NASPGHAN
714 N Bethlehem Pike
Suite 300
Ambler, PA 19002
215-641-9800
naspghan@naspghan.org

NORTH AMERICAN SOCIETY FOR PEDIATRIC GASTROENTEROLOGY, HEPATOLOGY AND NUTRITION

January 3, 2024

Ms. Lisa Morris, RPh
Vice President Clinical Pharmacy
CarelonRx
450 Headquarters Plaza, 7th Floor East Tower
Morristown, NJ 07960

Sent via email to: druginformation@wellpoint.com

Dear Ms. Morris,

The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) writes to draw your attention to coverage barriers for swallowed topical steroids for the treatment of Eosinophilic Esophagitis (EoE), a chronic condition that impacts more than 160,000 children, teens, and adults in the United States. **Specifically, we are concerned about the discontinuation of Flovent HFA and lack of a formulary preferred equivalent *swallowed* topical steroid medication.**

The lack of a formulary preferred equivalent will put EoE patients at risk of losing access to their treatment, resulting in disease recurrence, progression to more advanced disease, and more endoscopies and hospital admissions. **On behalf of NASPGHAN, I write to urgently request a meeting with you to further share our concerns.**

EoE is a chronic allergic inflammatory condition of the esophagus which can cause a wide array of GI symptoms in pediatric and adult populations. Approximately 1 in 2000 people in the United States have EoE and prevalence is rising. Numerous randomized clinical trials have demonstrated the effectiveness of swallowed topical steroids Flovent HFA (fluticasone propionate) and oral viscous budesonide (OVB) in treating EoE and these medications are considered standard of care in the pharmacologic treatment of EoE.

Increasingly, our physicians have been receiving denials for the coverage of Flovent HFA for EoE treatment as many insurance formularies have transitioned to breath-actuated inhalers as their preferred inhaled steroid formulation. Flovent HFA is administered by a metered dose inhaler (MDI) by which the aerosolized medication is swallowed by the patient to coat the esophagus for topical treatment. Breath-actuated dry-powder inhalers cannot be used for EoE because they cannot be swallowed and, therefore, are not acceptable alternative medications for effective EoE therapy.

Additionally, GlaxoSmithKline discontinued manufacture of brand Flovent HFA effective December 31, 2023, further limiting patient's access to this medication. While a generic fluticasone HFA has been approved, our patients face formulary restrictions.

While OVB is an alternative option, there are a number of barriers in its use, including lack of standardized mixing agents not specifically designed for esophageal delivery, and practical issues around palatability, medication mixing, and administration technique. While pharmacy compounded OVB has been shown to be effective in EoE and could overcome these obstacles, physicians have found that OVB compounding is typically denied by insurance. Very limited data is available regarding the efficacy of other steroid MDIs in regards to treating EoE and as such are not comparable alternatives for fluticasone HFA.

The transition to breath-actuated inhalers as the preferred steroid inhaler is putting our EoE patients at risk of losing access to their medication which will cause relapse of their disease, and negatively impact symptoms and health-related quality of life. Further, there is a significant risk of progression to fibrostenotic disease and esophageal strictures and subsequent costly avoidable emergency department visits, hospitalizations, endoscopies, esophageal dilations, and escalation of therapy.

In summary, access to fluticasone HFA is becoming increasingly limited due to insurance formulary changes preferring breath-actuated inhalers that are NOT effective for EoE and discontinuation of brand name Flovent HFA. **We ask that Elevance Health include fluticasone HFA as a preferred medication to ensure its beneficiaries have consistent access to medication for the treatment of EoE.** Without immediate action to create access to fluticasone HFA, the result will be negative patient outcomes and higher health care utilization and cost.

Thank you for your prompt attention to this urgent issue and your partnership to improve the health of our patients. To arrange a virtual meeting, please contact Camille Bonta, NASPGHAN Policy Advisor, at (202) 320-3658 or cbonta@summithealthconsulting.com.

Sincerely,

Jenifer Lightdale, MD
President
NASPGHAN

References:

Franciosi JP, Gordon M, Sinopoulou V, Dellon ES, Gupta SK, Reed CC, Gutiérrez-Junquera C, Venkatesh RD, Erwin EA, Egiz A, Elleithy A, Mougey EB. Medical treatment of eosinophilic esophagitis. Cochrane Database Syst Rev. 2023 Jul 20;7(7):CD004065.

Konikoff MR, Noel RJ, Blanchard C, Kirby C, Jameson SC, Buckmeier BK, Akers R, Cohen MB, Collins MH, Assa'ad AH, Aceves SS, Putnam PE, Rothenberg ME. A randomized, double-blind, placebo-controlled trial of fluticasone propionate for pediatric eosinophilic esophagitis. Gastroenterology. 2006 Nov;131(5):1381-91.

Butz BK, Wen T, Gleich GJ, Furuta GT, Spergel J, King E, Kramer RE, Collins MH, Stucke E, Mangeot C, Jackson WD, O'Gorman M, Abonia JP, Pentiuk S, Putnam PE, Rothenberg ME. Efficacy, dose reduction, and resistance to high-dose fluticasone in patients with eosinophilic esophagitis. Gastroenterology. 2014 Aug;147(2):324-33.e5.

Andreae DA, Hanna MG, Magid MS, Malerba S, Andreae MH, Bagiella E, Chehade M. Swallowed Fluticasone Propionate Is an Effective Long-Term Maintenance Therapy for Children With Eosinophilic Esophagitis. Am J Gastroenterol. 2016 Aug;111(8):1187-97.

Syverson EP, Tobin M, Patton T, Franciosi JP, Gupta SK, Venkatesh RD. Variability in Swallowed Topical Corticosteroid Practice Patterns for Treatment of Pediatric Eosinophilic Esophagitis. J Pediatr Gastroenterol Nutr. 2023 Aug 1;77(2):256-259.