Effective Date: 07/01/2010
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Next Review Due By: 11/2022
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 asoutlined 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 implythat 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 MolinaHealthcare 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 itscoverage 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 otherpractice 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 wasapproved. 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-bycase 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 ASTHMAWITH EOSINOPHILIC PHENOTYPE:
1. Documented diagnosis of moderate to severe asthma AND
2. Fasenra (benralizumab) is NOT being prescribed as: (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) is not being prescribed as concurrent therapy with other

monoclonal antibodies used to treat asthma [i.e., Xolair (omalizumab) OR other IL-5 inhibitors[Cinqair (reslizumab), Nucala (mepolizumab)]
AND

3. (a) Documentation of eosinophilic phenotype or predominantly eosinophil-driven disease with bloodeosinophil 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 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 intolerance, FDA labeled contraindication, or hypersensitivity to ICS [Appendix 2: Estimated Comparative Daily Dosages for ICS in ≥ 12 years and Adults]AND
        ii) ONE of the following ASTHMA CONTROLLER MEDICATION (LABA, LRTA,LAMA,AND theophylline), OR documented intolerance, FDA labeled contraindication, or hypersensitivity to all these medications (LABA, LRTA, LAMA, AND theophylline)
            - Long-acting beta-2 agonist (LABA) [e.g., salmeterol products (Serevent) formoterol (Foradil)], OR
            - Leukotriene receptor antagonist (LRTA) [e.g., montelukast (Singulair); zafirlukast(Accolate);zileuton (Zyflo)], OR
            - Long-acting muscarinic antagonist (LAMA) [e.g., tiotropium bromideinhalation 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 in #E1or #E2 within the last 90 days. For new members to Molina Healthcare, confirm medication use inmedical chart history. **Non-compliance, which can be documented by review of the prescription fill history, would not constitute therapeutic failure.**

AND

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. If yes, please 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. Consultation notes must be submitted for initial request and for continuation of treatment requests at least ONCE annually. The prescribing physician should periodically re-assess the need for continuation of therapy based on the member's disease severity and level of asthma control. Continuation of therapy requires submission of relevant medical records or chart notes documenting continued efficacy
AND
2. Member compliance with therapy as verified by Prescriber and member's medication fill history (review Rx history for compliance)
AND
3. Member has not experienced ANY of the following: Intolerable adverse effects or absence of 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]; Poor response to treatment as evidenced by physical findings and/or clinical symptoms
AND
4. Documentation that Fasenra (benralizumab) therapy has resulted in clinical improvement as documented by ONE or more of the following from baseline:
    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) Reduction use of ICS, leukotriene, or beta agonist therapy

    AND
5. Member is currently treated and is compliant with standard therapy (e.g., inhaled corticosteroids, long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LRTA), long-acting muscarinic antagonist (LAMA), theophylline) within the past 90 days, OR Has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL standard therapies
AND
6. 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)]

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:
Prescribed by, or in consultation with, a board-certified asthma specialist, (allergist, immunologist, pulmonologist) or physician experienced in the management of asthma. Consultation notes must be submitted for initial request and for continuation of treatment requests at least ONCE annually

AGE RESTRICTIONS:
12 years of age or older

QUANTITY:
Load: 30 mg (1 syringe) every 4 weeks for the first 3 doses**, THEN** Maintenance: 30 mg (1 syringe) every 8weeks**;** Max quantity: 30 mg every 8 weeks

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy or medicalbenefit 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 severe asthma in adults and children ≥12 years of age 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 thelong 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.

