

DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Corticosteroids (Nebulized) – Budesonide Drug Quantity Management Policy – Per Rx

- Pulmicort Respules® (budesonide inhalation suspension – AstraZeneca, generic)

REVIEW DATE: 02/01/2023

OVERVIEW

Indication

Budesonide inhalation suspension (Pulmicort Respules, generic) is indicated for the maintenance treatment of **asthma** and as prophylactic therapy in children 12 months to 8 years of age.¹

Dosing

Recommended dosing for budesonide inhalation solution is provided in Table 1. Additionally, for symptomatic children not responding to non-steroidal therapy, an initial dose of 0.25 mg once daily (QD) may be considered.

Table 1. Budesonide Inhalation Solution Dosing.¹

Previous Therapy	Recommended Starting Dose	Highest Recommended Dose
Bronchodilators alone	0.5 mg total daily dose. Administered either 0.5 mg QD or 0.25 mg BID.	0.5 mg total daily dose
ICS	0.5 mg total daily dose. Administered either QD or BID.	1 mg total daily dose
Oral Corticosteroids	1 mg total daily dose. Administered either as 0.5 mg BID or 1 mg QD.	1 mg total daily dose

QD – Once daily; BID – Twice daily; ICS – Inhaled corticosteroids.

Availability

Budesonide inhalation suspension is available 0.25 mg/2 mL, 0.5 mg/2 mL, and 1 mg/2 mL in respules.¹ The respules are supplied in sealed aluminum enveloped containing a plastic strip of five single-dose respules. There are 30 respules in a carton.

Off-Label Use

Budesonide inhalation suspension is used off-label in patients ≥ 9 years of age who require budesonide therapy to be delivered via a nebulizer.² Dosing in patients 9 to 11 years of age is generally similar to that for patients ≤ 8 years of age. However, for patients ≥ 11 years of age, doses of 1 to 2 mg twice daily (max dose of 4 mg/day) have been used. Additionally, for the management of chronic obstructive pulmonary disease exacerbations in adults, nebulized budesonide at a dose of 1 to 2 mg once every 6 hours is a common dose. In this setting, the reported total daily dose range is 4 to 8 mg/day.

Budesonide has been proven to be an effective therapy for the treatment of eosinophilic esophagitis in randomized trials.^{3,4} Doses of up to 2 mg daily, typically in divided doses of 1 mg twice daily, have been used.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of budesonide inhalation suspension (Pulmicort Respules, generic). If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration, unless otherwise noted below.

Automation: None.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Pulmicort Respules® (budesonide inhalation suspension, generic)	0.25 mg/2 mL respules	120 mL (60 respules) ^a	360 mL (180 respules) ^a
	0.5 mg/2 mL respules	120 mL (60 respules) ^a	360 mL (180 respules) ^a
	1 mg/2 mL respules	60 mL (30 respules) ^b	180 mL (90 respules) ^b

^a Provides a quantity sufficient for a 30-day supply at retail or a 90-day supply at home delivery at the recommended dosing intervals of once or twice daily; ^b Provides a quantity sufficient for a 30-day supply at retail or a 90-day supply at home delivery at maximum recommended dosing.

CRITERIA

Budesonide Inhalation Suspension (Pulmicort Respules, generic) 0.25 mg/2 mL and 0.5 mg/2 mL respules
No overrides recommended.

Budesonide Inhalation Suspension (Pulmicort Respules, generic) 1 mg/2 mL respules

1. If the patient has esophageal eosinophilia/eosinophilic esophagitis, approve the requested quantity, not to exceed 120 mL (60 respules) per dispensing at retail or 360 mL (180 respules) per dispensing at home delivery.
2. If the patient is ≥ 11 years of age and according to the prescriber requires a dose greater than 1 mg per day, approve the requested quantity, not to exceed 240 mL (120 respules) per dispensing at retail or 720 mL (360 respules) per dispensing at home delivery.
3. If the patient is ≥ 18 years of age and is experiencing a chronic obstructive pulmonary disease exacerbation, approve a one-time override for the requested quantity, not to exceed 480 mL (240 respules) at retail or home delivery.

REFERENCES

1. Pulmicort Respules® inhalation suspension [prescribing information]. Wilmington, DE; AstraZeneca: December 2018.
2. Clinical Pharmacology [database online]. Elsevier, Inc.; 2023. Available at: <https://www.clinicalkey.com/pharmacology/>. Accessed on January 19, 2023. Search terms: Budesonide.
3. Bonis PAL, Gupta SK. Treatment of eosinophilic esophagitis. Version 70.0. ©2023 UpToDate, Inc. Available at: www.uptodate.com. Updated November 21, 2022. Accessed on January 19, 2023.
4. 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):679-92.

COPD – Chronic obstructive pulmonary disease.