



**Medication Policy Manual**

**Policy No:** dru448

**Topic:** high-cost nasal corticosteroid-containing products:

**Date of Origin:** February 12, 2016

- Beconase AQ<sup>®</sup>
- budesonide nasal (generic, Rhinocort Aqua<sup>®</sup>)
- DermacinRx<sup>®</sup> Azenase Pak
- Dymista<sup>®</sup>
- mometasone nasal (generic, Nasonex<sup>®</sup>)
- Omnaris<sup>®</sup>
- Qnasl<sup>®</sup>
- Veramyst<sup>®</sup>
- Xhance<sup>®</sup>
- Zetonna<sup>®</sup>

**Committee Approval Date:** October 12, 2017

**Next Review Date:** February 2018

**Effective Date:** October 12, 2017

**IMPORTANT REMINDER**

This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medication policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

**Description**

Beconase AQ, budesonide nasal (generic, Rhinocort Aqua), mometasone nasal (generic, Nasonex), Omnaris, Qnasl, Veramyst, Xhance, and Zetonna are inhaled nasal corticosteroids (sprays and aerosols) used to treat nasal allergy symptoms. Fluticasone/azelastine nasal spray (Dymista) and DermacinRx Azenase Pak are a combination inhaled corticosteroid antihistamine nasal spray also used to treat nasal allergy symptoms.

## Policy/Criteria

- I. Most contracts require prior authorization approval of high-cost nasal corticosteroid-containing products prior to coverage. High-cost nasal corticosteroid products may be considered medically necessary when criterion A or B below is met.
- A. Beconase AQ, budesonide nasal (generic, Rhinocort Aqua), mometasone nasal (generic, Nasonex), Omnaris, Qnasl, Veramyst, Xhance, and Zetonna may be considered medically necessary when two low-cost nasal corticosteroids (listed in Appendix 1) have been ineffective, contraindicated, or not tolerated.

### OR

- B. Nasal corticosteroids included in Table 1 may be considered medically necessary when there is an intolerance or contraindication to an **inactive ingredient** in all specified alternative(s) listed in Table 1.

**Table 1. High cost nasal corticosteroids with comparable alternatives**

High Cost Drug	Alternative(s)
DermacinRx Azenase Pak	fluticasone propionate + azelastine
Dymista	fluticasone propionate + azelastine

- II. Administration and Authorization Period
- A. OmedaRx considers high-cost nasal corticosteroid-containing products to be self-administered medications.
- B. Authorization may be reviewed at least annually to confirm that current medical necessity criteria are met and that the medication is effective.

## Position Statement

- All nasal corticosteroid-containing products have similar efficacy and safety, as there is a lack of conclusive evidence to differentiate the products.
- For the treatment of seasonal allergic rhinitis, perennial allergic rhinitis or nasal polyps, there is no evidence demonstrating the superiority of one nasal corticosteroid-containing product over another.
- Low-cost generic options in the nasal corticosteroid class (flunisolide, fluticasone, and triamcinolone) provide the best value.
- Low-cost generic nasal corticosteroid-containing products have been well-studied and have a long track record of safety and efficacy with adults and children as young as age 2.
- Fluticasone propionate and azelastine are both available as low-cost generic options and contain the same active ingredients as Dymista (fluticasone/azelastine) and DermacinRx Azenase Pak (fluticasone/azelastine). There is no evidence that the high cost brand products are more effective or safer than the lower cost alternatives.

### *Clinical Efficacy*

- There is no clear evidence supporting the superiority of one nasal corticosteroid-containing product over another in the treatment of seasonal or perennial allergic rhinitis. [1, 2]
- Nasal corticosteroids appear to offer superior symptom relief in allergic rhinitis compared to antihistamines. [2, 3]
- There is no evidence supporting the superiority of the branded combination product, azelastine/fluticasone propionate (Dymista), over the many low-cost generically available intranasal corticosteroid and antihistamine products. [2,3]
- National (American Academy of Allergy, Asthma & Immunology, AAAAI) and International (British Society for Allergy and Clinical Immunology) allergic rhinitis guidelines consider all of the nasal corticosteroid products to have similar effectiveness. [4, 5]

### *Safety [2,4]*

- All nasal corticosteroids have similar side effect profiles.
- Studies in both children and adults have failed to demonstrate any consistent, clinically relevant effect from nasal corticosteroids on the hypothalamic-pituitary-adrenal (HPA) axis, ocular pressure or cataract formation, or bone density.[2,4]
- Nasal corticosteroids have been used during pregnancy. There is insufficient evidence that demonstrates that one nasal steroid is safer in pregnancy than another. Beclomethasone (Pregnancy Category C) and budesonide (Pregnancy Category B), and fluticasone propionate (Pregnancy Category C) have more accumulated safety data than triamcinolone, mometasone, and flunisolide,[4] as well as ciclesonide.
- The most common side effects from nasal corticosteroids include local nasal irritation, sore throat and nose bleeds. Nasal antihistamines may have a bitter aftertaste and cause sedation.
- Proper administration technique may help to minimize side effects.

