatment of other eosinophilic conditions or for the relief of acute bronchospasm or status asthmaticus

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
- Controller medications: suppress the inflammatory causes of asthma to provide clinical control over the long term, whereas reliever medications relieve bronchoconstriction quickly. Controller medications include inhaled glucocorticoids, long-acting beta-agonists (LABAs) and Leukotriene receptor antagonists (LTRA). Theophylline (Theo-24, Uniphyl, TheoChron ER, generics) is also a controller agent, however, it is not as efficacious as LABAs.

Molina Healthcare, Inc. confidential and proprietary © 2022
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

Inhaled Corticosteroids (list not all inclusive):

Beclometasone dipropionate (QVAR)

Budesonide DPI (PulmicortFlexhaler)
Budesonide nebules (Pulmicort Respules)
Ciclesonide (Alvesco)
Flunisolide (Aerospan)
Fluticasone furoate (Arnuity Ellipta)
Mometasone furoate (Asmanex Twisthaler)
Fluticasone propionate (Flovent Diskus)
Mometasone furoate (Asmanex HFA)*
Fluticasone propionate (Flovent HFA)
**HFA: hydrofluoroalkane propellant metered dose inhaler*
**DPI: dry powder inhaler*

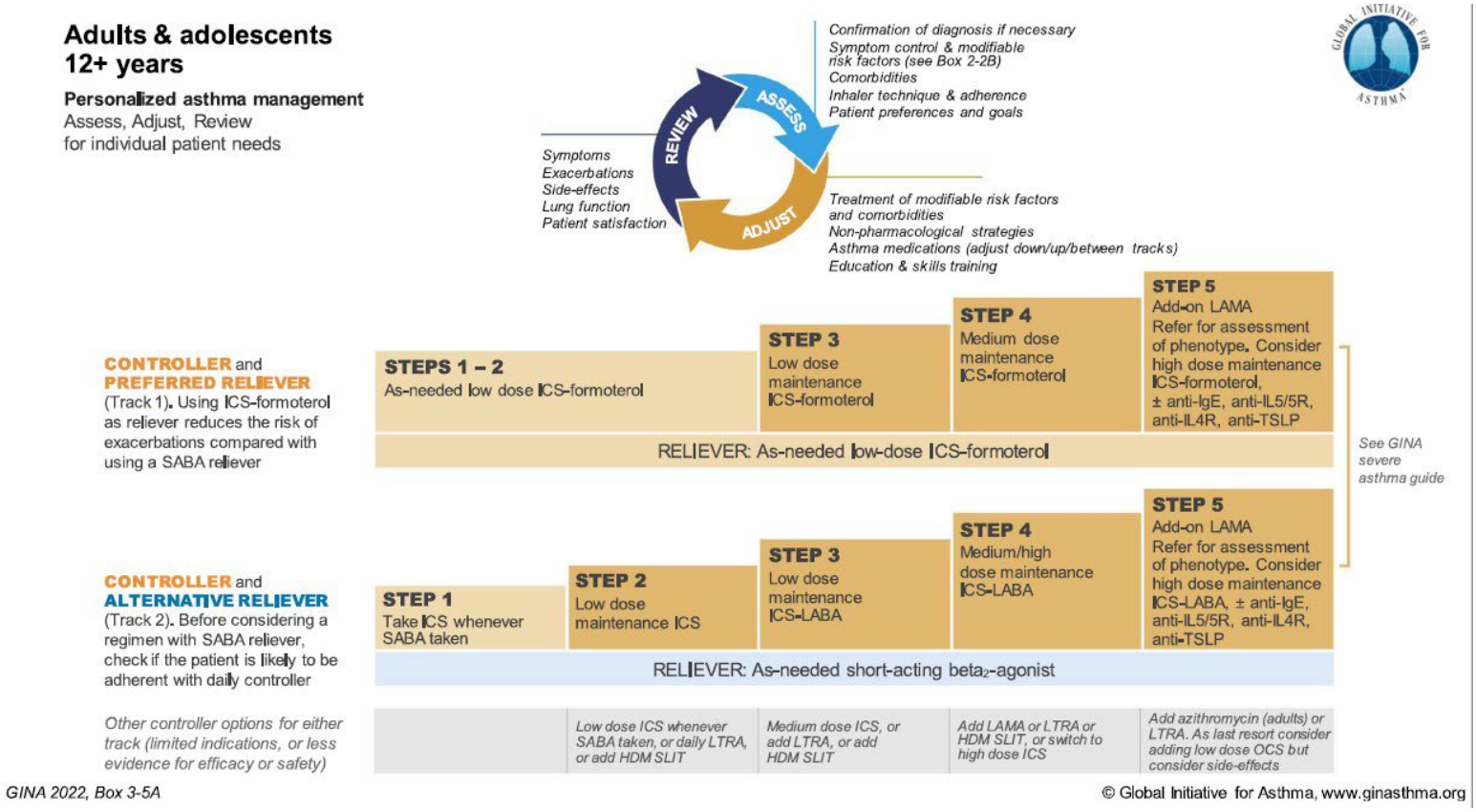
Combination Long-Acting Bronchodilator and Corticosteroid (list not all inclusive):
Budesonide/formoterol (Symbicort)
Fluticasone/salmeterol (Advair Diskus)
Fluticasone/salmeterol (Advair HFA)
Fluticasone/vilanterol(Breo Ellipta)
Mometasone/formoterol (Dulera)

