PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

PULMICORT RESPULES 0.5 MG AND 1 MG ONLY
(budesonide)

Status: CVS Caremark® Criteria
Type: Post Limit Prior Authorization

POLICY

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.

Compendial Uses
Eosinophilic esophagitis (EoE)[3-5]

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 NOT for continuation of therapy
    AND
    - The prescriber attests that the patient has chart notes supporting the diagnostic findings of eosinophilic esophagitis (EoE) (e.g., eosinophil-predominant inflammation on biopsy)

    AND
    - The patient has a history of clinical symptoms of esophageal dysfunction (e.g., eating problems, abdominal pain, heartburn, dysphagia, vomiting, food impaction, weight loss) at baseline

  OR
  - The request is for continuation of therapy
    AND
    - The patient has achieved or maintained a positive clinical response (e.g., improvement in symptoms of esophageal dysfunction, histologic remission on biopsy)

Quantity Limits apply.

POST LIMIT QUANTITY

Medication	**Maximum Daily Dose**	**Package Size**	**1 Month Limit* 3 Month Limit***
Pulmicort Respules 0.5 mg (budesonide)	4 respules (2 mg)	30 respules (2 mL each) per carton	4 packages (120 respules x 2 mL) / 25 days 12 packages (360 respules x 2 mL) / 75 days
Pulmicort Respules 1 mg	2 respules (2 mg)	30 respules (2 mL each)	2 packages (60 respules x 2 mL) / 25 days 6 packages (180 respules x 2 mL) / 75 days

(budesonide)		per carton	
**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.*			

Duration of Approval (DOA):

- 2495-J: Initial therapy DOA: 6 months; Continuation of therapy DOA: 12 months

REFERENCES

1. Pulmicort Respules [package insert]. Wilmington, DE: AstraZeneca LP; October 2019.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed September 10, 2023.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: *02/29/2024*).
4. Dellon E, Gonsalves N, Hirano I, et al. ACG Clinical Guideline: Evidenced Based Approach to the Diagnosis and Management of Esophageal Eosinophilia and Eosinophilic Esophagitis (EoE). *Am J Gastroenterol.* 2013;108:679–692.
5. 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.
6. 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.
7. Dohil R, Newbury R, Fox L, et al. Oral Viscous Budesonide Is Effective in Children With Eosinophilic Esophagitis in a Randomized, Placebo-Controlled Trial. *Gastroenterology*. 2010;139:418-429.
8. Warzecha J, Dziekiewicz M, Bieńkowska-Tokarczyk A, et al. A New Viscous Budesonide Formulation for the Treatment of Eosinophilic Esophagitis in Children: A Preliminary Experience and Review of the Literature. *J Clin Med*. 2022;11(22):6730.