Clinical Policy: Mometasone (Nasonex)

Reference Number: HIM.PA.93
Effective Date: 12.01.14
Last Review Date: 08.20
Line of Business: HIM

Revision Log

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.
   Approval duration: Duration of request or 12 months (whichever is less); or
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 or evidence of coverage documents.

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.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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

Indication	Dosing Regimen	Maximum Dose
Allergic rhinitis	Age 2-11 years: 1 spray in each nostril QD	2 sprays/nostril/day

Indication	Dosing Regimen	Maximum Dose
	Age ≥ 12 years: 2 sprays in each nostril QD	
Nasal polyps	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

1. Nasonex Prescribing Information. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; July 2019. Available at: https://www.merck.com/product/usa/pi_circulars/n/nasonex/nasonex_pi.pdf. Accessed April 6, 2020.
2. Jankowski R, Klossek JM, Attali V, Coste A, Serrano E. Long-term study of fluticasone propionate aqueous nasal spray in acute and maintenance therapy of nasal polyposis. Allergy. 2009; 64(6): 944-50.
3. Stjärne P, Blomgren K, Cayé-Thomasen P, Salo S, Søderstrøm T. The efficacy and safety of once-daily mometasone furoate nasal spray in nasal polyposis: a randomized, double-blind, placebo-controlled study. Acta Otolaryngol. 2006 Jun;126(6):606-12.
4. Filiaci F, Passali D, Puxeddu R, Schrewelius C. A randomized controlled trial showing efficacy of once daily intranasal budesonide in nasal polyposis. Rhinology. 2000 Dec;38(4):185-90.
5. Lund VJ, Flood J, Sykes AP, Richards DH. Effect of fluticasone in severe polyposis. Arch Otolaryngol Head Neck Surg. 1998 May;124(5):513-8.
6. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed April 6, 2020.
7. Wallace DV, Dykewicz MS, Bernstein DI, et al. The diagnosis and management of rhinitis: an updated practice parameter. J Allegy Clin Immunol. 2008. 122(2 Suppl): S1-S84.
8. Wallace DV, Dykewicz MS, Oppenheimer J 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):876-881. doi: 10.7326/M17-2203.
9. Dykewicz MS, Wallace DV, Baroody F, et al. Treatment of seasonal allergic rhinitis: An evidence-based focused 2017 guideline update. Ann Allergy Immunol. 2017; 119: 489-511.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Expanded approval to all FDA approved indications. Removed workflow document. Updated referenced to reflect current literature search.	08.16	08.16
Converted to new template. Updated policy name from "Nasal Steroids" to mometasone (Nasonex) since generic budesonide (Rhinocort Aqua) no longer requires a PA per formulary; added max dose. Updated references.	04.17	08.17
3Q 2018 annual review: no significant changes; added age; references reviewed and update.	06.16.18	08.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2019 annual review: no significant changes; references reviewed and updated.	04.22.19	08.19
3Q 2020 annual review: no significant changes; modified from t/f any 2 formulary intranasal steroids to 1 intranasal corticosteroid (either generic Flonase or generic Nasacort) per SDC decision 1/23/18; references reviewed and updated.	04.06.20	08.20

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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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