STEP THERAPY POLICY

POLICY: Nasal Steroids Step Therapy Policy

- Beconase AQ® (beclomethasone nasal spray GlaxoSmithKline)
- Dymista® (azelastine hydrochloride/fluticasone propionate nasal spray MEDA, generic)
- flunisolide nasal spray (generic only)
- fluticasone propionate nasal spray (generic only)
- mometasone furoate nasal spray (generic only)
- Omnaris[®] (ciclesonide nasal spray Covis)
- Qnasl®/Qnasl® Children's (beclomethasone dipropionate nasal aerosol Teva)
- Ryaltris® (olopatadine hydrochloride/mometasone furoate nasal spray Hikma)
- Xhance[®] (fluticasone propionate nasal spray OptiNose)
- Zetonna[®] (ciclesonide nasal aerosol Covis)

REVIEW DATE: 05/22/2024

OVERVIEW

Prescription nasal corticosteroids, with the exception of Xhance, are indicated for the treatment of symptoms of seasonal allergic rhinitis (SAR) and/or perennial allergic rhinitis (PAR). $^{1-8,19}$ Some of the agents in the class are also approved for additional indications (refer to Table 1 for a complete list of FDA-approved indications). Xhance is indicated for the treatment of chronic rhinosinusitis (CRS) with or without nasal polyps in adults. 9 Xhance utilizes an OptiNose Exhalation Delivery System (EDS) for bi-directional drug delivery, which differs from traditional nasal sprays. 9,10 Xhance and mometasone nasal spray provided comparable benefits in terms of polyp grade and congestion scores. 4,9 In addition to mometasone and Beconase AQ, which are also indicated for use in patients with nasal polyps, several of the other nasal steroids have been proven effective in reducing nasal polyp size and associated symptoms in clinical trials. $^{11-18}$ The FDA-approvals of several other nasal steroids have been changed from prescription to overthe-counter (OTC) status. OTC nasal steroid products are not addressed in this policy. Prescription brand Nasonex (mometasone nasal spray) was indicated in patients ≥ 2 years of age prior to its approval being switched from a prescription product to an OTC product. Generic prescription mometasone nasal spray remains on the market and now is indicated in patients ≥ 12 years of age. However, the same data that supported Nasonex's use in younger patients supports the use of mometasone nasal spray.

Table 1. Prescription Nasal Steroid Indications.^{1-9,19} Table 1 (continued). Prescription Nasal Steroid Indications.^{1-9,19}

 $SAR-Seasonal\ allergic\ rhinitis;\ PAR-Perennial\ allergic\ rhinitis;\ VMR-Vasomotor\ rhinitis;\ ^*Prevention\ of\ nasal\ polyprecurrence\ following\ surgery;\ CRSwNP-Chronic\ rhinosinusitis\ with\ nasal\ polyps;\ ^Prescription\ mometasone\ furoate\ is\ indicated\ for\ prophylaxis\ of\ seasonal\ allergic\ rhinitis\ (in\ patients \ge 12\ years),\ and\ treatment\ of\ nasal\ polyps\ (in\ patients \ge 18\ years).$

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration. Note: Over-the-counter nasal steroids are not addressed in this policy.

<u>Automation</u>: A patient with a of one Step 1 drug within the 130-day look-back period is excluded from step therapy.

- **Step 1:** fluticasone propionate nasal spray
- **Step 2:** azelastine hydrochloride/fluticasone propionate nasal spray, Beconase AQ, Dymista, flunisolide nasal spray, mometasone furoate nasal spray, Omnaris, Qnasl, Qnasl Children's, Ryaltris, Xhance, Zetonna

CRITERIA

- 1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
- **2.** If the patient is < 4 years of age, approve mometasone furoate nasal spray.
- 3. No other exceptions are recommended.

REFERENCES

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- 3. Flunisolide solution [prescribing information]. Bridgewater, NJ: Bausch & Lomb; February 2024.
- 4. Nasonex® [prescribing information]. Whitehouse Station, NJ: Merck; June 2022.
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- 19. Ryaltris® nasal spray [prescribing information]. Columbus, OH: Hikma Specialty; August 2023.