

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)

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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 only indicated for the treatment of nasal polyps in adult patients.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 over-the-counter (OTC) status. OTC nasal steroid products are not addressed in this policy.

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

Prescription Brand (generic and dosage form)	FDA-Approved Indications				
	SAR	PAR	Non-Allergic Rhinitis (VMR)	Prevention of nasal polyps*	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, generic)	≥ 6 years				
flunisolide nasal solution (generic only)	≥ 6 years	≥ 6 years			
fluticasone propionate nasal spray (generic only)			≥ 4 years		
mometasone furoate monohydrate spray (generic only) [^]	≥ 2 years	≥ 2 years			≥ 18 years
Omnaris® (ciclesonide nasal spray)	≥ 6 years	≥ 12 years			

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

Prescription Brand (generic and dosage form)	FDA-Approved Indications				
	SAR	PAR	Non-Allergic Rhinitis (VMR)	Prevention of nasal polyps*	Treatment of nasal polyps
Qnasl [®] Qnasl [®] Children's (beclomethasone dipropionate nasal aerosol)	≥ 4 years	≥ 4 years			
Ryaltris [™] (olopatadine hydrochloride/mometasone furoate nasal spray)	≥ 12 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; * Prevention of nasal polyp recurrence following surgery; ^ 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).

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.

Automation: 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; May 2019.
4. Nasonex[®] [prescribing information]. Whitehouse Station, NJ: Merck; September 2020.
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