Clinical Policy: Topical Steroid Use For Eosinophilic Esophagitis

Reference Number: GA.PMN.11
Effective Date: 09/01/16
Last Review Date: 7/2024 Revision Log
Line of Business: Medicaid

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

Description
The intent of the criteria is to ensure that patients follow selection elements established by Centene® medical policy for the use of Pulmicort Respules, Flovent and Alvesco for the treatment of eosinophilic esophagitis (EoE).

FDA Approved Indication(s)
- Budesonide (Pulmicort Respules®) is indicated for maintenance treatment of asthma and as prophylactic therapy in children 12 months to 8 years of age.
- Ciclesonide (Alvesco®) is indicated for maintenance treatment of asthma as prophylactic therapy in adult and adolescent patients 12 years of age and older.
- Fluticasone (Flovent HFA) is indicated for maintenance treatment of asthma as prophylactic therapy in patients aged 4 years and older.

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, Flovent HFA and Alvesco are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Eosinophilic Esophagitis (must meet all)**:**

1. Diagnosis of eosinophilic esophagitis (EoE);
2. Prescribed by or in consultation with a gastroenterologist or allergy/immunology specialist;
3. Failure of an 8-week trial of a proton pump inhibitor (PPI) at up to maximally indicated doses (Adults: 20-40mg twice daily omeprazole equivalent, Children: 1-2mg/kg or equivalent), unless contraindicated or clinically significant adverse effects are experienced;
4. If Alvesco is requested, medical justification supports inability to use Fluticasone HFA authorized generic and Pulmicort Respules;
5. Dose does not exceed recommended dosing regimens and medication will be swallowed.

Approval Duration: 2 months

B. Other diagnosis/indication
Not applicable

II. Continued Therapy

A. Eosinophilic Esophagitis (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Prescription records or chart notes documenting continued adherence to therapy since last authorization;
3. For relapse, prior authorization form or chart notes documenting a relapse after treatment was discontinued since last approval;
4. For non-responders, prior authorization form or chart notes documenting lack of response since last approval;
5. For maintenance, request meets one of the following:
    a. Severe dysphagia or food impaction
    b. High grade esophageal stricture
    c. Rapid symptomatic/histological relapse after initiation

Approval duration:
For relapse - 6 months
For non-responders - 6 months
For maintenance - 12 months

B. Other diagnosis/indication
Not applicable

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

Not applicable

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
EoE: Eosinophilic Esophagitis
FDA: Food and Drug Administration
GERD: gastroesophageal reflux disease
IgE: immunoglobulin E
PPI: proton pump inhibitor

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: General Information
Eosinophilic esophagitis is a chronic immunological condition that involves inflammation of the esophagus. The disease can happen at any age with patients typically presenting in childhood (mean age 8.6 years) or in the third or fourth decade of life. Males are three times more likely to have a diagnosis of eosinophilic esophagitis than females. Signs and symptoms of esophageal dysfunction include unexplained feeding difficulties, vomiting, solid-food dysphagia, esophageal strictures and GERD-like symptoms. Children with eosinophilic esophagitis are more

likely to display GERD-like symptoms than adults. The exact cause of eosinophilic esophagitis is unknown; however, there is a strong association with other immunologic conditions such as asthma, allergic rhinitis, IgE mediated food allergy and atopic dermatitis. Topical steroids are first line therapy for patients with eosinophilic esophagitis. Goals of treatment are improvement in symptoms and inflammation. The following glucocorticoids were studied in patients with eosinophilic esophagitis: fluticasone metered dose inhaler, budesonide and ciclesonide. In children, swallowed topical steroids like fluticasone metered dose inhaler and budesonide were shown to improve symptoms and stimulate histological remission. Clinical trials displayed a 50% complete and 95% partial response when using topical steroids over 1-3 months. In addition, swallowed fluticasone metered dose inhaler may improve nausea which is often observed in patients with eosinophilic esophagitis. Patients should not eat or drink for 30 minutes after taking fluticasone metered dose inhaler.

