

## Pharmacy Medical Necessity Guidelines: Nasal Corticosteroid Medications

Effective: May 12, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p><b>Commercial Products</b></p> <input type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input type="checkbox"/> Tufts Health Freedom Plan products – small group plans <ul style="list-style-type: none"> <li>CareLink<sup>SM</sup> – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</li> </ul> <p><b>Tufts Health Public Plans Products</b></p> <input type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan		<p><b>Fax Numbers:</b>  RXUM:  617.673.0988</p>	

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

### OVERVIEW

#### FDA-APPROVED INDICATIONS

##### **Beclomethasone:**

- Beconase AQ is indicated for the relief of symptoms of seasonal or perennial allergic and nonallergic (vasomotor) rhinitis. It is also indicated for the prevention of recurrence of nasal polyps following surgical removal. The safety and effectiveness of Beconase AQ nasal spray have been established in children aged 6 years and older.
- Qnasl is indicated for the treatment of the nasal symptoms associated with seasonal and perennial allergic rhinitis in patients 4 years of age and older.

**Budesonide** intranasal is indicated for the management of nasal symptoms of seasonal or perennial allergic rhinitis in adults and children 6 years of age and older.

##### **Ciclesonide:**

Omnaris and Zetonna are indicated for the treatment of nasal symptoms associated with perennial allergic rhinitis in adults and adolescents 12 years and older, and for the treatment of nasal symptoms associated with seasonal allergic rhinitis in adults and children 6 years and older (Omnaris) or adults and adolescents 12 years and older (Zetonna).

**Flunisolide** intranasal (generic, Nasarel) is indicated for the relief and management of nasal symptoms of seasonal and perennial allergic rhinitis.

##### **Fluticasone:**

- Flonase (generic and Flonase Rx) is indicated for the management of the nasal symptoms of seasonal and perennial allergic and nonallergic rhinitis in patients 4 years and older.
- Flonase OTC is indicated for the relief of hay fever or other upper respiratory allergies (e.g., itchy and watery eyes, nasal congestion, runny nose, sneezing, itchy nose) in patients 4 years and older.
- Flonase Sensimist is indicated for the relief of hay fever or other upper respiratory allergies (e.g., itchy and watery eyes, nasal congestion, runny nose, sneezing, itchy nose) in patients 2 years of age and older.

**Mometasone** (Nasonex) is indicated for the treatment of the nasal symptoms of seasonal allergic and perennial allergic rhinitis in adults and children 2 years of age and older, for the treatment of nasal congestion associated with seasonal allergic rhinitis in adults and children 2 years of age and older, for

the treatment of nasal polyps in patients 18 years of age and older, and for the prophylaxis of the nasal symptoms of for seasonal allergic rhinitis in adults and children 12 years of age and older.

**Triamcinolone:**

- Generic triamcinolone and Nasacort Rx are indicated for the management of seasonal and perennial allergic rhinitis in adults and children 2 years and older.
- Nasacort OTC is indicated for the relief of hay fever and other upper respiratory allergies (e.g., nasal congestion, runny nose, sneezing, itchy nose) in adults and children 2 years and older.

<b>Tufts Health RITogether Preferred Drug List Status</b>		
<b>Brand Name</b>	<b>Generic Name</b>	<b>Utilization Management (UM)</b>
Beclomethasone	Beconase AQ	PA
<b>Rhinocort Aqua<sup>1</sup></b>	<b>Budesonide 32mcg*</b>	<b>Covered</b>
Flunisolide (Nasarel) <sup>1</sup>	Flunisolide	PA
<b>Fluticasone (Flonase)<sup>1</sup></b>	<b>Fluticasone propionate*</b>	<b>Covered</b>
Nasonex <sup>1</sup>	Mometasone Furoate	PA
Omnaris	Ciclesonide	PA
Qnasl, Qnasl Childrens	Beclomethasone Dipropionate	PA
<b>Triamcinolone (Nasacort AQ)<sup>1</sup></b>	<b>Triamcinolone acetonide*</b>	<b>Covered</b>
Flonase Sensimist	Fluticasone Furoate	PA
Zetonna	Ciclesonide	PA

**\* Preferred products are the generic formulations, budesonide, fluticasone, and OTC triamcinolone.**

<sup>1</sup> Brand name medications with AB-rated generics are non-covered. They are included in the table to serve as a reference. Requests for the brand-name products, with AB-rated generics, will also require review according to Brand Name criteria.

**COVERAGE GUIDELINES**

The plan may authorize coverage of a non-preferred nasal corticosteroid agent for Members when one of the following criterions is met and limitations do not apply:

1. The Member has tried and failed therapy with two of the preferred nasal corticosteroid agents: fluticasone (generic Flonase), budesonide (generic Rhinocort), and OTC triamcinolone (Nasacort)
- OR**
2. The Member is between 2 and 4 years of age with the diagnosis of allergic rhinitis and has tried and failed therapy with intranasal triamcinolone (Nasacort)

**LIMITATIONS**

1. Requests for brand-name products, with AB-rated generics, will also be reviewed according to Brand Name criteria.

**CODES**

None

**REFERENCES**

1. Beconase AQ (beclomethasone dipropionate monohydrate) [package insert]. Research Triangle Park, NC: GlaxoSmithKline; April 2019.
2. Nasacort AQ (triamcinolone) [package insert]. Bridgewater, NJ: Aventis; 2002.
3. Rhinocort Aqua (budesonide) [package insert]. Wilmington, DE: AstraZeneca; December 2010.
4. Flunisolide [package insert]. Allendale, NJ: Rising Pharmaceuticals; January 2012.
5. Flonase (fluticasone propionate) [package insert]. Research Triangle Park, NC: GlaxoSmithKline; January 2019.
6. Nasonex (mometasone furoate) [package insert]. Whitehouse, NJ: Merck & Co., Inc.; June 2018.
7. Omnaris (ciclesonide) [package insert]. Zug, Switzerland: Covis Pharma; May 2019.
8. Zetonna (ciclesonide) [package insert]. Marlborough, MA: Sunovion Pharmaceuticals; October 2014.
9. Qnasl (beclomethasone dipropionate) [package insert]. Frazer, PA: Teva Respiratory; March 2018.

**APPROVAL HISTORY**

February 10, 2015: Reviewed by Pharmacy & Therapeutics Committee; approval duration limited to one year; triamcinolone (Nasacort) over-the-counter added as a preferred agent.

Subsequent endorsement date(s) and changes made:

1. September 16, 2015: Approval duration approved for life of plan.
2. January 1, 2016: Administrative change to rebranded template.
3. January 12, 2016: Updated FDA-approval for Qnasl which is indicated in patients 4 years of age and older; added a table depicting the PDL status of the medications; no change in clinical criteria.
4. January 10, 2017: No changes.
5. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether. Updated criteria to require a trial and failure of two preferred agents.
6. April 10, 2018: Administrative update, updated the name of Veramyst to Flonase Sensimist
7. March 12, 2019: Effective 4/1/2019, updated criteria to indicate that budesonide is covered. Administrative changes made to template. Effective 7/1/2019, updated criteria to indicate the flunisolide requires prior authorization.
8. June 11, 2019: Administrative update, added Beconase AQ to the coverage chart in the background section of the MNG.
9. May 12, 2020: No changes.

#### **BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION**

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

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