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Section:	Prescription Drugs	**Effective Date:**	July 1, 2025
Subsection:	Respiratory Agents	**Original Policy Date:**	April 25, 2025
Subject:	Pulmicort Respules	**Page:**	1 of 4

Last Review Date: June 12, 2025

Pulmicort Respules

Description

Pulmicort Respules (budesonide inhalation suspension)

Background
Pulmicort Respules are a formulation of inhalable budesonide that is indicated for the maintenance treatment of asthma. Budesonide is an anti-inflammatory corticosteroid with potent glucocorticoid activity and weak mineralocorticoid activity. Although budesonide's mechanism of action in asthma is not completely understood, inflammation is a primary component in the disease process of asthma (1).

Regulatory Status
FDA-approved indications: Pulmicort Respules is an inhaled corticosteroid indicated for: (1)

- Maintenance treatment of asthma and as prophylactic therapy in children 12 months to 8 years of age.

Limitations of Use: (1)

- Not indicated for the relief of acute bronchospasm

Pulmicort Respules are also used off-label for the management of eosinophilic esophagitis. Studies indicated that an initial treatment with 2 mg per day is efficacious, but doses may be titrated up to 4mg per day if there is no response. In maintenance therapy, the lowest effective dose should be considered (2-3).

Pulmicort Respules have been associated with localized infections (such as *Candida albicans*), immunosuppression, and the potential worsening of infections. Caution should be used in administering Pulmicort Respules to patients with existing tuberculosis, fungal, bacterial, viral, or parasitic infections, or ocular herpes simplex (1).

Orally inhaled corticosteroids such as budesonide may cause a reduction in growth velocity in pediatric patients. Pediatric patient's growth should be monitored routinely during routine and the lowest effective dosage administered to minimize systemic effects and potential for growth reduction (1).

Long term administration of inhaled corticosteroids has also been associated with reductions in bone mineral density, glaucoma, and cataracts. Patients at potential risk for negative outcomes due to changes in bone mineral density should be monitored and managed according to established standard of care. Patients with changes in vision or history of increased intraocular pressure, glaucoma, or cataracts should be monitored closely (1).

The safety and effectiveness of Pulmicort Respules in pediatric patients aged 12 months to 8 years of age have been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Pulmicort Respules may be considered **medically necessary** if the conditions indicated below are met.

Pulmicort Respules may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have the following:

1. Corticosteroid-responsive inflammatory condition supported by compendial evidence or FDA-approval

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

Quantity

Medication	Maximum Daily Dose	Quantity Limit
Pulmicort Respules 0.5 mg (budesonide)	6 respules per day (3 mg)	540 respules per 90 days
Pulmicort Respules 1 mg (budesonide)	4 respules per day (4 mg)	360 respules per 90 days

Prior - Approval Limits

Quantity

Medication	Maximum Daily Dose	Quantity Limit
Pulmicort Respules 0.5 mg (budesonide)	6 respules per day (3 mg)	Pre-PA allows for maximum dosage
Pulmicort Respules 1 mg (budesonide)	4 respules per day (4 mg)	Pre-PA allows for maximum dosage

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Pulmicort Respules are an inhalable form of budesonide, a corticosteroid indicated for the maintenance treatment of asthma. The exact mechanism of action is unclear, but budesonide reduces inflammation, and inflammation is a key component in the pathogenesis of asthma. Pulmicort Respules are also used for the off-label treatment of eosinophilic esophagitis. Pulmicort Respules have been associated with reduced bone mineral density, reductions in pediatric growth velocity, worsening of ocular diseases, and immunosuppression (1-3).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Pulmicort Respules while maintaining optimal therapeutic outcomes.

References

1. Pulmicort Respules [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2019.
2. Micromedex® (electronic version). Merative, Ann Arbo, Michigan, USA. Available at: https://micromedexsolutions.com/. Accessed on February 11, 2025
3. Dellon ES, 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(5):679-693. doi:10.1038/ajg.2013.71

Policy History

Date	Action
April 2025	Addition to PA
June 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 12, 2025 and is effective on July 1, 2025.