Clinical Policy: Fluticasone Propionate (Xhance)

Reference Number: ERX.NPA.59
Effective Date: 03.01.18
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

Revision Log

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

Description
Fluticasone propionate (Xhance®) is a synthetic trifluorinated corticosteroid with anti-inflammatory activity with a unique nasal delivery device.

FDA Approved Indication(s)
Xhance is indicated for the treatment of nasal polyps in patients 18 years of age or older.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Xhance is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Nasal Polyps (must meet all)**:**
1. Diagnosis of nasal polyps;
2. Age ≥ 18 years;
3. Failure of two formulary intranasal steroids (e.g., fluticasone propionate, budesonide), unless clinically significant adverse effects are experienced or all are contraindicated;
4. Dose does not exceed 744 mcg per day (2 devices per 30 days).

Approval duration: 6 months

B. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Nasal Polyps (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy (e.g., improvement in nasal congestion or obstruction, reduction of bilateral polyp grade);
3. If request is for a dose increase, new dose does not exceed 744 mcg per day (2 devices per 30 days).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
mometasone furoate (Nasonex®)	2 sprays/nostril (50 mcg/spray) IN BID (400 mcg/day)	400 mcg/day
fluticasone propionate (Flonase®)	2-4 sprays/nostril (50 mcg/spray) IN QD or BID (200 - 800 mcg)	800 mcg/day
budesonide (Rhinocort®)	2 sprays/nostril (32 mcg/spray) IN QD (128 mcg)	128 mcg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity to any ingredient in Xhance
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Nasal polyps	1 to 2 sprays per nostril (93 mcg/spray) IN BID	744 mcg/day

VI. Product Availability

Nasal spray: 93 mcg of fluticasone propionate in each 106-mg spray with 120 metered sprays per device

VII. References

1. Xhance Prescribing Information. Yardley, PA: Optinose; April 2021. Available at: https://www.xhance.com. Accessed September 13, 2021.
2. Newton JR, Ah-see KW. A review of nasal polyposis. Ther Clin Risk Manag. 2008;4(2):507-12. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2504067/. Accessed September 13, 2021.
3. Sotores D., Messina J., Carothers J., et al. A randomized, double-blind of an Exhalation Delivery System with fluticasone (EDS-FLU) for treatment of chronic rhinosinusitis with nasal polys (CRSwNP) (NAVIGATE I). Journal of Allergy and Clinical Immunology, Volume 139, Issue 2, AB66. Feb 2017 Available at: http://www.optinose.com/wp-content/uploads/2017/10/AAAI_NAVIGATE_I_EDS-FLU_CRSwNP.pdf. Accessed September 13, 2021.
4. Leopold D., Elkayam D., Messina J. et al. A randomized double-blind trial of fluticasone propionate exhalation delivery system (FLU-EDS) for treatment of chronic rhinosinusitis with nasal polyps (NAVIGATE II). The University of Vermont, Optinose. 2017 Available at: http://www.optinose.com/wp-content/uploads/2017/10/NAVIGATE_II_FLU-EDS_for_CRSwNP.pdf. Accessed September 13, 2021.
5. Filiaci F, Passali D, Puxeddu R, Schrewelius C. A randomized controlled trial showing efficacy of once daily intranasal budesonide in nasal polyposis. Rhinology. 2000 Dec;38(4):185-90. Available at: https://www.ncbi.nlm.nih.gov/pubmed/11190754. Accessed September 13, 2021.

6. Jankowski R, Klossek JM, Attali V, Coste A, Serrano E. Long-term study of fluticasone propionate aqueous nasal spray in acute and maintenance therapy of nasal polyposis. Allergy. 2009 Jun;64(6):944-50. Available at: https://www.ncbi.nlm.nih.gov/pubmed/19298572. Accessed September 13, 2021.
7. Han JK, Bosson JV, Cho SH, et al. Multidisciplinary consensus on a stepwise treatment algorithm for management of chronic rhinosinusitis with nasal polyps. Int Forum Allergy Rhinol. 2021;1-10. Available at: https://onlinelibrary.wiley.com/doi/10.1002/alr.22851. Accessed September 13, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10.24.17	02.18
1Q 2019 annual review: no significant changes; references reviewed and updated.	11.06.18	02.19
1Q 2020 annual review: modified from 2 to 3 intranasal corticosteroids and adjusted criteria to require one of the intranasal corticosteroids member must T/F be fluticasone; added criteria requiring medical justification why Xhance will work if generic fluticasone did not; adjusted approval duration from "length of benefit" to 6 months initial and 12 months reauthorization; references reviewed and updated.	10.30.19	02.20
1Q 2021 annual review: no significant changes; references reviewed and updated.	10.09.20	02.21
Modified requirement from 3 intranasal steroids including fluticasone to any 2 intranasal steroids; removed criteria requiring medical justification since 2021 consensus panel treatment algorithm now recommends Xhance after traditional intranasal steroids due to its unique delivery method and improved deposition of fluticasone.	06.16.21	08.21
1Q 2022 annual review: no significant changes; references reviewed and updated.	09.13.21	02.22

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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