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

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

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
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<tbody>
<tr>
<td>Asthma</td>
<td>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)</td>
<td>0.5 mg/day</td>
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<tr>
<td></td>
<td>Starting dose for patients who received oral corticosteroids: 1 mg inhaled per day (1 mg QD or 0.5 mg BID)</td>
<td>1 mg/day</td>
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</table>
VI. Product Availability
Inhalation suspension: 0.25 mg/2 mL, 0.5 mg/2 mL, 1 mg/2 mL

VII. References

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

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