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5.45.013

Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Respiratory Agents	**Original Policy Date:**	November 27, 2020
Subject:	Xhance	**Page:**	1 of 5

Last Review Date: December 13, 2024

Xhance

Description

Xhance (fluticasone propionate) nasal spray

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 indications: 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).

Related policies
Sinus Implants

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Xhance may be considered **medically necessary** if the conditions indicated below are met.

Xhance may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Chronic rhinosinusitis

AND ALL of the following:

1. Inadequate treatment response to at least **TWO** of the following corticosteroid nasal sprays for a combined duration of at least three months:
    a. Mometasone
    b. Fluticasone
    c. Budesonide
    d. Triamcinolone
2. **NO** recent nasal ulcerations, nasal surgery, or nasal trauma
3. Prescriber agrees to monitor the patient for changes in vision and for increased intraocular pressure
4. Prescribed by or recommended by an Ear, Nose, and Throat (ENT) specialist or an allergist
5. Prescriber agrees to monitor the patient for systemic corticosteroid effects such as hypercorticism and adrenal suppression (including adrenal crisis)

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Chronic rhinosinusitis

AND ALL of the following:

1. **NO** recent nasal ulcerations, nasal surgery, or nasal trauma
2. Prescriber agrees to monitor the patient for changes in vision and for increased intraocular pressure
3. Prescriber agrees to monitor the patient for systemic corticosteroid effects such as hypercorticism and adrenal suppression (including adrenal crisis)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 6 bottles

Duration 3 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

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.

Policy History

Date	Action
November 2020	Addition to PA
March 2021	Annual review. Revised the t/f requirement so that patient must have inadequate response to at least three corticosteroid nasal sprays per MQA
June 2021	Annual review and reference update
January 2022	Changed the required number of corticosteroid nasal sprays to two, from three, per FEP
March 2022	Annual review and reference update
November 2022	Per MQA review: Revised duration of approval to 3 months and added initiation requirement that medication be prescribed by or recommended by an ENT. Changed policy number to 5.45.013.

December 2022	Annual review and reference update
April 2023	Per FEP, added allergist as acceptable prescriber to the specialist requirement and changed otolaryngologist to ear, nose, and throat specialist. Reference update
September 2023	Per FEP, clarified criterion for intranasal steroids to require a trial of at least 2 ingredients
December 2023	Annual review
April 2024	Per PI, removed nasal polyps requirement, added indication of chronic rhinosinusitis
September 2024	Annual review
December 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.