Leukotriene receptor antagonist (LTRA) (list not all-inclusive):
Montelukast (Singulair), Zafirlukast (Accolate), Zileuton (Zyflo)

- FEV1 (forced expiratory volume in 1 second): A measure of airway obstruction determined using spirometry. Individual FEV1 values are compared to predicted values based on age, height, sex and race.
- PEF (peak expiratory flow): PEF is often described as a percent of personal best measurement. Personal best PEF is the highest PEF value attained after 2 to 3weeks of testing when asthma is in good control.

Molina Healthcare, Inc. confidential and proprietary © 2022
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

APPENDIX 1: Managing Asthma in Adults and Adolescents 12+ Years



ABBREVIATIONS: HDM: house dust mite; ICS: inhaled corticosteroid; LABA: long-acting beta2-agonist; LAMA: long-acting muscarinic antagonist; LTRA: Leukotriene Receptor Antagonist; OCS: oral corticosteroids; SABA: short-acting beta2-agonist; SLIT: sublingual immunotherapy
REFERENCE: Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2022. Available from: www.ginasthma.org

NOTE: Alphabetical order is used when more than one treatment option is listed within either preferred or alternative therapy.
ABBREVIATIONS: ICS, inhaled corticosteroid; LABA, inhaled long-acting beta2-agonist; Leukotriene Receptor Antagonists (LTRAs), SABA, inhaled short-acting beta2-agonist
REFERENCE: Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2021. Available from www.ginasthma.org,

Molina Healthcare, Inc. confidential and proprietary © 2022
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

APPENDIX 2: SUGGESTED TOTAL DAILY DOSAGES for INHALED CORTICOSTEROIDS (ICS) IN ADULTS AND ADOLESCENTS (12 years and older):

Inhaled Corticosteroid	Low Dose ICS (mcg)	Medium Dose ICS (mcg)	High Dose ICS (mcg)
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	>500-1000	>1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle, HFA)	100-200	>200-400	>400
Budesonide (DIP, or pMDI, standard particle, HFA)	200-400	>400-800	>800
Ciclesonide (pMDI, extrafine particle, HFA)	80-160	>160-320	>320
Fluticasone furoate (DPI)	100	100	200
Fluticasone propionate (DPI)	100-250	>250-500	>500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	>250-500	>500
Mometasone furoate (pMDI, standard particle, HFA)	200-400	200-400	>400

Reference: Box 3-6. Low, medium and high daily metered doses of inhaled corticosteroids (alone or with LABA) Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2022. Available from: www.ginasthma.org

