



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

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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

Prescription Brand (generic and dosage form)	FDA-Approved Indications					
	SAR	PAR	Non-Allergic Rhinitis (VMR)	NP* Prevention	CRSsNP Treatment	CRSwNP Treatment
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.

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

Nasal Steroid Step Therapy product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

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.

REFERENCES

1. Beconase AQ® nasal spray [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; February 2021.
2. Flonase® nasal spray [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; January 2019.
3. Flunisolide solution [prescribing information]. Bridgewater, NJ: Bausch & Lomb; February 2024.
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; February 2023.
8. Dymista® nasal spray [prescribing information]. Somerset, New Jersey: MEDA; August 2022.
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 16, 2024.
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19. Ryaltris® nasal spray [prescribing information]. Columbus, OH: Hikma Specialty; August 2023.

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

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