Cigna National Formulary Coverage Policy

Effective Date..... 3/1/2023
Next Review Date..... 3/1/2024

Drug Quantity Management – Per Rx
Corticosteroids (Nebulized) – Budesonide

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Product Identifier(s)

Effective 1/1/23 to 2/6/23: 108911

Effective 2/7/23: 40472

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

Drug(s) Affected

- Pulmicort Respules® (budesonide inhalation suspension – generic)

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.

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)[α]	360 mL (180 respules)[α]
	0.5 mg/2 mL respules	120 mL (60 respules)[α]	360 mL (180 respules)[α]
	1 mg/2 mL respules	60 mL (30 respules)[β]	180 mL (90 respules)[β]

[α] 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; [β] Provides a quantity sufficient for a 30-day supply at retail or a 90-day supply at home delivery at maximum recommended dosing.

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

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 individual 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 individual 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 individual 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.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

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.

References

1. Pulmicort Respules® inhalation suspension [prescribing information]. Wilmington, DE; AstraZeneca: December 2018.
2. Clinical Pharmacology [database online]. Elselvier, Inc.; 2023. Available at: https://www.clinicalkey.com/pharmacology/. Accessed on Jauary 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.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. • Approval duration was changed from 3 years to 1 year.	02/01/2023