Xhance Prior Authorization with Quantity Limit Program Summary

This program applies to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx formularies.

This is a FlexRx Standard and GenRx Standard program.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
03-01-2024	07-01-2021

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Xhance® (fluticasone propionate) Nasal spray	Treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age or older		1

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

CRSwNP	Chronic rhinosinusitis with nasal polyps (CRSwNP) is an inflammatory condition affecting the paranasal sinuses that is diagnosed by the presence of both subjective and objective evidence of chronic sinonasal inflammation. Hallmarks of the disease consist of at least two out of four cardinal symptoms (i.e., facial pain/pressure, hyposmia/anosmia, nasal drainage, and nasal obstruction) for at least 12 consecutive weeks. The objective evidence of sinonasal inflammation and nasal polyps is needed to confirm the diagnosis may be obtained by physical examination (anterior rhinoscopy, nasal endoscopy) or from sinus computed tomography (CT).(2-4) The exact cause of CRSwNP is unknown, but biopsies of nasal polyps have shown elevated levels of eosinophils.(2) First line therapy for CRSwNP consists of nasal saline irrigation in combination with intranasal corticosteroids.(2-4) The American Academy of Family Physicians notes that no one intranasal corticosteroid is superior to another or that increased dosing provides greater effectiveness. The American Academy of Otolaryngology recommends a short course of oral corticosteroids if no response is seen with intranasal corticosteroids after 3-months of appropriate use.(4) Short courses of oral corticosteroids (up to three weeks) can improve sinonasal symptoms and endoscopic findings. Surgical intervention may be required in patients who fail medical management.(2,3)
Efficacy	The efficacy of Xhance was evaluated in two randomized, double-blind, parallel group, multicenter, placebo-controlled, dose-ranging trials in adults 18 years and older with nasal polyps and associated moderate to severe nasal congestion (NCT 01622569, NCT 01624662). The two trials included a total of 646 subjects. Subjects were randomized 1:1:1:1 to receive 93 mcg, 186 mcg, or 372 mcg twice daily or placebo for a period of 16 weeks. At baseline 90.6% of patients reported previous use of a topical steroid nasal spray for the treatment of nasal polyps. The co-primary efficacy endpoints were 1) change from baseline to Week 4 in nasal congestion/obstruction averaged over the preceding 7 days of treatment and 2) change from baseline to

	Week 16 in bilateral polyp grade. Nasal congestion was rated by the patient on a 0 to 3 categorical severity scale at the time immediately prior to the next dose (instantaneous). Polyp grade was determined by the clinician using nasal endoscopy. Polyps on each side of the nose were graded on a categorical scale. Efficacy was demonstrated for both Xhance 186-mcg twice daily and Xhance 372-mcg twice daily. Onset of action, evaluated by determining the starting period that the treatment effect of Xhance on daily instantaneous AM congestion score started to achieve statistical significance in comparison to placebo and roughly maintained thereafter, was generally observed within 2 weeks for both Xhance doses.(1)
Safety	Xhance is contraindicated in patients with a hypersensitivity to any ingredient.(1)

REFERENCES

Number	Reference
1	Xhance prescribing information. OptiNose US, Inc. January 2023.
2	Stevens, W. W., Schleimer, R. P., & Kern, R. C. (2016). Chronic Rhinosinusitis with Nasal Polyps. The journal of allergy and clinical immunology. In practice, 4(4), 565–572. doi:10.1016/j.jaip.2016.04.012.
3	Sedaghat, A. R. (2017). Chronic Rhinosinusitis. American Family Physicians, 96(8), 500-506.
4	Rosenfeld, R.M., Piccirillo, J.F., Chandrasekhar, S.S., Itzhak, B., Kumar, K. A., Kramper, M., Orlandi, R. R., Palmer, J. N., Patel, Z. M., Peters, A., Walsh, S. A., Corrigan, M. D. (2015). Clinical practice guideline (update): adult sinusitis. Otolaryngol Head Neck Surg. 2015; 152(2 suppl): S1-S39.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Xhance	fluticasone propionate nasal exhaler susp	93 MCG/ACT	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Xhance	Fluticasone Propionate Nasal Exhaler Susp 93 MCG/ACT	93 MCG/ACT	2	Bottles	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Xhance	fluticasone propionate nasal exhaler susp	93 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Xhance	Fluticasone Propionate Nasal Exhaler Susp 93 MCG/ACT	93 MCG/ACT	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) **OR** B. The patient has another FDA approved indication for the requested agent **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response with ONE generic OR OTC intranasal corticosteroid **OR** B. The patient has an intolerance or hypersensitivity to therapy with ONE generic or OTC intranasal corticosteroid that is not expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to ALL generic AND OTC intranasal corticosteroids that is not expected to occur with the requested agent **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL generic AND OTC intranasal corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months Note: If Quantity Limit applies, please refer to Quantity Limit criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met:

Module	Clinical Criteria for Approval
	1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent (e.g., decreased nasal congestion, pain, pressure, rhinorrhea, nasal polyps; increased sense of smell) **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months Note: If Quantity Limit applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. BOTH of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: 12 months