STEP THERAPY POLICY

POLICY: Nasal Steroids Step Therapy

DATE REVIEWED: 03/25/2020

DRUGS AFFECTED:

- Beconase AQ® (beclomethasone nasal spray – GlaxoSmithKline)
- Dymista® (azelastine hydrochloride/fluticasone propionate nasal spray – MEDA, generics)
- flunisolide nasal spray (generics)
- fluticasone propionate nasal spray (generics)
- Nasonex® (mometasone furoate nasal spray – Merck, generics)
- Omnaris® (ciclesonide nasal spray – Covis)
- Qnasl®/Qnasl® Children's (beclomethasone dipropionate nasal aerosol – Teva)
- Xhance™ (fluticasone propionate nasal spray – OptiNose)
- Zetonna® (ciclesonide nasal aerosol – Covis)

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] 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 only indicated for the treatment of nasal polyps in adult patients.[9] Mometasone furoate (Nasonex) is also indicated for the treatment of polyps; Beconase AQ is indicated for the prevention of recurrence of nasal polyps following surgical removal.[1,4] Xhance utilizes an OptiNose® Exhalation Delivery System (EDS) for bi-directional drug delivery, which differs from traditional nasal sprays.[9,14] 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, several of the other nasal steroids have been proven effective in reducing nasal polyp size and associated symptoms in clinical trials.[15-22]

Of note, the FDA-approvals of Flonase, Nasacort AQ, Rhinocort Aqua, and Veramyst have been changed from prescription to over-the-counter (OTC) status; therefore, there are now four OTC nasal steroid products available: Flonase® Allergy Relief (fluticasone propionate nasal spary, generics), Nasacort® Allergy 24HR (mometasone furoate nasal spray), Rhinocort® Allergy Spray (budesonide nasal spray), Flonase® Sensimist® (fluticasone furoate nasal spray).[10-13] However, the OTC nasal steroid products are not addressed in this policy.

Table 1. Prescription Nasal Steroid Indications.[1-9]

Prescription Brand (generic and dosage form)	FDA-Approved Indications				
	SAR	PAR	Non-Allergic Rhinitis (VMR)	Prevention of nasal polyp recurrence following surgery	Treatment of nasal polyps
Beconase AQ® (beclomethasone dipropionate, monohydrate nasal spray)	≥ 6 years	≥ 6 years	≥ 6 years	≥ 6 years	
Dymista® (azelastine hydrochloride and fluticasone propionate nasal spray, generics)	≥ 6 years				
flunisolide nasal solution (generics only)	≥ 6 years	≥ 6 years			
fluticasone propionate nasal spray (generics only)			≥ 4 years		
Nasonex® (mometasone furoate monohydrate spray, generics)^	≥ 2 years	≥ 2 years			≥ 18 years
Omnaris® (ciclesonide nasal spray)	≥ 6 years	≥ 12 years			
Qnasl® **Qnasl® Children's** (beclomethasone dipropionate nasal aerosol)	≥ 4 years	≥ 4 years			
Xhance™ (fluticasone propionate nasal spray)					≥ 18 years
Zetonna® (ciclesonide nasal aerosol)	≥ 12 years	≥ 12 years			

SAR – Seasonal allergic rhinitis; PAR – Perennial allergic rhinitis; VMR - Vasomotor rhinitis; ^ Mometasone furoate is indicated for treatment of nasal symptoms of allergic rhinitis, treatment of nasal congestion associated with SAR (in patients ≥ 2 years), prophylaxis of SAR (in patients ≥ 12 years), and treatment of nasal polyps (in patients ≥ 18 years).

Guidelines

The American Academy of Otolaryngology (AAO) published a clinical practice guideline for allergic rhinitis in 2015.[23] Nasal steroids are recommended for patients with allergic rhinitis whose symptoms affect their quality of life. Nasal steroids control nasal congestion and also have beneficial effects on ocular allergic symptoms, including itching, tearing, redness, and puffiness. The guidelines do not recommend one nasal corticosteroid product over another; all have comparable efficacy. The AAO guidelines also highlight the available data regarding growth inhibition in children with the nasal corticosteroids. With the data currently available, it is prudent to use preparations of nasal steroids that have not been found to negatively impact growth when prescribing these agents to children.

The AAO clinical practice guideline for adult sinusitis (2015) also addresses the use of nasal steroids.[24] Nasal steroids are recommended as an option for symptomatic relief in patients with viral rhinosinusitis (VRS), despite the fact that these agents are not FDA-approved for use in VRS. In this setting, nasal steroids may relieve facial pain and nasal congestion. Nasal steroids are also an option for symptomatic relief in patients with acute bacterial rhinosinusitis. Mometasone, fluticasone, flunisolide, and budesonide have been studied in this patient population.

The American Academy of Allergy, Asthma, and Immunology (AAAAI), the American College of Allergy, Asthma and Immunology (ACAAI), and the Joint Council of Allergy, Asthma, and Immunology (JCAAI) published a practice parameter for management of rhinitis in 2008 (2017 evidence-based update).[25,26] When comparing the available nasal steroids, the overall clinical response does not appear to vary significantly between products irrespective of the differences in topical potency, lipid solubility, and binding affinity. In addition, the nasal steroids have similar efficacy in relieving ocular symptoms associated with allergic rhinitis. No recommendations are made for one particular nasal corticosteroid vs. another.

POLICY STATEMENT

A step therapy 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 agent at the point of service, coverage will be determined by the step therapy criteria below. Note: Over-the-counter nasal steroids are not addressed in this policy. All approvals are provided for 1 year in duration.

Automation: Patients with a history of one Step 1 drug within the 130-day look-back period are 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, Nasonex, Omnaris, Qnasl, Qnasl Children's, Xhance, Zetonna

CRITERIA

1. If the patient has tried a Step 1 product, then authorization for a Step 2 product may be given.

2. Authorization for mometasone furoate nasal spray or Nasonex may be given for patients < 4 years of age.

3. No other exceptions are recommended.

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4. Nasonex® nasal spray [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; June 2018.
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