Original Effective Date: 08/24/2016
Current Effective Date: 11/29/2023
Last P&T Approval/Version: 10/25/2023
Next Review Due By: 10/2024
Policy Number: C4724-A

Pulmicort Respules (budesonide)

PRODUCTS AFFECTED

Pulmicort respules (budesonide inhalation suspension), Budesonide inhalation susp

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes.
Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Chronic asthma, Eosinophilic esophagitis, Chronic obstructive pulmonary disease (COPD)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. CHRONIC ASTHMA:

1. Documented diagnosis of chronic asthma
   AND
2. (a) Member is 8 years of age or YOUNGER
   OR
   (b) Member is not able to use an oral aerosol inhaler device

B. EOSINOPHILIC ESOPHAGITIS:
1. Documented diagnosis of eosinophilic esophagitis
   AND
2. Documentation that the member has been evaluated for dietary allergens
   AND
3. Prescriber attests member will follow an elimination diet
   AND
4. Documentation of treatment failure, serious side effects or clinical contraindication to one formulary/preferred proton pump inhibitor OR proton pump inhibitor will be used concurrently
   AND
5. Documentation of trial, failure or intolerance to fluticasone therapy
   NOTE TO REVIEWER: Should Pulmicort Respules be denied for this element, be sure that the fluticasone appropriate approval is processed, if necessary, based on benefit.

C. CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD):
1. Documented diagnosis of chronic obstructive pulmonary disease (COPD)
   AND
2. Prescriber attests that member will not be using budesonide as monotherapy
   AND
3. Prescriber attests that member has severe exacerbations (defined as requiring hospitalization or ED visit and may also be associated with acute respiratory failure) in which nebulized medication is required rather than MDI dosage form

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member's medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of stabilization or improvement in clinical signs and symptoms of disease state

DURATION OF APPROVAL:

Initial authorization: 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

No requirements

AGE RESTRICTIONS:

Asthma:12 months to 8 years of age
All other indications: no restriction

QUANTITY:

Asthma: maximum 1 mg/day
COPD: maximum 2 mg/day
Eosinophilic esophagitis: Oral induction: 2 mg/day as an oral budesonide viscous liquid/suspension;

Maintenance therapy: 0.5 to 1 mg/day

PLACE OF ADMINISTRATION:
The recommendation is that inhalation medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Inhalation via Nebulizer
Off-Label: Compounded as an oral budesonide viscous liquid/suspension

DRUG CLASS:
Steroid Inhalants

FDA-APPROVED USES:
Indicated for the maintenance treatment of asthma and as prophylactic therapy in children 12 months to 8 years of age
Limitations of use: Not indicated for the relief of acute bronchospasm

COMPENDIAL APPROVED OFF-LABELED USES:
Eosinophilic esophagitis, Chronic obstructive pulmonary disease (acute exacerbation); Chronic obstructive pulmonary disease (stable)

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
For the treatment of laryngotracheobronchitis (croup)
Budesonide efficacy has been demonstrated in several studies. Most studies have shown comparable efficacy outcomes with dexamethasone for the treatment of croup; however, some studies have shown dexamethasone to be superior to budesonide. The addition of budesonide to dexamethasone therapy has not resulted in an additive benefit in clinical studies.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Pulmicort respules (budesonide inhalation suspension) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindication to Pulmicort respules (budesonide inhalation suspension) include: primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are requires, hypersensitivity to budesonide or any of the ingredients of the respule.

OTHER SPECIAL CONSIDERATIONS:
Viscous budesonide for eosinophilic esophagitis can be compounded by mixing two or four 0.5 mg/2 mL Pulmicort Respules with sucralose (Splenda; 10 1-gram packets per 1 mg of budesonide, creating a volume of approximately 8 mL) or another carrier vehicle that is not liquid.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
N/A	N/A

AVAILABLE DOSAGE FORMS:
Budesonide Inhalation Suspension: 0.25mg/2mL, 0.5mg/2mL, 1mg/2mL

REFERENCES

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3. O'Byrne PM, Pederson S, Busse WW, Tan WC, Chen YZ, Ohlsson SV, et al. Effects of early intervention with inhaled budesonide on lung function in newly diagnosed asthma. Chest. 2006 Jun. 129(6):1478-85.
4. Bisgaard H, Hermansen MN, Loland L, Halkjaer LB, Buchvald F. Intermittent inhaled corticosteroids in infants with episodic wheezing. N Engl J Med. 2006 May; 354(19):1998- 2005.
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6. Berger WE, Qaqundah PY, Blake K, Rodriguez-Santana J, Irani AM, Xu J, Goldman M. Safety of budesonide inhalation suspension in infants aged six to twelve months with mild to moderate persistent asthma or recurrent wheeze. J Pediatr. 2005 Jan; 146(1):91-5.
7. Klassen TP, Craig WR, Moher D, et al. Nebulized budesonide and oral dexamethasone for treatment of croup. JAMA 1998;279:1629-32
8. Dellon ES, Liacouras CA, Molina-Infante J, et al. Updated International Consensus Diagnostic Criteria for Eosinophilic Esophagitis: Proceedings of the AGREE Conference. Gastroenterology2018; 155:1022.
9. Dohil, R., Newbury, R., Fox, L., Bastian, J., & Aceves, S. (2010). Oral Viscous Budesonide Is Effective in Children With Eosinophilic Esophagitis in a Randomized, Placebo-Controlled Trial. Gastroenterology, 139(2), 418-429.e1. doi: 10.1053/j.gastro.2010.05.001

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Diagnosis Required Medical Information FDA-Approved Uses Contraindications/Exclusions/Discontinuation Other Special Considerations	Q4 2023
REVISION- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Age Restrictions Quantity Other Special Considerations References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file