I. Medication Description

Xhance (fluticasone propionate) is a synthetic trifluorinated corticosteroid with anti-inflammatory activity. Xhance is formulated as a unique nasal device employing an exhalation delivery system (EDS) for the treatment of nasal polyps.

In the treatment of nasal polyps, the precise mechanism through which intranasal fluticasone propionate affects nasal polyps and associated inflammatory symptoms is not known. Corticosteroids have been shown to have a wide range of effects on multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, cytokines) involved in inflammation. The anti-inflammatory action of corticosteroids contributes to their efficacy. In addition, studies suggest that carbon dioxide, which is present in the exhaled breath delivered into the nose through the device, may influence inflammatory mediator activity and neuropeptide activity, possibly through mechanisms of action that also include removal of nitric oxide, change in pH, or positive pressure. The direct relationship of these findings to long-term symptom relief is not known.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Xhance is provided when the following criteria are met:

- Member is at least 18 years of age AND
- Medication is prescribed by an Otolaryngologist or Allergist/Immunologist AND
- Member has been diagnosed with nasal polyps and the following documentation has been provided:
  - Progress notes documenting symptoms (e.g. nasal congestion or obstruction, etc) AND
  - Baseline total bilateral polyp grade (determined by nasal endoscopy) OR
  - CT scan findings documenting nasal polyps AND
- When requesting coverage of a brand medication for which a plan-preferred A/B rated generic is available, there is sufficient evidence that the use of the A/B rated generic equivalent has resulted in inadequate results AND
- Coverage will be provided when the member has experienced intolerance or therapeutic failure with at least ONE plan-preferred medication (intranasal corticosteroid) first OR when at least ONE of the following criteria have been met:
Drug Therapy Guidelines | Xhance™ (fluticasone propionate) | Last Review Date: 12/18

- The plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member.
- The plan-preferred medications are expected to be ineffective based on the known clinical history and conditions of the member and the member’s prescription drug regimen.
- The member has tried the plan-preferred medications or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy of effectiveness, diminished effect, or an adverse event.
- The member is stable on the medication selected by their healthcare professional for the medical condition under consideration (where “stable” is defined as receiving the medication for an adequate period of time, have achieved optimal response, and continued favorable outcomes are expected UNLESS the medication was initially selected solely due to the availability of a drug sample or a coupon card and the member does not otherwise meet the definition of “stable”).
- The plan-preferred medication is not in the best interest of the member because it will likely cause a significant barrier to the member’s adherence or to compliance with the member’s plan of care, will likely worsen a comorbid condition of the member, or will likely decrease the member’s ability to achieve or maintain reasonable functional ability in performing daily activities.

IV. **Quantity Limitations**

Coverage is available for a maximum of 2 nasal spray devices per each 30 day period.

V. **Coverage Duration**

Initial coverage is available for 6 months and may be renewed.

VI. **Coverage Renewal Criteria**

Coverage can be renewed for up to 12 months at a time based upon the following criteria:
- Member is responding positively to therapy (e.g. reduction of bilateral polyp grade, improvement in nasal congestion or obstruction, etc) **AND**
- Absence of unacceptable toxicity from the drug

VII. **Billing/Coding Information**

Xhance is available as a nasal spray device containing 120 metered sprays; each 106-mg spray delivers 93 mcg of fluticasone propionate per actuation.

VIII. **Summary of Policy Changes**

5/9/18: new policy
1/15/19: no policy changes

IX. **References**
1. Xhance (fluticasone propionate) [prescribing information]. Yardley, PA: OptiNose US Inc; September 2017.

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.