

<b>Clinical Policy Title:</b>	benralizumab
<b>Policy Number:</b>	RxA.637
<b>Drug(s) Applied:</b>	Fasenra®
<b>Original Policy Date:</b>	07/30/2020
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	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  $\geq 150$  cells/mcL within the past 3 months or blood eosinophil count  $\geq 300$  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.

#### B. Eosinophilic Granulomatosis with Polyangiitis (must meet all):

1. Diagnosis of eosinophilic granulomatosis with polyangiitis;
2. Patient's disease has relapsed or is refractory to standard of care therapy (e.g., corticosteroids, immunosuppressants);
3. Patient is currently receiving corticosteroid therapy, unless contraindicated or clinically significant adverse events are experienced.

#### Approval Duration

**All Lines of Business (except Medicare):** 12 months

### II. Continued Therapy Approval

#### A. Severe Asthma (must meet all):

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met been initial approval criteria;
2. Patient continues to be treated with an inhaled corticosteroid (ICS) with or without an additional asthma controller medication (e.g., LTRA, LABA) unless there is a contraindication or intolerance to these medications.

#### B. Eosinophilic Granulomatosis with Polyangiitis (must meet all):

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met been initial approval criteria.

**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 March 21, 2025.
2. Global Initiative for Asthma. Global strategy for asthma management and prevention, 2020. Available at: [www.ginasthma.org](http://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 March 21, 2025.
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 March 21, 2025.
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](https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(17)30344-2/fulltext). Accessed March 21, 2025.
6. Global Initiative for Asthma. Difficult-to-treat & severe asthma in adolescent and adult patients, 2023. Available at: <https://ginasthma.org/wp-content/uploads/2023/09/GINA-Severe-Asthma-Guide-2023-WEB-WMS.pdf>. Accessed March 21, 2025.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	07/28/2020	7/30/2020
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Last Review Date was updated.</li> <li>2. Dosing information was updated for maximum dose as 30 mg/dose.</li> <li>3. Clinical policy verbiage was updated to “The provision of provider samples does not guarantee....”.</li> <li>4. APPENDIX B: Therapeutic Alternatives verbiage was updated to "Below are suggested therapeutic alternatives based on clinical guidance...."</li> <li>5. Dosing regimen and maximum dose were updated for therapeutic alternatives (inhaled corticosteroids).</li> <li>6. Aerospan®, Zylflo® CR, Deltasone® were removed from therapeutic alternatives table because of discontinuation.</li> <li>7. References were updated.</li> </ol>	03/04/2021	06/10/2021
Policy was reviewed:	01/31/2022	04/18/2022

<ol style="list-style-type: none"> <li>1. Appendix A: Updated to include abbreviation BEC.</li> <li>2. Appendix B, Drug Name: Updated to remove unavailable generic therapeutic alternatives ciclesonide, fluticasone propionate, fluticasone furoate, mometasol, salmeterol, mometasone/formoterol, fluticasone/vilanterol.</li> <li>3. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are 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".</li> <li>4. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C.</li> <li>5. References were reviewed and updated</li> </ol>		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.5: Updated criteria pertaining to indication from Patient has experienced ≥ 1 exacerbations to Patient has experienced ≥ 2 exacerbations.</li> <li>2. Appendix B, Drug Name: Updated to remove discontinued therapeutic alternatives: <ol style="list-style-type: none"> <li>a. beclomethasone (QVAR®);</li> <li>b. Flovent®;</li> <li>c. Serevent®;</li> <li>d. Dexamethasone (Decadron®) oral tablets.</li> </ol> </li> <li>3. Appendix B, Drug Name: Updated to include generic therapeutic alternative fluticasone furoate/vilanterol trifenate.</li> <li>4. References were reviewed and updated.</li> </ol>	01/25/2023	04/13/2023
<p>Policy was reviewed.</p>	10/19/2023	10/19/2023
<p>Policy was reviewed.</p> <ol style="list-style-type: none"> <li>1. Removed age criteria.</li> <li>2. Removed prescriber criteria.</li> <li>3. Removed dosing criteria.</li> <li>4. Removed reauthorization requirement for positive response to therapy.</li> </ol>	12/12/2023	11/30/2023
<p>Policy was reviewed.</p> <ol style="list-style-type: none"> <li>1. Updated criteria in asthma exacerbation within the past 12 months</li> <li>2. Added "One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Breo Ellipta</li> </ol>	4/01/2024	

(fluticasone/vilanterol)] “ as another treatment option.		
Policy was reviewed: 1. Updated continuation of therapy language.	03/21/2025	04/10/2025
Policy reviewed.	12/11/2025	12/11/2025