Inhaled Corticosteroids (list not all inclusive):
Beclometasone dipropionate (QVAR)
Budesonide DPI (PulmicortFlexhaler)
Budesonide nebules (Pulmicort Respules)
Ciclesonide (Alvesco)
Flunisolide (Aerospan)
Fluticasone furoate (Arnuity Ellipta)
Mometasonefuroate (AsmanexTwisthaler)

Fluticasone propionate (Flovent Diskus)Mometasone furoate (Asmanex HFA)*
Fluticasone propionate (Flovent HFA) Mometasone furoate (Asmanex HFA)*
**HFA: hydrofluoroalkane propellant metered dose inhaler*
**DPI: dry powder inhaler*

Combination Long-Acting Bronchodilator and Corticosteroid (list not all inclusive):

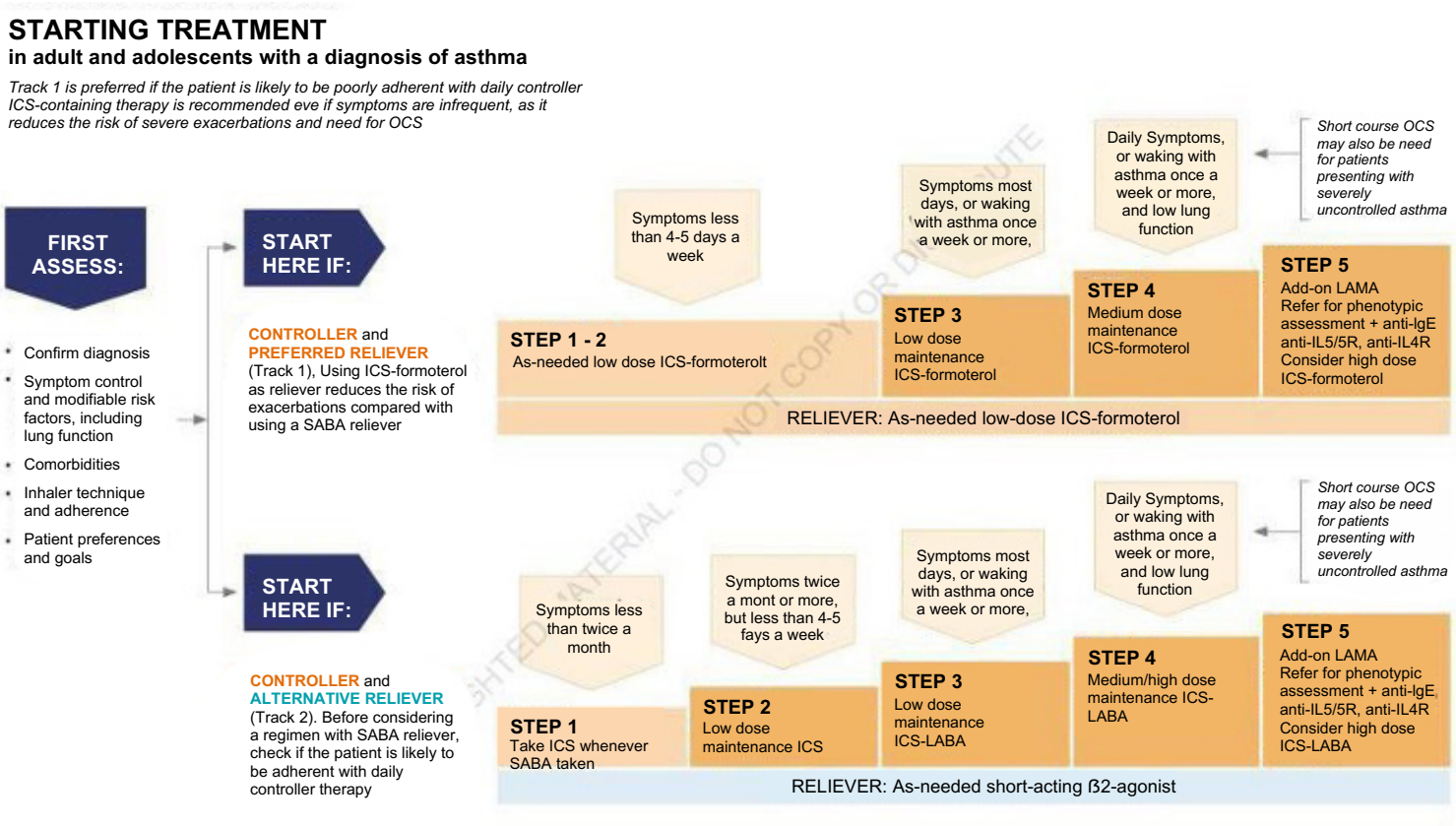
Budesonide/formoterol (Symbicort)
Fluticasone/salmeterol (Advair Diskus)
Fluticasone/salmeterol (Advair HFA)
Fluticasone/vilanterol(Breo Ellipta)
Mometasone/formoterol (Dulera)

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 andrace.
- 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 ingood control.

