Clinical Policy: Fluticasone Propionate (Xhance)

Reference Number: CP.PMN.95
Effective Date: 03.01.18
Last Review Date: 08.23
Line of Business: Commercial*, HIM, 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.

**For the Commercial line of business, this policy applies to Oregon formularies only. For California Commercial formularies, refer to the step therapy policy, CP.CPA.83.*

FDA Approved Indication(s)

Xhance is indicated for the treatment of

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

Policy/Criteria

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

It is the policy of health plans affiliated with Centene Corporation® that Xhance is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chronic Rhinosinusitis (must meet all)**:**

1. Diagnosis of CRS;
2. Age ≥ 18 years;
3. Failure of one formulary intranasal steroid (e.g., fluticasone propionate, mometasone, budesonide), unless clinically significant adverse effects are experienced or all are contraindicated;
4. Dose does not exceed (a and b):
   a. 744 mcg per day;
   b. 2 devices per 30 days.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business:

CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Chronic Rhinosinusitis (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
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 (a and b):
   a. 744 mcg per day;
   b. 2 devices per 30 days.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
CRS:chronic rhinosinusitis
CRSsNP: chronic rhinosinusitis without nasal polyps
CRSwNP: chronic rhinosinusitis with nasal polyps

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/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
CRSwNP, CRSsNP	1 to 2 sprays (93 mcg/spray) per nostril 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 US, Inc.; March 2024. Available at: https://www.xhance.com. Accessed March 20, 2024.

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 Accessed May 8, 2023.
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 May 8, 2023.
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 May 8, 2023.
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 May 8, 2023.
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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 May 8, 2023.
8. Rank MA, Chu DK, Bognanni A, et al. The Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis. *J Allergy Clin Immunol*. 2023; 151(2): 386-392.
9. Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter update. *Ann Allergy Asthma Immunol*. 2014;113(4):347-385. doi:10.1016/j.anai.2014.07.025

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2019 annual review: no significant changes; references reviewed and updated.	11.06.18	02.19
1Q 2020 annual review: increased requirement to require a trial of 3 preferred intranasl corticosteroids; 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; changed commercial approval duration from length of benefit to 6/12 months; references reviewed and updated.	10.30.19	02.20

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added HIM line of business.	04.27.20	
1Q 2021 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; 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
Template changes applied to other diagnoses/indications and continued therapy section.	10.10.22	
1Q 2023 annual review: no significant changes; references reviewed and updated.	11.03.22	02.23
RT4: clarified diagnosis from "nasal polyps" to "CRSwNP" per updated language in FDA approved indication.	02.10.23	
Per February SDC, modified requirement from two formulary intranasal steroids to require only one.	02.21.23	05.23
Per SDC, added the following clarification: For the Commercial line of business, this policy applies to Oregon formularies only. For California Commercial formularies, refer to the step therapy policy, CP.CPA.83.	05.04.23	
3Q 2023 annual review: no significant changes; references reviewed and updated.	05.19.23	08.23
RT4: added new indication for CRSsNP.	03.27.24	

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.