

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: 05/07/2025

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 over-the-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}

Prescription Brand (generic and dosage form)	FDA-Approved Indications					
	SAR	PAR	Non-Allergic Rhinitis (VMR)	NP* Prevention	CRSsNP Treatment	CRSwNP Treatment
Beconase AQ[®] (beclomethasone dipropionate, monohydrate nasal spray) [discontinued]	≥ 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			

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)	NP* Prevention	CRSsNP Treatment	CRSwNP Treatment
mometasone furoate monohydrate spray (generic only)^	≥ 12 years					≥ 18 years
Omnaris® (ciclesonide nasal spray)	≥ 6 years	≥ 12 years				
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	≥ 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; CRSwNP – Chronic rhinosinusitis with nasal polyps; ^ Prescription mometasone furoate is indicated for prophylaxis of seasonal allergic rhinitis (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 history 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

1. Beconase AQ® nasal spray [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; April 2019.
2. Flonase® nasal spray [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; January 2019.
3. Flunisolide solution [prescribing information]. Bridgewater, NJ: Bausch & Lomb; January 2025.
4. Nasonex® [prescribing information]. Whitehouse Station, NJ: Merck; June 2022.
5. Omnaris® nasal spray [prescribing information]. Zug, Switzerland: Covis; November 2022.
6. Qnasl®/Qnasl® Children’s [prescribing information]. Frazer, PA: Teva; September 2022.
7. Zetonna® [prescribing information]. Zug, Switzerland: Covis; September 2024.
8. Dymista® nasal spray [prescribing information]. Somerset, New Jersey: MEDA; December 2024.
9. Xhance® nasal spray [prescribing information]. Yardley, PA: OptiNose; March 2024.
10. Liquid delivery device. OptiNose Web site. Available at: <http://www.optinose.com/exhalation-delivery-systems/liquid-delivery-device>. Accessed on May 5, 2025.
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19. Ryaltris® nasal spray [prescribing information]. Columbus, OH: Hikma Specialty; May 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	05/17/2023
Annual Revision	No criteria changes.	05/22/2024
Annual Revision	No criteria changes.	05/07/2025

