

Pharmacy Policy Bulletin

Title: Intranasal Corticosteroids

Policy #: Rx.01.45

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

▶ **Intent:**

The intent of this policy is to communicate the medical necessity criteria for **beclomethasone (Beconase AQ®), fluticasone propionate (Xhance™), ciclesonide (Omnaris®), beclomethasone (Qnasl®/ Qnasl®Children's), mometasone furoate (Nasonex®), azelastine hydrochloride and fluticasone propionate (Dymista®), and ciclesonide (Zetonna®)** as provided under the member's prescription drug benefit.

▶ **Description:**

Intranasal steroids are used for a variety of disorders including nasal polyps, non-allergic rhinitis, perennial allergic rhinitis and seasonal allergic rhinitis.

Intranasal steroids provide anti-inflammatory effects on the nasal mucosa. Their exact mechanism is unknown but corticosteroids have been shown to have a wide range of actions on multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, cytokines) involved in inflammation.

▶ **Policy:**

1. For the management of nasal polyps (treatment or prevention of reoccurrence), Beconase AQ® fluticasone propionate (Xhance™), and mometasone (Nasonex®), are approved when there is inadequate response or inability to tolerate generic fluticasone propionate; OR

2. For all other FDA approved indications, Beconase AQ®, Children's Qnasl®*, azelastine hydrochloride and fluticasone propionate (Dymista), mometasone (Nasonex®), Omnaris®, Qnasl®, and Zetonna® are approved when there is inadequate response or inability to tolerate BOTH of the following generic nasal sprays:

- a. Flunisolide; AND
- b. Fluticasone propionate

*Fluticasone propionate is approved for children under 6 years of age

▶ **Black Box Warning as shown in the drug Prescribing Information:**

None

▶ **Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

▶ **References:**

Beconase AQ (beclomethasone dipropionate) [package insert]. Research Triangle Park, NC. GlaxoSmithKline. September 2015. Available at: https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Beconase_AQ/pdf/BECONASE-PI-PIL.PDF Accessed on February 18, 2019.

Dymista (azelastine hydrochloride and fluticasone propionate) [package insert]. Somerset, NJ. Meda Pharmaceutical. September 2015. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/202236s008lbl.pdf. Accessed on February 18, 2019.

Nasonex® (mometasone) [package insert]. Whitehouse Station, NJ. Merck and Co, Inc. June 2018. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=12df48a0-fd2e-4e1c-b135-e616a1f31f42&type=display>. Accessed on February 18, 2019.

Qnasl® (beclomethasone) [package insert]. Northridge, CA. Teva Respiratory, LLC. March 2018. Available at: <http://qnasl.com/Content/pdf/pi.pdf> Accessed on February 18, 2019.

Omnaris (ciclesonide) [package insert]. Marlborough, MA. Sunovion Pharmaceuticals, Inc. March 2013. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=a131e33f-00dc-4601-88b3-ab19b24865ee&type=display>. Accessed on February 18, 2019.


Zetonna (ciclesonide) [package insert]. Marlborough, MA. Sunovion Pharmaceuticals, Inc. October 2014. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=0abe441f-804f-4feb-8c8c-9169fcf002bf&type=display>. Accessed on February 18, 2019.

Seidman MD et al. Clinical practice guideline: allergic rhinitis executive summary. Otolaryngol Head Neck Surg. 2015 Feb; 152(2): 197-206.

Wallace DV et al. Pharmacologic treatment of seasonal allergic rhinitis: synopsis of guidance from the 2017 Joint Task Force on practice parameters. Ann Intern med. 2017 Dec 19; 167(12):867-881.

Peters AT et al. Diagnosis and management of rhinosinusitis: a practice parameter update. Ann Allergy Asthma Immunol. 2014 Oct; 113(4): 347-85.

Applicable Drugs:

 Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Beconase AQ®	beclomethasone
Dymista®	azelactine hydrochloride and fluticasone propionate
Nasonex®	mometasone furoate
Omnaris®	ciclesonide
Qnasl®	beclomethasone dipropionate
Qnasl®Childrens	beclomethasone dipropionate
Zetonna®	ciclesonide
Xhance™	Fluticasone propionate

Cross References:

N/A

Policy Version Number:	17.00
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Policy Effective Date:	April 01, 2019
Next Required Review Date:	January 10, 2020

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.