Appendix E: Signs and Symptoms of Esophageal Dysfunction

Children	**Adults**
Feeding dysfunction	Dysphagia
Vomiting	Food impaction
Abdominal pain	Chest pain
Dysphagia	GERD/Heartburn
Food impaction	Abdominal pain

Appendix F: Examples of Secondary Causes of EoE

- GERD
- Recurrent vomiting
- Parasitic/Fungal infections
- Crohn's disease
- Drug hypersensitivity

V. Dosage and Administration

Drug Name	Recommended Dosing Regimen	Notes
Fluticasone HFA authorized generic 44mcg, 110 mcg, 220 mcg	• 1-11 years old: 110mcg/spray, 8 sprays daily in divided doses. • ≥12 years old: 220mcg/spray, 8 sprays daily in divided doses. • ≥ 18 years old: 220mcg/spray, 4 sprays daily in divided doses.	• 1-11 years old: Divide total daily dose as two to four times daily • ≥12 years old: Divide total daily dose as two to four times daily • ≥18 years old: Divide total daily dose as twice daily *Doses are swallowed*
Budesonide (Pulmicort	• <10 years old: 1mg/day • ≥ 10 years old: 2mg/day	• Oral viscous slurry dosing: Mix and swallow 10-1 gram

Drug Name	Recommended Dosing Regimen	Notes
Respules) 0.5mg/2 ml		packets of Splenda per 1 mg of Budesonide. Maybe divided in 2 doses • Nebulized dosing: Swallow accumulated liquid
Ciclesonide (Alvesco) 80 mcg, 160 mcg	≥ 4 years old: 80 or 160mcg, Swallow 2 sprays twice daily	*Doses are swallowed*

VI. Product Availability

Drug Name	Availability
Budesonide (Pulmicort Respules)	Inhalation suspension: 0.25 mg/2ml, 0.5 mg/2ml, 1 mg/2 ml
Ciclesonide (Alvesco)	Inhalation aerosol: 80mcg/actuation, 160mcg/actuation
Fluticasone HFA authorized generic	Inhalation aerosol: 44mcg, 110mcg, 220 mcg

VII. References

1. Dellon ES, Gonsalves N, Hirano I et al. ACG clinical guideline: Evidence-based approach to the diagnosis and management of esophageal eosinophilia and eosinophilic esophagitis. Am J Gastroenterol 2013;108(5):679-92; doi: 10.1038/ajg.2013.71. Epub 2013 Apr 9.
2. Papadopoulou A, Koletzko S, Heuschkel R, et al. European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) Eosinophilic Esophagitis Working Group and the Gastroenterology Committee. Management guidelines of eosinophilic esophagitis in childhood. J Pediatr Gastroenterol Nutr 2014;58(1):107-18.
3. Schaefer ET, Fitgerald JF, Molleston JP et al. Comparison of oral prednisone and topical fluticasone in the treatment of EoE: Trial in children. Clin Gastroenterol Hepatol 2008; 6: 165-173.
4. Konikoff MR, Noel RJ, Blanchard C et al. A randomized, double blind placebo-controlled trial of fluticasone propionate for pediatric eosinophilic esophagitis. Aliment Pharmacol Therapy 2012; 35: 300-307.
5. Lucendo A, Molina-Infante J, Arias A, et al. Guidelines on eosinophilic esophagitis: evidence-based statements and recommendations for diagnosis and management in children and adults. United European Gastroenterology 2017:vol 5(3), 335-358
6. Bonos P, Gupta S. Treatment of eosinophilic esophagitis. In: UptoDate, Post TW (Ed), UptoDate, Waltham MA (Accessed on March 22, 2021.)
7. Gupta M and Grinman M. Diagnosis and Management of eosinophilic esophagitis. CMAJ 2024 February 5;196:E121-8. doi: 10.1503/cmaj.230378
8. Gonsalves N and Aceves S. Diagnosis and treatment of eosinophilic esophagitis. J Allergy Clin Immunol 2020;145:1-7.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	09.01.16	09.16
4Q 2017 annual review: references reviewed and updated.	12.01.17	12.17
2Q 2018 annual review: added ciclesonide as a therapeutic option under initial therapy with dosing recommendations; added new criteria for maintenance therapy; references reviewed and updated.	04.01.18	04.18
4Q 2018 annual review: no significant changes.	12.01.18	12.18
Changed current Georgia policy templates to corporate standard templates for drug coverage criteria to meet corporate compliance. Changes/revisions included; new formatting, font size, use of standard policy language for each section of policy, and rearranged order of certain steps in criteria and sections.	2/21/19	
Annual Review. Updated fonts	3/19	4/19
Annual review. Added dosing recommendations for adults in children in initial criteria. Updated references.	4/2020	4/2020
Annual review. Changed to fluticasone (Flovent) to reflect recommended formulation of the fluticasone metered dose inhaler (Flovent HFA). Updated dosing recommendations. Updated references.	4/2021	4/2021
3Q 2022 annual review. No changes made.	7/2022	7/2022
3Q 2023 annual review. No changes made.	7/2023	7/2023
3Q 2024 annual review. Replaced Flovent HFA with Fluticasone HFA authorized generic as a preferred drug list treatment alternative. Updated references	7/2024	7/2024

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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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.