**MDWISE PRIOR AUTHORIZATION CRITERIA**

**Budesonide** Inhalation Suspension: 0.25mg/2mL, 0.5mg/2mL, 1mg/2mL  **FORMULARY STATUS** Preferred

**PA CRITERIA FOR APPROVAL**
- Diagnosis of chronic asthma for patients up to (not including) 4 years of age will process at the point-of-sale without prior authorization required if dosed within appropriate dosing guidelines as follows:
  - 0.25mg/2mL once daily
  - 0.5mg/2mL once daily or twice daily
  - 1mg/2mL once daily or twice daily
- A dose of 0.25mg/2mL twice daily will be approved if prescriber indicates that once daily dosing is not efficacious and determines that increasing the dose (i.e. 0.5mg once daily) is not appropriate for the patient.
- All other requests will be referred to a Medical Director for medical necessity review.

If the above conditions are met, the request will be approved with a 6 month duration; if the above conditions are not met, the request will be referred to a Medical Director for medical necessity review.

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

**DOSAGE AND ADMINISTRATION**
Budesonide respules are to be administer by the inhaled route via jet nebulizer connected to an air compressor in asthmatic patients 12 months to 8 years of age. Individual patients will experience a variable onset and degree of symptom relief. Improvement in asthma control following inhaled administration of budesonide can occur within 2 to 8 days of initiation of treatment, although maximum benefit may not be achieved for 4 to 6 weeks. In all patients, it is desirable to downward-titrerate to the lowest effective dose once asthma stability is achieved.

<table>
<thead>
<tr>
<th>Previous Therapy</th>
<th>Recommended Starting Dose</th>
<th>Highest Recommended Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bronchodilators alone</td>
<td>0.5mg total daily dose administered either once daily or twice daily in divided doses</td>
<td>0.5mg total daily dose</td>
</tr>
<tr>
<td>Inhaled Corticosteroids</td>
<td>0.5mg total daily dose administered either once daily or twice daily in divided doses</td>
<td>1mg total daily dose</td>
</tr>
<tr>
<td>Oral Corticosteroids</td>
<td>1mg total daily dose administered either as 0.5mg twice daily or 1mg once daily</td>
<td>1mg total daily dose*</td>
</tr>
</tbody>
</table>

*The NHLBI Asthma Guidelines recommend up to a maximum total daily dose of 2 mg.

In symptomatic children not responding to non-steroidal therapy, a starting dose of 0.25mg once daily of Pulmicort Respules may also be considered. If once-daily treatment with Pulmicort Respules does not provide adequate control of asthma symptoms, the total daily dose should be increased and/or administered as a divided dose.

**REFERENCES**

Revision/Review Date: MAC 10/12/2011
Associated Policy: Prior Authorization of Medications 236.200