### **Appendix 1: Low-Cost Generic Nasal Corticosteroid Product Alternatives**

- budesonide (OTC Rhinocort Allergy®) <sup>a</sup>
- flunisolide (generic Nasarel®)
- fluticasone propionate (generic Flonase® or OTC Flonase Allergy Relief®)
- triamcinolone (generic Nasacort AQ® or OTC Nasacort Allergy 24 hr®)

<sup>a</sup> Budesonide (generic, prescription) is considered a high-cost option.

OTC: over-the-counter, non-prescription

<b>Appendix 2: Subpopulation considerations for nasal corticosteroid-containing products</b> [6]		
	<b>Age<sup>a</sup></b>	<b>Pregnancy category</b>
<b><i>Low-Cost products</i></b>		
flunisolide	≥ 6 years	C
fluticasone propionate	≥ 4 years	C
triamcinolone	≥ 2 years	C
<b><i>High-cost products</i></b>		
Beconase AQ (beclomethasone)	≥ 6 years	C
budesonide	≥ 6 years	B
Dymista (fluticasone propionate/azelastine)	≥12 years	C
Nasonex (mometasone)	≥ 2 years	C
Omnaris (ciclesonide)	≥ 6 years	C
Qnasl (beclomethasone aerosol)	≥4 years	C
Veramyst (fluticasone furoate)	≥ 2 years	C
Xhance (fluticasone propionate)	≥18 years	
Zetonna (ciclesonide aerosol)	≥12 years	C

<sup>a</sup> FDA-approved for use in the listed age groups

<b>Cross References</b>
None

<b>Codes</b>	<b>Number</b>	<b>Description</b>
N/A		

## References

- Nielsen LP, Dahl R. Comparison of intranasal corticosteroids and antihistamines in allergic rhinitis: a review of randomized, controlled trials. *Am J Respir Med.* 2003; 2(1):55-65. PMID: 14720022.
- Glacy J, Putnam K, Godfrey S, Falzon L, Mauger B, Samson D, et al. Treatments for Seasonal Allergic Rhinitis. Comparative Effectiveness Review No. 120. (Prepared by the Blue Cross and Blue Shield Association Technology Evaluation Center Evidence-based Practice Center under Contract No. 290-2007-10058-I.) AHRQ Publication No.13-EHC098-EF. Rockville, MD: Agency for Healthcare Research and Quality; July 2013. Available online at: [www.effectivehealthcare.ahrq.gov/reports/final.cfm](http://www.effectivehealthcare.ahrq.gov/reports/final.cfm)
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2002. Available online at: <http://www.ncbi.nlm.nih.gov/books/NBK11954/>
4. Wallace, et al. The American Academy of Allergy, Asthma & Immunology, Inc. (AAAAI) The diagnosis and management of rhinitis: An updated practice parameter. 2008. *J Allergy Clin Immunol.* 122(2) S1-S84. PMID: 18662584.
  5. Scadding GK, Durham SR, Mirakian R, et al. BSACI guidelines for the management of allergic and non-allergic rhinitis. *Clin Exp Allergy.* 2008; 38:19-42. PubMed PMID: 18081563.
  6. Facts & Comparisons 4.0 (electronic version, updated periodically). Wolters Kluwer Health, Inc.

*Revision History*

<b>Revision Date</b>	<b>Revision Summary</b>
10/12/2017	Added new fluticasone formulation (Xhance) to policy.
2/17/2017	No changes to criteria with this annual update.
2/12/2016	New policy, re-named to “high-cost,” to allow for step therapy with the new high-cost generics and encourage the use of the lowest cost generic (and OTC) options.
3/28/2016	Added generic mometasone nasal and DermacinRx Azenase Pak to policy.
9/9/2016	Updated criteria for Dymista and DermacinRx Azenase Pak, to allow coverage in limited populations.