

Clinical Policy Title:	fluticasone propionate
Policy Number:	RxA.567
Drug(s) Applied:	Xhance®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Fluticasone propionate (Xhance®) is a corticosteroid indicated for the treatment of nasal polyps in patients 18 years of age or older.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Fluticasone propionate (Xhance®)	Nasal polyps	1 to 2 sprays (93 mcg/spray) per nostril BID	744 mcg/day

Dosage Forms

- Nasal spray: 93 mcg of fluticasone propionate in each 106-mg spray

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Nasal Polyps (must meet all):

- Diagnosis of nasal polyps;
- Age ≥ 18 years;
- Failure of two formulary intranasal steroids (e.g., fluticasone propionate, mometasone, budesonide) unless contraindicated or clinically significant adverse effects are experienced;
- Dose does not exceed 744 mcg per day (2 devices per 30 days).

Approval Duration

Commercial: 12 months

Medicaid: 12 months

II. Continued Therapy Approval

A. Nasal Polyps (must meet all):

- Currently receiving medication that has been authorized RxAdvance or member has previously met initial approval criteria listed in this policy;

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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

Commercial: 12 months

Medicaid: 12 months

III. Appendices

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

APPENDIX D: General Information

- Not Applicable

References

1. Xhance Prescribing Information. Yardley, PA; OptiNose US, Inc.; September 2017. Available at: https://www.xhance.com/files/XHANCE_Full_Prescribing_Information.pdf. Accessed September 8, 2020.
2. Newton JR, Ah-see KW. A review of nasal polyposis. Ther Clin Risk Manag 2008; 4(2):507-512. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2504067/>. Accessed September 8, 2020.
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 polyps (CRSwNP) (NAVIGATE I). Journal of Allergy and Clinical Immunology, Volume 139, Issue 2, AB66. Feb 2017. Available at:

- http://www.optinose.com/wpcontent/uploads/2017/10/AAAI_NAVIGATE_I_EDS-FLU_CRSwNP.pdf. September 8, 2020.
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_FLUEDS_for_CRSwNP.pdf. Accessed September 8, 2020.
 5. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed September 8, 2020.
 6. 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 8, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	1/2020	03/06/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Clinical Policy Title was updated. 2. Drug(s) Applied was updated. 3. Line of Business Policy Applies to was update to all lines of business. 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. Initial Approval criteria: Commercial approval duration was updated from length of benefit to 6 months. 6. Continued Approval criteria: Commercial approval duration was updated from length of benefit to 12 months. 7. References were updated. 8. Updated background: Fluticasone propionate (Xhance®) is a corticosteroid indicated for the treatment of nasal polyps in patients 18 years of age or older. 9. Updated Dosing: 1 to 2 sprays (93 mcg/spray) per 	09/08/2020	12/07/2020

<p>nostril BID</p> <p>10. Updated dosage form: Nasal spray: 93 mcg of fluticasone propionate in each 106-mg spray</p>		
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