MEDICAL MUTUAL®

Drug Policy

Policy:	**Intranasal Steroids Preferred Step Therapy**	**Annual Review Date:** **01/18/2024**
Impacted Drugs:	**Azelastine/fluticasone** **Dymista** **Mometasone furoate**	**Last Revised Date:** **01/18/2024**

OVERVIEW

Nasal corticosteroids are indicated for the treatment of symptoms of seasonal allergic rhinitis (SAR) and perennial allergic rhinitis (PAR). No clinical studies directly compare all of the agents in this class. In the absence of more comprehensive data, single comparison clinical trials must suffice to give a general indication of the comparability of these agents. Comparative clinical studies suggest that, at equipotent doses, the intranasal corticosteroids have similar efficacy in the treatment of allergic rhinitis (AR) and perhaps non-allergic rhinitis; however, individual responses to agents may vary. The newer single-agent nasal corticosteroids have demonstrated higher topical potency; the clinical significance of this difference in potency has not been established.

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

Preferred Medication

- Generic fluticasone propionate nasal spray
- Generic flunisolide nasal spray

Non-Preferred Medication

- Dymista
- Generic azelastine/fluticasone nasal spray
- Generic mometasone furoate nasal spray

PREFERRED STEP THERAPY CRITERIA

1. If the patient has EXPERIENCED INTOLERANCE (that is, sensitivity, drug allergy, or adverse effect) OR THERAPEUTIC FAILURE with the use of a preferred product, then a nonpreferred product may be approved.
2. If the patient is between the ages of 2 and 4 years old, approve mometasone furoate nasal spray.

Approval Duration: 365 days (1 year)

MEDICAL MUTUAL®

Drug Policy

Step Therapy Exception Criteria
In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Approval Duration: 365 days (1 year)

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or

performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Beconase AQ® nasal spray [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; April 2019.
2. Flonase® nasal spray [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; January 2019.
3. Flunisolide solution [prescribing information]. Bridgewater, NJ: Bausch & Lomb Inc.; May 2019.
4. Nasonex® nasal spray [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; September 2020.
5. Omnaris® nasal spray [prescribing information]. Zug, Switzerland: Covis Pharma; May 2019.
6. Qnasl®/Qnasl® Children's [prescribing information]. Frazer, PA: Teva Respiratory; March 2018.
7. Veramyst® nasal spray [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; July 2016.
8. Zetonna® [prescribing information]. Zug, Switzerland: Covis Pharma; December 2021.
9. Dymista® nasal spray [prescribing information]. Somerset, New Jersey: MEDA Pharmaceuticals; April 2021.
10. Nasacort® Allergy 24HR nasal spray OTC/Child Nasacort® Allergy 24HR nasal spray OTC [drug label information]. Chattanooga, TN: Chattem, Inc.; October 2018.
11. Flonase® Allergy Relief nasal spray OTC/Child Flonase® Allergy Relief nasal spray OTC [drug label information]. Parsippany, NJ: GlaxoSmithKline Consumer Healthcare LP; August 2017.
12. Rhinocort® Allergy Spray OTC [drug label information]. Fort Washington, PA: Johnson & Johnson Consumer Inc./McNeil Consumer Healthcare; May 2017.
13. Flonase® Sensimist™ nasal spray OTC [drug label information]. Parsippany, NJ: GlaxoSmithKline Consumer Healthcare LP; April 2017.
14. Liquid delivery device. OptiNose Web site. Available at: http://www.optinose.com/exhalation-delivery-systems/liquid-delivery-device. Accessed on August 9, 2019.
15. Bachert C. Evidence-based management of nasal polyposis by intranasal corticosteroids: from the cause to the clinic. *Int Arch Allergy Immunol*. 2011;155(4):309-321.
16. Bachert C, Watelet JB, Gevaert P, Van Cauwenberge P. Pharmacological management of nasal polyposis. *Drugs*. 2005;65(11):1537-1552.
17. Jankowski R, Klossek JM, Attali V, et al. Long-term study of fluticasone propionate aqueous nasal spray in acute and maintenance therapy of nasal polyposis. *Allergy*. 2009;64:944-950.
18. Badia L, Lund V. Topical corticosteroids in nasal polyposis. *Drugs*. 2001;61(5):573-578.
19. Snidvongs K, Kalish L, Sacks R, et al. Sinus surgery and delivery method influence the effectiveness of topical corticosteroids for chronic rhinosinusitis: systematic review and meta-analysis. *Am J Rhinol Allergy*. 2013;27:221-33.
20. Rudmik L, Schlosser RJ, Smith TL, Soler ZM. Impact of topical nasal steroid therapy on symptoms of nasal polyposis: a meta-analysis. *Laryngoscope*. 2012;122:1431-1437.
21. Venkatesan N, Lavigne P, Lavigne F, et al. Effects of fluticasone furoate on clinical and immunological outcomes (IL-17) for patients with nasal polyposis naïve to steroid treatment. *Ann Otol Rhinol Laryngol*. 2016;125(3):213-218.
22. Vento SI, Blomgren K, Hytoren M, et al. Prevention of relapses of nasal polyposis with intranasal triamcinolone acetonide after polyp surgery: a prospective double-blind, placebo-controlled, randomized study with a 9-month follow-up. *Clin. Otolaryngol*. 2012;37:117-23.
23. Seidman MD, Gurgel RK, Lin SY, et al. Clinical practice guideline: allergic rhinitis. *Otolaryngol Head Neck Surg*. 2015;152(IS):S1-S43.
24. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline (update): adult sinusitis. *Otolaryngol Head Neck Surg*. 2015;152(2S):S1-S39.
25. 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.
26. Dykewicz MS, Wallace DV, Baroody F, et al. Treatment of seasonal allergic rhinitis: an evidence-based focused 2017 guideline update. *Ann Allergy Asthma Immunol*. 2017;119(6):489-511.
27. Alhussien AH, Alhedaithy RA, Alsaleh SA. Safety of intranasal corticosteroid sprays during pregnancy: an updated review. *Eur Arch Otorhinolaryngol*. 2018;275(2):325-333.