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NASPGHAN
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition

January 3, 2024

Dot Verbrugge, MD
Vice President Clinical Quality, Medical Affairs
Aetna Inc.
151 Farmington Avenue
Hartford, CT 06156

Sent via email to: VerbruggeD@aetna.com

Dear Dr. Verbrugge,

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 Aetna include fluticasone HFA as a preferred medication to ensure their 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:

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