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Nasal Steroids and Nasal Steroid/Antihistamine Combinations

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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. 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.

Overview

This policy supports medical necessity review for Nasal Steroids and Nasal Steroid/Antihistamine Combination Products.

Coverage for Nasal Steroids and Nasal Steroid/Antihistamine Combination products (**Beconase AQ, Dymista, Nasonex, Omnaris, QNasl Children's, QNasl, Ryaltris, Xhance, and Zetonna**) varies across plans and requires the use of preferred products in addition to the criteria listed below. Refer to the customer's benefit plan document for coverage details.

Nasal Steroid therapy is specifically excluded under some Employer Group Plans [Value, Advantage, and Cigna Total Savings Prescription Drug List Plans]. Please refer to the applicable benefit plan document to determine benefit availability,

Receipt of sample product does not satisfy any criteria requirements for coverage.

Criteria

Coverage criteria are listed for products **in below table:**

Non-Covered Product	Criteria
NASAL STEROIDS	
Beconase AQ® (beclomethasone dipropionate) 42mcg/spray	**Standard/Performance** **Beconase AQ** is medically necessary when there is documentation of failure, contraindication, or intolerance to **ALL** the following: a. flunisolide 25mcg/spray nasal solution b. fluticasone 50mcg/spray nasal suspension c. mometasone furoate 50mcg/spray nasal suspension
Nasonex® (mometasone furoate) 50mcg/spray	**Standard/Performance** **Nasonex** is medically necessary when there is documentation of the following: There is documentation the individual has tried **mometasone furoate 50mcg/spray nasal suspension** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.
Omnaris® (ciclesonide) 50mcg/spray	**Standard/Performance** **Omnaris** is medically necessary when there is documentation of failure, contraindication, or intolerance to **ALL** the following: a. flunisolide 25mcg/spray nasal solution b. fluticasone 50mcg/spray nasal suspension c. mometasone furoate 50mcg/spray nasal suspension
QNasl®, Children's (beclomethasone dipropionate) 40mcg/spray	**Standard/Performance** **QNasl Children's** is medically necessary when there is documentation of failure, contraindication, or intolerance to **ALL** the following: a. flunisolide 25mcg/spray nasal solution b. fluticasone 50mcg/spray nasal suspension c. mometasone furoate 50mcg/spray nasal suspension
QNasl® (beclomethasone dipropionate) 80mcg/spray	**Standard/Performance** **QNasl** is medically necessary when there is documentation of failure, contraindication, or intolerance to **ALL** the following: a. flunisolide 25mcg/spray nasal solution b. fluticasone 50mcg/spray nasal suspension c. mometasone furoate 50mcg/spray nasal suspension
Xhance™ (fluticasone propionate) 93mcg/spray	**Standard/Performance** **Xhance** is medically necessary for the treatment of nasal polyps when there is documentation of **ALL** of the following: 1. 18 years of age or older 2. Medication is prescribed by, or in consultation with, an allergist, immunologist, or otolaryngologist (ear, nose, and throat [ENT]) 3. Failure, contraindication, or intolerance to **ALL** of the following: • flunisolide 25mcg/spray nasal solution • fluticasone 50mcg/spray nasal suspension • mometasone furoate 50mcg/spray nasal suspension
Zetonna®	**Standard/Performance**

Non-Covered Product	Criteria
(ciclesonide) 37mcg/spray	**Zetonna** is medically necessary when there is documentation of failure, contraindication, or intolerance to **ALL** the following: a. flunisolide 25mcg/spray nasal solution b. fluticasone 50mcg/spray nasal suspension c. mometasone furoate 50mcg/spray nasal suspension
NASAL STEROID AND ANTIHISTAMINE COMBINATION NASAL STEROIDS	
Dymista® (azelastine/ fluticasone) 137 mcg/50mcg/spray	**Standard/Performance** **Dymista** is medically necessary when there is documentation of **BOTH** of the following: 1. 6 years of age or older 2. Individual has tried **azelastine/fluticasone 137 mcg/50mcg/spray** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.
Ryaltris™ (olopatadine hydrochloride and mometasone furoate nasal spray)	**Standard/Performance/Value/Advantage/Cigna Total Savings/Legacy** **Ryaltris** is medically necessary when there is documentation of **ALL** of the following: 1. 12 years of age or older 2. Individual is unable to use single agent olopatadine nasal spray and mometasone nasal spray concurrently 3. Failure, contraindication, or intolerance to azelastine/fluticasone nasal spray and **ONE** of the following: • flunisolide 25mcg/spray nasal solution • fluticasone 50mcg/spray nasal suspension • mometasone furoate 50mcg/spray nasal suspension

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Continuation of Therapy

Nasal steroids and nasal steroid/antihistamine combinations are considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration is up to 12 months.
Reauthorization approval duration is up to 12 months.

Conditions Not Covered

Nasal steroids and nasal steroid/antihistamine combinations are considered not medically necessary for ANY other use.

Background

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 chronic rhinosinusitis with 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 CRSwNP
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)^	≥ 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
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).

References

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2. Flonase nasal spray [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; January 2019.
3. Flunisolide solution [prescribing information]. Bridgewater, NJ: Bausch & Lomb; May 2019.
4. Nasonex [prescribing information]. Whitehouse Station, NJ: Merck; June 2022.
5. Omnaris nasal spray [prescribing information]. Zug, Switzerland: Covis; May 2019.
6. Qnasl/Qnasl Children's [prescribing information]. Frazer, PA: Teva; March 2018.
7. Zetonna [prescribing information]. Zug, Switzerland: Covis; February 2023.
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19. Ryaltris™ nasal spray [prescribing information]. Columbus, OH: Hikma Specialty; September 2022.