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Asthma is a heterogeneous syndrome that might be better described as a constellation of phenotypes, each with distinct cellular and molecular mechanisms, rather than as a singular disease. One of these phenotypes is eosinophilic asthma. Eosinophilic asthma is a sub phenotype of severe asthma characterized by elevated sputum and blood eosinophil levels as well as increased asthma severity, atopy, late-onset disease, and steroid refractoriness. Severe asthma is defined as “asthma that requires treatment with high dose inhaled corticosteroids (ICS) plus a second controller and/or systemic corticosteroids to prevent it from becoming ‘uncontrolled’ or which remains ‘uncontrolled’ despite this therapy.” Several biomarkers including blood eosinophilic counts and sputum eosinophilic counts are used in diagnosing severe asthma with an eosinophilic phenotype. Development of eosinophilic inflammation is dependent on the biological activity of Interleukin-5 (IL-5), an inflammatory cytokine. IL-5is responsible for growth, differentiation, recruitment, activation, and survival of eosinophils. Nucala (mepolizumab), Cinqair (reslizumab), and Fasenra (benralizumab), IL-5 antagonist monoclonal antibodies, antagonize the IL- 5/eosinophil inflammatory pathway. Nucala and Cinqair binds to IL-5, and Fasenra binds directly through the IL-5 surface receptors on eosinophils. Similar to other severe forms of asthma, the Gold Standard/International Guidelines treatment for severe asthma, including eosinophilic asthma, is high dose ICS plus a long acting beta-2 agonist (LABA), leukotriene modifier or theophylline and/or continuous systemic corticosteroids as background therapy. Cinqair (reslizumab), Fasenra (benralizumab), and Nucala (mepolizumab) are FDA indicated for severe eosinophilic asthma. Fasenra (benralizumab)

- Benralizumab is the third anti-IL-5 antibody to be approved for treatment of severe eosinophilic asthma; mepolizumab (Nucala) and reslizumab (Cinqair), which target IL-5 itself, were approved earlier

Molina Healthcare, Inc. confidential and proprietary © 2022
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

Drug and Biologic Coverage Criteria

- FDA approved in combination with other asthma medications as add-on maintenance treatment of severe asthma in patients 12 years and older with an eosinophilic phenotype
- Benralizumab is not approved for the treatment of other eosinophilic conditions or for the relief of acute bronchospasm or status asthmaticus
- Administered via subcutaneous injection [similar to Nucala (mepolizumab)]; while Cinqair (reslizumab) is administered via IV infusion only
- FDA Approval was based on results obtained from Phase III clinical trials SIROCCO, CALIMA, and ZONDA from the WINDWARD program [which included six phase III trials SIROCCO, CALIMA, ZONDA, BISE, BORA, and GREGALE]
- The SIROCCO and CALIMA trials were powered for efficacy analysis in patients with baseline blood eosinophil count (BEC) ≥ 300 cells/μL. In addition, the ZONDA trial found Fasenra to significantly reduce oral corticosteroid dose in patients with baseline BEC ≥ 150 cells/μL.

Global Initiative for Asthma (GINA, 2022)