APPENDIX 1: Managing Asthma in Youths > 12 years of age and adults

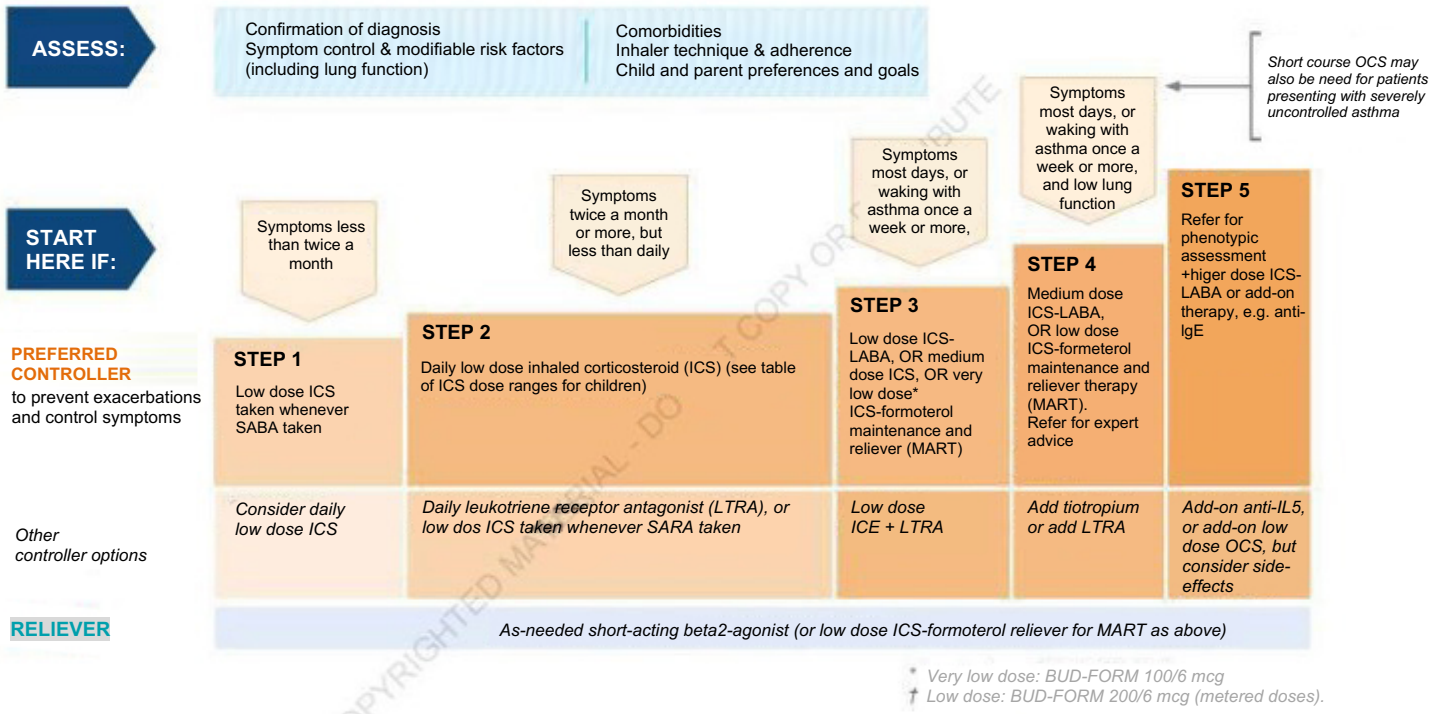


ICS: inhaled corticosteroid; LABA: long-acting beta$_2$-agonist; LAMA: long-acting muscarinic antagonist; MART: maintenance and reliever therapy with ICS-formoterol; OCS: oral corticosteroids; SABA: short-acting beta$_2$-agonist

