Clinical Policy Title:	benralizumab
Policy Number:	RxA.637
Drug(s) Applied:	Fasenra®
Original Policy Date:	07/30/2020
Last Review Date:	4/1/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)
Criteria	

I. Initial Approval Criteria

A. Severe Asthma with eosinophilic phenotype (must meet all):

1. Diagnosis of severe asthma;
2. Patient has an absolute blood eosinophil count ≥ 150 cells/mcL within the past 3 months or blood eosinophil count ≥ 300 cells/mcL within the past 12 months;
3. Patient has experienced one of the following within the last 12 months (a or b):
    a. Two or more asthma exacerbations requiring systemic corticosteroid treatment;
    b. One or more asthma exacerbations requiring hospital admission;
4. Patient is currently being treated with the following medications, unless there is a contraindication or intolerance (a or b):
    a. High dose inhaled corticosteroid (ICS) and additional asthma controller medication (e.g., long-acting beta-2 agonist (LABA) or leukotriene modifier (LTRA));
    b. One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Breo Ellipta (fluticasone/vilanterol)]

Approval Duration
All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Severe Asthma (must meet all):

1. Patient is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples
2. Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications.

Approval Duration
All Lines of Business (except Medicare): 12 months

References

1. National Asthma Education and Prevention Program: Expert panel report III: Guidelines for the diagnosis and

management of asthma. Bethesda, MD: National Heart, Lung, and Blood Institute, 2007. (NIH publication no. 07-4051). Available at: https://www.ncbi.nlm.nih.gov/books/NBK7232/. Accessed January 25, 2023.
2. Global Initiative for Asthma. Global strategy for asthma management and prevention, 2020. Available at: www.ginasthma.org. Published April 3, 2020. Accessed January 25, 2023.
3. Global Strategy for Asthma Management and Prevention (2022 update). Available at: https://ginasthma.org/wp-content/uploads/2022/07/GINA-Main-Report-2022-FINAL-22-07-01-WMS.pdf. Accessed January 25, 2023.
4. Bleecker ER, FitzGerald JM, Chanez P, et al. Efficacy and safety of benralizumab for patients with severe asthma uncontrolled with high-dosage inhaled corticosteroids and long-acting β2-agonists (Sirocco): a randomised, multicentre, placebo-controlled phase 3 trial. Lancet. 2016;388(10056):2115-2127.Available at: https://pubmed.ncbi.nlm.nih.gov/27609408/. Accessed February 02, 2023.
5. FitzGerald JM, Bleecker ER, Menzies-Gow A, et al. Predictors of enhanced response with benralizumab for patients with severe asthma: pooled analysis of the SIROCCO and CALIMA studies. The Lancet Respiratory Medicine. 2018;6(1):51-64. Available at: https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(17)30344-2/fulltext. Accessed February 02, 2023.
6. Global Initiative for Asthma. Difficult-to-treat & severe asthma in adolescnet and adult patients, 2023. Available at: https://ginasthma.org/wp-content/uploads/2023/09/GINA-Severe-Asthma-Guide-2023-WEB-WMS.pdf. Accessed April 1st, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	07/28/2020	7/30/2020
Policy was reviewed: 1. Last Review Date was updated. 2. Dosing information was updated for maximum dose as 30 mg/dose. 3. Clinical policy verbiage was updated to “The provision of provider samples does not guarantee….”. 4. APPENDIX B: Therapeutic Alternatives verbiage was updated to "Below are suggested therapeutic alternatives based on clinical guidance...." 5. Dosing regimen and maximum dose were updated for therapeutic alternatives (inhaled corticosteroids). 6. Aerospan®, Zyflo® CR, Deltasone® were removed from therapeutic alternatives table because of discontinuation. 7. References were updated.	03/04/2021	06/10/2021
Policy was reviewed: 1. Appendix A: Updated to include abbreviation BEC. 2. Appendix B, Drug Name: Updated to remove unavailable generic therapeutic alternatives ciclesonide, fluticasone propionate, fluticasone furoate, mometason, salmeterol, mometasone/formoterol, fluticasone/vilanterol. 3. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are	01/31/2022	04/18/2022

listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 4. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C. 5. References were reviewed and updated		
Policy was reviewed: 1. Initial Approval Criteria, I.A.5: Updated criteria pertaining to indication from Patient has experienced ≥ 1 exacerbations to Patient has experienced ≥ 2 exacerbations. 2. Appendix B, Drug Name: Updated to remove discontinued therapeutic alternatives: a. beclomethasone (QVAR®); b. Flovent®; c. Serevent®; d. Dexamethasone (Decadron®) oral tablets. 3. Appendix B, Drug Name: Updated to include generic therapeutic alternative fluticasone furoate/vilanterol trifenatate. 4. References were reviewed and updated.	01/25/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed. 1. Removed age criteria. 2. Removed prescriber criteria. 3. Removed dosing criteria. 4. Removed reauthorization requirement for positive response to therapy.	12/12/2023	11/30/2023
Policy was reviewed. 1. Updated criteria in asthma exacerbation within the past 12 months 2. Added “One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Breo Ellipta (fluticasone/vilanterol)] “ as another treatment option.	4/01/2024	