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.

Medical Necessity Criteria

Coverage for nasal steroids and nasal steroid/antihistamine combinations varies across plans. Refer to the customer’s benefit plan document for coverage details.

Where coverage requires the use of preferred products, the following criteria apply.

For Employer Group Plans:

<table>
<thead>
<tr>
<th>Product</th>
<th>Standard Drug List Plan</th>
<th>Value Drug List Plan</th>
<th>Legacy Drug List Plan</th>
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</thead>
<tbody>
<tr>
<td><strong>Nasal Steroids</strong></td>
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</table>
| Beconase AQ® (beclomethasone dipropionate 42mcg/spray) | ● Documented failure / inadequate response, contraindication per FDA label, intolerance, inability to use, or not a candidate for **ALL** of the following:  
  ▪ flunisolide 25mcg/spray nasal solution  
  ▪ fluticasone 50mcg/spray nasal suspension  
  ▪ mometasone furoate 50mcg/spray nasal suspension | Non-preferred Brands (subject to step therapy, please refer to the related coverage policy links above) |
<table>
<thead>
<tr>
<th>Drug</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Omnaris®</strong></td>
<td>(ciclesonide 50mcg/spray)</td>
</tr>
<tr>
<td><strong>QNasi®</strong>, Children’s</td>
<td>(beclomethasone dipropionate 40mcg/spray)</td>
</tr>
<tr>
<td><strong>QNasi®</strong></td>
<td>(beclomethasone dipropionate 80mcg/spray)</td>
</tr>
<tr>
<td><strong>Zetonna®</strong></td>
<td>(ciclesonide 37mcg/spray)</td>
</tr>
<tr>
<td><strong>Xhance™</strong></td>
<td>(fluticasone propionate 93mcg/spray)</td>
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**ALL of the following:**

- Individual is 18 years of age or older
- Documented diagnosis of nasal polyps as evidenced by **BOTH** of the following:
  - Symptoms persisting for at least 12 weeks (for example; nasal obstruction, rhinorrhea, or reduction/loss of smell)
  - Evidence of nasal polyposis by direct examination, endoscopy, or sinus CT scan
- Documented failure / inadequate response, contraindication per FDA label, intolerance, inability to use, or not a candidate for intranasal corticosteroid therapy at appropriate doses to treat nasal polypsis with **TWO** of the following:
  - flunisolide 25mcg/spray nasal solution
  - fluticasone 50mcg/spray nasal suspension
  - mometasone furoate 50mcg/spray nasal suspension
- Prescribed by, or in consultation with, an allergist, immunologist, or otolaryngologist (ear, nose, and throat [ENT])

<table>
<thead>
<tr>
<th>Nasal Steroid + Antihistamine Combination</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Dymista®</strong></td>
<td>(azelastine 137mcg/ fluticasone 50mcg/spray)</td>
</tr>
</tbody>
</table>

**ALL of the following:**

- Documented intolerance to 1 generic formulation of Dymista® nasal spray or intolerance to concurrent use of azelastine (0.1% or 0.15%) and fluticasone nasal sprays as separate agents.
- Documented failure / inadequate response, contraindication per FDA label, intolerance, inability to use, or not a candidate for concurrent use of azelastine (0.1% or 0.15%) nasal spray **AND BOTH** of the following intranasal corticosteroids:
  - flunisolide 25mcg/spray nasal solution
  - mometasone 50mcg/spray nasal suspension

<table>
<thead>
<tr>
<th>Non-preferred Brand</th>
<th>Description</th>
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<tr>
<td></td>
<td>(subject to step therapy, please refer to the related coverage policy links above)</td>
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</table>
Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

*If you're a Cigna provider, please log in to the Cigna for Health Care Professionals website and search for specific patients to view their covered medications.

**FDA Summary**

**Indications**
All of the prescription nasal steroids, with the exception of Xhance, are used for the treatment of seasonal allergic rhinitis (SAR) and/or perennial allergic rhinitis (PAR). The over-the-counter (OTC) nasal steroid products are labeled to temporarily relieve symptoms of hay fever or other upper respiratory allergies. Xhance is only indicated for the treatment of nasal polyps.