- Provides a stepwise approach to asthma management, adjusting treatment in a continuous cycle of assessment, treatment, and review of the patient's response as it relates to symptom control, future risk of exacerbations, and side effects
- Fasenra (benralizumab) is recommended as add-on for patients ≥12 years old with severe eosinophilic asthma that is uncontrolled on Step 4-5 treatment (Evidence A). Higher blood eosinophil levels, more exacerbations in the previous year, adult-onset asthma, nasal polyposis, maintenance oral corticosteroids at baseline, and low lung function may predict a good asthma response to Fasenra.
- Anti–IL-5 therapy with mepolizumab is recommended in patients 6 years and older and reslizumab is recommended in patients 18 years and older with severe eosinophilic asthma that is uncontrolled despite optimized doses of inhaled corticosteroids (ICSs) plus long-acting beta-agonists (LABAs) with or without other controller drugs (e.g., long- acting muscarinic antagonist, leukotriene receptor antagonist, theophylline). All patients should have access to a reliever medication (SABA or low-dose ICS-formoterol) for as-needed symptom control.
- Phenotype-guided add-on treatment:
  - Patients with severe asthma, uncontrolled on Step 4 treatment, may benefit from phenotyping into categories such as severe allergic, aspirin- exacerbated, or eosinophilic asthma
  - Patients > 6 years with severe allergic asthma with elevated IgE levels may benefit from omalizumab (anti-IgE) therapy (Evidence A)
  - Those with severe eosinophilic asthma may benefit from anti-IL5 therapy (subcutaneous mepolizumab (Nucala) > 6 years; intravenous reslizumab (Cinqair) > 18 years) or anti-IL receptor therapy (subcutaneous benralizumab (Fasenra) > 12 years) (Evidence A)
  - LTRAs may be helpful of patients found to be aspirin sensitive (Evidence B)
- Suggested initial trial of add-on anti-IL5 for severe eosinophilic asthma is at least 4 months. At that point, response to initial trial of add-on therapy should be reviewed. There are no well defined criteria for good response, but exacerbations, symptom control, lung function, side effects, treatment intensity, and patient satisfaction should be considered. If the response is unclear, consider extending the trial to 6-12 months. If there is no response, stop the biologic therapy and consider switching to a different targeted therapy, if available.

European Respiratory Society (ERS)/American Thoracic Society (ATS)

- The guidelines recommend "While the anti-IL5 antibody, mepolizumab, was not beneficial in unselected adult patients with moderate asthma, when studied in severe asthma patients with persistent sputum eosinophilia, two anti- IL-5 antibodies, mepolizumab and reslizumab, have been shown to decrease exacerbations and oral corticosteroid use, as well as improve symptoms and lung function to varying degrees."

Molina Healthcare, Inc. confidential and proprietary © 2022
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

- Asthma is classified as severe when it requires treatment with high-dose inhaled corticosteroids plus a second asthma controller therapy (e.g., long-acting β2-agonist), and/or systemic corticosteroids to prevent asthma from becoming or remaining uncontrolled despite this therapy.
  - Although there are no widely accepted definitions for specific asthma phenotypes, an eosinophilic phenotype (i.e., eosinophilic asthma) is generally characterized by blood and sputum eosinophilia and eosinophilic inflammation, recurrent exacerbations, and, frequently, responsiveness to corticosteroids.
  - Sputum eosinophil counts are used as a reliable biomarker for eosinophilic lung inflammation; ATS and ERS currently recommend treatment of severe asthma guided by sputum eosinophil counts in addition to clinical criteria in adults, and treatment guided by clinical criteria alone in pediatric patients. However, sputum eosinophil counts are difficult to use in routine practice because testing must be performed in specialized centers experienced in using the technique.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Fasenra (benralizumab) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy Contraindications to Fasenra (benralizumab) include: known hypersensitivity to benralizumab or excipients, previous anaphylactic reaction to benralizumab, treatment of other eosinophilic conditions or for the relief of acute bronchospasm or status asthmaticus.

OTHER SPECIAL CONSIDERATIONS:
Fasenra should be administered via subcutaneous injection only by a healthcare professional. Monitoring of patients after administration for hypersensitivity-type reactions (e.g., anaphylaxis, angioedema, urticaria, rash) after each injection is recommended. One trial found that most patients and caregivers could administer benralizumab using the prefilled syringe in their home environment (Ferguson GT, et al. 2017). No formal drug interaction studies have been conducted and none are anticipated based on benlizumab's mechanism of action. Cytochrome P450 enzymes, efflux pumps, and protein-binding mechanisms are not involved in the clearance of benralizumab.
Safety of concurrent use of Nucala, Cinqair, Fasenra, and Dupixent with other monoclonal antibodies used to treat inflammation (TNF-inhibitors, interleukin antagonists, etc.) has not been established. Warnings and precautions include hypertensive reactions (e.g., anaphylaxis, angioedema), parasitic (Helminth) infection, and reduction in corticosteroid dosage (not to discontinue systemic or inhaled corticosteroid abruptly upon initiation of therapy, must decrease gradually, if appropriate).

