Clinical Policy: Budesonide Suspension (Pulmicort Respules)

Reference Number: HIM.PA.48
Effective Date: 09.01.18
Last Review Date: 08.20
Line of Business: HIM

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Budesonide suspension (Pulmicort Respules®) is an inhaled corticosteroid.

FDA Approved Indication(s)

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

Limitation(s) of use: Pulmicort Respules is not indicated for the relief of acute bronchospasm.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Pulmicort Respules is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Asthma (must meet all)**:**

1. Diagnosis of asthma;
2. Member meets one of the following (a or b):
   a. Age between 1 to 8 years;
   b. Documentation supports inability to use inhaler devices;
3. Dose does not exceed 1 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

II. Continued Therapy

A. Asthma (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If age > 8 years, documentation supports inability to use inhaler devices;
4. If request is for a dose increase, new dose does not exceed 1 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PHAR.21 for health insurance marketplace or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): patients with status asthmaticus or other acute episodes of asthma where intensive measures are required, hypersensitivity to any of the ingredients in Pulmicort Respules
- Boxed warning(s): none reported

Appendix D: General Information
- Historical management of asthma has involved an as-needed short-acting beta agonist for reliever therapy, with stepwise approach to add on controller maintenance therapies such as inhaled corticosteroids and long-acting beta agonists. In 2019, the Global Initiative for Asthma (GINA) guidelines for asthma management and prevention began recommending that inhaled corticosteroids be initiated as soon as possible after diagnosis of asthma, including use as reliever therapy (to be administered as-needed alongside a short-acting beta agonist).

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Asthma	Starting dose for patients who received bronchodilators alone or inhaled corticosteroids: 0.5 mg inhaled per day (0.5 mg QD or 0.25 mg BID)	0.5 mg/day
	Starting dose for patients who received oral corticosteroids: 1 mg inhaled per day (1 mg QD or 0.5 mg BID)	1 mg/day

VI. Product Availability

Inhalation suspension: 0.25 mg/2 mL, 0.5 mg/2 mL, 1 mg/2 mL

VII. References

1. Pulmicort Respules Prescribing Information. Wilmington, DE: AstraZeneca; October 2019. Available at http://www.pulmicortrespules.com. Accessed April 13, 2020.
2. National Heart, Lung, and Blood Institute. Expert panel report 3: guidelines for the diagnosis and management of asthma. National Asthma Education and Prevention Program. Published August 28, 2007. Available from: http://www.nhlbi.nih.gov/health-pro/guidelines/current/asthma-guidelines/full-report/. Accessed April 13, 2020.
3. Global Initiative for Asthma (GINA): Global strategy for asthma management and prevention (2020 report). Available from: www.ginasthma.org. Accessed April 6, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2018 annual review: policy split from HIM.PA.73 Inhaled corticosteroids to individual Pulmicort Respules policy; no significant changes; references reviewed and updated.	04.17.18	08.18
3Q 2019 annual review: no significant changes; references reviewed and updated.	04.22.19	08.19
3Q 2020 annual review: no significant changes; references reviewed and updated.	04.13.20	08.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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