

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

PULMICORT RESPULES 1MG ONLY
(budesonide)

Status: CVS Caremark Criteria

Type: Post Limit Prior Authorization

FDA-APPROVED INDICATIONS

Pulmicort Respules is indicated for the maintenance treatment of asthma and as prophylactic therapy in children 12 months to 8 years of age.

Limitations of Use:

Pulmicort Respules is NOT indicated for the relief of acute bronchospasm.

Off-Label / Rare Disease / Orphan Drug Uses

Eosinophilic Esophagitis²⁻⁸

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has the diagnosis of eosinophilic esophagitis (EoE)

AND

- The request is for continuation of therapy with Pulmicort (budesonide) Respules at a dose of 1mg twice daily (2mg daily), and the patient has been evaluated for improvement or relapse in symptoms or inflammation

OR

- The patient had all of the following: A) Eosinophil-predominant inflammation on biopsy, B) Trial of a proton pump inhibitor (PPI), C) Secondary causes of esophageal eosinophilia were ruled out

Quantity Limits apply.

[120 mL (2 packages of 30 respules each) / 25 days*, or 360 mL (6 packages of 30 respules each) / 75 days*]

*The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

REFERENCES

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3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed September 6, 2022.
4. Dellon E, Gonsalves N, Hirano I, et al. ACG Clinical Guideline: Evidence Based Approach to the Diagnosis and Management of Esophageal Eosinophilia and Eosinophilic Esophagitis (EoE). *Am J Gastroenterol* 2013; 108:679–692.
5. Liacouras C, Furuta G, Hirano I, et al. Eosinophilic esophagitis: Updated Consensus Recommendations for Children and Adults. *J Allergy Clin Immunol* 2011;128:3-20.
6. FDA. Orphan Drug Designations and Approvals. Available at: <https://www.accessdata.fda.gov/scripts/opdlisting/oopd/listResult.cfm>. Accessed September 6, 2022.
7. Chenga K, Gupta S, Kantor S, et al. Creating a Multi-center Rare Disease Consortium – the Consortium of Eosinophilic Gastrointestinal Disease Researchers (CEGIR). *Translational Science of Rare Diseases* 2 (2017) 141–155.

8. Dellon E, Liacouras C, Molina-Infante J, et al. Updated International Consensus Diagnostic Criteria for Eosinophilic Esophagitis: Proceedings of the AGREE Conference. *Gastroenterology* 2018;155:1022–1033.
9. Hirano I, Chan ES, Rank MA, et al. AGA institute and the joint task force on allergy-immunology practice parameters clinical guidelines for the management of eosinophilic esophagitis. *Gastroenterology*. 2020;158(6):1776-1786.