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J0517	Injection, benralizumab, 1mg

AVAILABLE DOSAGE FORMS:
Fasenra SOSY 30MG/ML (prefilled syringe)
Fasenra SOAJ 30MG/ML (auto-injector)

REFERENCES

1. Fasenra (benralizumab) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2021
2. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2022. Available from www.ginasthma.org

Molina Healthcare, Inc. confidential and proprietary © 2022
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

3. Bleecker ER, FitzGerald JM, Chanez P, et al; SIROCCO Study Investigators. Efficacy andsafety of benralizumab for patients with severe asthma uncontrolled with high-dosage inhaled corticosteroids and long-acting β2-agonists (SIROCCO): a randomized, multicenter, placebo-controlled phase 3 trial. Lancet. 2016; 388(10056):2115- 2127.[PubMed27609408]
4. FitzGerald JM, Bleecker EG, Nair P, et al; CALIMA Study Investigators. Benralizumab, an anti- interleukin-5 receptor α monoclonal antibody, as add-on treatment for patients with severe, uncontrolled, eosinophilic asthma (CALIMA): a randomized, double-blind, placebo-controlled phase 3 trial. Lancet. 2016; 388(10056):2128-2141.[PubMed 27609406]
5. Ferguson GT, Mansur AH, Jacobs JS, et al. Functionality, reliability, and performance of an accessorized pre-filled syringe with home-administered subcutaneous benralizumab for adult patients with severe asthma [abstract]. Am J Resp Crit Care Med. 2017;195:A3194.
6. Goldman M, Hirsch I, Zangrilli JG, Newbold P, Xu X. 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; 33(9):1605- 1613.[PubMed 28640104]10.1080/03007995.2017.1347091
7. Nair P, Wenzel S, Rabe KF, et al; ZONDA Trial Investigators. Oral glucocorticoid-sparing effect of benralizumab in severe asthma. N Engl J Med. 2017; 376(25):2448-2458.[PubMed 28530840]10.1056/NEJMoa1703501
8. Lieberman P, Nicklas RA, Randolph C, et al. Anaphylaxis--a practice parameter update2015. Ann Allergy Asthma Immunol. 2015;115(5):341-384.[PubMed 26505932]10.1016/j.anai.2015.07.019
9. Walford H and Doherty T. Diagnosis and management of eosinophilic asthma: a US perspective. Journal of Asthma and allergy 2014:7 53-65.
10. European Respiratory Society (ERS)/American Thoracic Society (ATS). Chung KF, Wenzel SE, Brozek JL, Bush A, Castro M, Sterk PJ et al. International ERS/ATS guidelines on definition, evaluation, and treatment of severe asthma. Eur Respir J 2014;43:343-373.
11. National Asthma Education and Prevention Program (NAEPP): Expert panel report III: Guidelines for the diagnosis and management of asthma. Bethesda, MD: National Heart, Lung, and Blood Institute, 2007. (NIH publication no. 08-4051). Available at: http://www.nhlbi.nih.gov/healthpro/guidelines/current/asthma-guidelines. Accessed April2019.
12. National Asthma Education and Prevention Program (NAEPP): 2020 Focused updates to the asthma management guidelines. Bethesda, MD: National Heart, Lung, and Blood Institute, 2020. (NIH publication no. 20-HL-8140). Available at https://www.nhlbi.nih.gov/resources/2020-focused-updates-asthma-management-guidelines. Accessed September 2022.
13. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2022. Available from: www.ginasthma.org

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements Quantity FDA-Approved Uses Appendix Contraindications/Exclusions/Discontinuation Available Dosage Forms References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file

Molina Healthcare, Inc. confidential and proprietary © 2022
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.