Clinical Policy: Mometasone (Nasonex)
Reference Number: HIM.PA.93
Effective Date: 12.01.14
Last Review Date: 08.20
Line of Business: HIM

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Mometasone (Nasonex®) is a corticosteroid.

FDA Approved Indication(s)
Nasonex is indicated for the:
- Treatment of the nasal symptoms of seasonal allergic and perennial allergic rhinitis, in adults and pediatric patients 2 years of age and older
- Relief of nasal congestion associated with seasonal allergic rhinitis, in adults and pediatric patients 2 years of age and older
- Prophylaxis of the nasal symptoms of seasonal allergic rhinitis in adult and adolescent patients 12 years and older
- Treatment of nasal polyps in patients 18 years of age and older

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Nasonex is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Allergic Rhinitis or Nasal Polyps (must meet all):
      1. Diagnosis of allergic rhinitis or nasal polyps;
      2. Member meets one of the following (a or b):
         a. Request for allergic rhinitis: Age ≥ 2 years;
         b. Request for nasal polyps: Age ≥ 18 years;
      3. Failure of intranasal fluticasone (generic Flonase®) or intranasal triamcinolone (generic Nasacort®), unless clinically significant adverse effects are experienced or both are contraindicated;
      4. Dose does not exceed 400 mcg per day (8 sprays per day, or 2 bottles per 30 days).
   Approval duration: 12 months

   B. Other diagnoses/indications
      1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.
II. Continued Therapy
   A. Allergic Rhinitis or Nasal Polyps (must meet all):
      1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
      2. Member is responding positively to therapy;
      3. If request is for a dose increase, new dose does not exceed 400 mcg per day (8 sprays per day, or 2 bottles per 30 days).
   
   Approval duration: 12 months

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
      2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

III. Diagnoses/Indications for which coverage is NOT authorized:
   A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PHAR.21 for health insurance marketplace.

IV. Appendices/General Information
   Appendix A: Abbreviation/Acronym Key
   FDA: Food and Drug Administration

   Appendix B: Therapeutic Alternatives
   This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/ Maximum Dose</th>
</tr>
</thead>
</table>
| fluticasone propionate (Flonase®) | Age ≥ 12 years: 2 sprays in each nostril BID  
                                  Age 2 to 11 years: 1 spray in each nostril BID | 4 sprays/nostril/day |
| triamcinolone (Nasacort®) | Age ≥ 6 years: 1-2 sprays in each nostril QD  
                                    Age 2 to 5 years: 1 spray in each nostril QD | 4 sprays/nostril/day |

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

   Appendix C: Contraindications/Boxed Warnings
   - Contraindication(s): known hypersensitivity to mometasone furoate or any of the ingredients of Nasonex
   - Boxed warning(s): none reported

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
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<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allergic rhinitis</td>
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<td>2 sprays/nostril/day</td>
</tr>
</tbody>
</table>
**Indication** | **Dosing Regimen** | **Maximum Dose**
--- | --- | ---
Age ≥ 12 years | 2 sprays in each nostril | QD
Age ≥ 18 years | 2 sprays in each nostril | BID 4 sprays/nostril/day

**VI. Product Availability**
Nasal spray: 50 mcg/100 mcL spray

**VII. References**
### Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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