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, -

STARTING TREATMENT

Children 6-11 years with a diagnosis of asthma



BUD-FORM: budesonide-formoterol; ICS: inhaled corticosteroid; LABA: long-acting beta$_2$-agonist; LTRA: leukotriene receptor antagonist; MART: maintenance and reliever therapy with ICS-formoterol; OCS: oral corticosteroids; SABA: short-acting beta$_2$-agonist

APPENDIX 2: ESTIMATED COMPARATIVE DAILY DOSAGES for INHALED CORTICOSTEROIDS (ICS) in YOUTH ≥12 YEARS of AGE and ADULTS

Drug	Low Daily Dose Adult	Medium Daily Dose Adult	High Daily Dose Adult
Beciomethasone HFA 40 o 80 mcg/puff	80-240 mcg	>240-80 mcg	>480 mcg
Budesonide DPI 90, 180, or 200 mcg/inhalation	180-600 mcg	>600-1,200 mcg	>1,200 mcg
Flunisolide 250 mcg/puff	500-1,000 mcg	>1,000-2,000 mcg	>2,000 mcg
Flunisolide HFA 80 mcg/puff	320 mcg	>320-640 mcg	>640 mcg
Fluticasone **HFA/MDI:** 44, 110 or 220 mcg/puff **DPI:** 50, 100 or 250 mcg/inhalation	88-264 mcg 100-300 mcg	>264-440 mcg >300-500 mcg	>440 mcg >500 mcg
Mometasone DPI 200 mcg/inhalation	200 mcg	400 mcg	>400 mcg
Triamcinolone acetonide 75 mcg/puff	300-750 mcg	>750-1,500 mcg	>1,500 mcg

Reference: Section 4, Stepwise Approach for Managing Asthma in Youths ≥12 Years of Age and Adults Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. National Asthma Education and Prevention Program,Third Expert Panel on the Diagnosis and Management of Asthma. Bethesda (MD): National Heart, Lung, and Blood Institute (US); 2007 Aug.

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 characterizedby 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
- 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

Drug and Biologic Coverage Criteria

- 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, 2020)

- 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)
- Anti–IL-5 therapy (mepolizumab, reslizumab) is recommended in patients 12 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 short-acting beta2- agonist (SABA) for as-needed symptom control. Benralizumab was not available when the guideline was published. (GINA, 2017)
- 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) > 12 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 A)

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."
- 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; Severe hypersensitivity reaction (e.g., anaphylaxis, angioedema, urticaria, rash) to benralizumab OR previous anaphylactic reaction to benralizumab; treatment of other eosinophilic conditions or for the relief of acute bronchospasm or status asthmaticus
Exclusions: 1) Concurrent Respiratory Disease: Presence of a clinically important lung condition other than asthma; 2) Concurrent use with Xolair (omalizumab) NOTE: If currently treated with Xolair (omalizumab), then Xolair (omalizumab) must be discontinued when starting Fasenra (benralizumab); 3) Concurrent use with any other IL-5 inhibitor [Nucala (mepolizumab), Cinqair (reslizumab)]; 4) Known or suspected infection; Helminth infections NOTE: Members with pre- existing helminth infections should undergo treatment of the infection prior to initiation of reslizumabtherapy. It is unknown if reslizumab will influence a patient's response against parasitic infections (patients with known parasitic infections were excluded from the clinical trials), AND 5) Non-FDA approved indications [includes: urticaria and other eosinophilic conditions; severe allergic asthma without documentation of severe eosinophilia]; Aspirin-exacerbated respiratory disease (AERD); Eosinophilic granulomatosis with polyangiitis (EGPA; Churg-Strauss syndrome); Hypereosinophilic syndromes (other than severe eosinophilic asthma as indicated), including: Angiolymphoid hyperplasia, Atopic dermatitis, Eosinophilic esophagitis, Nasal polyposis, Acute bronchospasm and/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 patientsand 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 beenestablished. Warnings and precautions include hypertensive reactions (e.g., anaphylaxis, angioedema), parasitic (Helminth) infection, and reduction in corticosteroid dosage (not to discontinue systemicor 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

REFERENCES

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