- Flonase, Nasacort AQ, Rhinocort, and Veramyst have been changed from prescription to OTC status; therefore, the branded prescription products have been discontinued. Some prescription generics to these brands remain available.
- For rhinitis, Nasacort Allergy 24HR OTC, triamcinolone acetonide, mometasone furoate, Flonase Sensimist OTC, and Veramyst are indicated in patients ≥ 2 years old; Flonase Allergy Relief OTC, fluticasone propionate, and Qnasl are indicated in patients ≥ 4 years old; Beconase AQ, Dymista, flunisolide, Rhinocort Allergy Spray OTC, and budesonide are indicated in patients ≥ 6 years old; Omnaris is indicated for SAR in children ≥ 6 years old and for PAR in children ≥ 12 years old; Zetonna is indicated in patients ≥ 12 years old.
- Xhance and mometasone nasal spray are indicated for the treatment of nasal polyps in patients ≥ 18 years of age; Beconase AQ is approved for the prevention of nasal polyp recurrence following surgical removal in patients ≥ 6 years of age. However, several other nasal steroids (e.g., fluticasone propionate, budesonide, triamcinolone acetonide, Veramyst) have also been found to be effective in reducing nasal polyp size and rhinitis symptoms associated with nasal polyps in clinical trials.

**Dosing**
All of the single-entity and combination nasal steroids, with the exception of Beconase AQ, Dymista, flunisolide, and Xhance, may be administered once daily (QD).

**Formulation/Device Considerations**
The sensory attributes of each nasal steroid product may have an important role in product selection and adherence to therapy. Nasal steroids are available as aqueous (“wet”) and aerosol (“dry”) [Qnasl and Zetonna only] formulations. Some patients may prefer aerosol products due to less anterior/posterior runoff and subsequently less throat irritation. However, many patients find aqueous products to provide a soothing (moistening) effect. Xhance utilizes an exhalation delivery system (EDS). The patient places the nosepiece deep into one nostril and mouthpiece into the mouth and then blows into the mouthpiece while simultaneously actuating the spray pump. This closes the soft palate and creates “positive-pressure” which expands nasal passages, allowing for higher and deeper drug deposition.

**Background**
Employer group plans may adopt a Prescription Drug List that does not cover certain drugs or biologics unless those products are approved based on a medical necessity review as there are generally covered therapeutic alternatives available. Covered therapeutic alternatives are products usually in the same therapeutic class that can be expected to have equivalent clinical efficacy and safety when administered to patients under the conditions specified in the FDA-approved product information (Label). The number of Covered Alternative Drugs may vary by employer group plan and Prescription Drug Lists (e.g. “closed” versus “open” formulary plan designs).
Generics
The FDA's generic drug approval process does not require the drug sponsor to repeat costly animal and clinical research on ingredients or dosage forms already approved for safety and effectiveness. Generic drugs must establish the following for approval:
• contain the same active ingredients as the innovator drug (inactive ingredients may vary)
• be identical in strength, dosage form, and route of administration
• have the same use indications
• be bioequivalent
• meet the same batch requirements for identity, strength, purity, and quality
• be manufactured under the same strict standards of FDA's good manufacturing practice regulations required for innovator products

A generic drug is the same as a brand-name drug in dosage, safety, strength, quality, the way it works, the way it is taken and the way it should be used. FDA requires generic drugs have the same high quality, strength, purity and stability as brand-name drugs. Not every brand-name drug has a generic drug. When new drugs are first made they have drug patents. Most drug patents are protected for 20 years. The patent, which protects the company that made the drug first, doesn't allow anyone else to make and sell the drug. When the patent expires, other drug companies can start selling a generic version of the drug. But, first, they must test the drug and the FDA must approve it.

Guidelines
Current rhinitis guidelines state that the nasal steroids are the most effective agents for the treatment of nasal congestion and other symptoms of allergic rhinitis (AR). Current guidelines on the management of nasal polyps recommend corticosteroid nasal sprays to reduce nasal polyp size and improve associated nasal symptoms. These guidelines have not been updated to include Xhance. One nasal steroid is not recommended over another for rhinitis or nasal polyps. (AAAAI/ACAAI/JCAAI, 2008 & 2017; Seidman, 2015)

References
3. Joint Task Force on Practice Parameters: American Academy of Allergy, Asthma and Immunology; the American College of Allergy, Asthma and Immunology; and the Joint Council of Allergy, Asthma and Immunology. The diagnosis and management of rhinitis: An updated practice parameter. J Allergy Clin Immunol. 2008;122(2):S1-S84.