BlueCross BlueShield
Federal Employee Program

XHANCE
(fluticasone propionate) nasal spray

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Xhance (fluticasone propionate) is a synthetic trifluorinated corticosteroid with anti-inflammatory activity. The precise mechanism through which Xhance affects nasal polyps and associated inflammatory symptoms is not known. Corticosteroids have been shown to have a wide range of effects on multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, cytokines) involved in inflammation. The anti-inflammatory action of corticosteroids contributes to their efficacy (1).

Regulatory Status

FDA-approved indication: Xhance is a corticosteroid indicated for the treatment of (1):

- Chronic rhinosinusitis with nasal polyps (CRSwNP) in adults
- Chronic rhinosinusitis without nasal polyps (CRSsNP) in adults

Xhance has a warning regarding local nasal effects, such as epistaxis, erosion, ulceration, septal perforation, *Candida albicans* infection, and impaired wound healing. Patients should be monitored periodically for signs of adverse effects on the nasal mucosa. Use should be avoided in patients with recent nasal ulcerations, nasal surgery, or nasal trauma (1).

Nasal and inhaled corticosteroids may result in the development of glaucoma and/or cataracts. Close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts (1).

Hypercorticism and adrenal suppression may occur when intranasal corticosteroids, such as Xhance, are used at higher than recommended dosages or in susceptible individuals at recommended dosages. Since fluticasone propionate is absorbed into the circulation and can be systemically active at higher doses, recommended dosages of Xhance should not be exceeded to avoid hypothalamic-pituitary-adrenal (HPA) dysfunction. Patients treated with Xhance should be observed carefully for any evidence of systemic corticosteroid effects such as hypercorticism and adrenal suppression (including adrenal crisis) (1).

Decreases in bone mineral density (BMD) have been observed with long-term oral inhalation of

products containing corticosteroids into the lungs. Patients with major risk factors for decreased bone mineral content, such as prolonged immobilization, family history of osteoporosis, postmenopausal status, tobacco use, advanced age, poor nutrition, or chronic use of drugs that can reduce bone mass (e.g., anticonvulsants, oral corticosteroids), should be monitored and treated with established standards of care (1).

The safety and effectiveness of Xhance in pediatric patients have not been established (1).

Summary

Xhance (fluticasone propionate) is a synthetic trifluorinated corticosteroid with anti-inflammatory activity. The precise mechanism through which Xhance affects nasal polyps and associated inflammatory symptoms is not known. Corticosteroids have been shown to have a wide range of effects on multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, cytokines) involved in inflammation. The anti-inflammatory action of corticosteroids contributes to their efficacy (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Xhance while maintaining optimal therapeutic outcomes.

References

1. Xhance [package insert]. Yardley, PA: OptiNose US, Inc.; March 2024.