Xhance Quantity Limit Program Summary

Quantity limits apply to Medicaid.

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 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 – 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	Medicaid

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL Standalone	**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. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months