Clinical Policy: Mometasone Furoate (Sinuva)

Reference Number: IL.ERX.PHAR.448
Effective Date: 06.01.21
Last Review Date: 05.21
Line of Business: Illinois Medicaid

Revision Log

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

Description
Mometasone furoate (Sinuva™) sinus implant is a self-expanding, bioabsorbable, corticosteroid-eluting implant provided with a crimper and a single-use delivery system.

FDA Approved Indication(s)
Sinuva sinus implant indicated for the treatment of nasal polyps in patients ≥ 18 years of age who have had ethmoid sinus surgery.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Sinuva is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Nasal Polyps (must meet all)**:**

1. Diagnosis of nasal polyps;
2. Age ≥ 18 years;
3. Prescribed by or in consultation with an otolaryngologist;
4. Member has had ethmoid sinus surgery;
5. Failure of fluticasone propionate, unless contraindicated or clinically significant adverse effects are experienced;
6. Medical justification why Sinuva will work despite inadequate response to generic fluticasone nasal spray (e.g., contraindications to excipients);
7. Sinuva will be inserted by an otolaryngologist;
8. Dose does not exceed 1350 mcg (1 implant) per 90 days.

Approval duration: 4 months (1 implant)

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Nasal Polyps (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy (e.g., improvement in nasal congestion or obstruction, reduction of bilateral polyp grade);
3. If request is for a dose increase, new dose does not exceed 1,350 mcg (1 implant) per 90 days.

Approval duration: 12 months (4 implants)

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy. **Approval duration: Duration of request or 12 months (whichever is less)**; or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 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®)	2-4 sprays/nostril (50 mcg/spray) IN QD or BID (200 - 800 mcg)	800 mcg/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 and any of the ingredients of the Sinuva sinus implant
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Nasal polyps	1 implant (1350 mcg) inserted in the ethmoid sinus via endoscopic visualization. The implant may be left in the sinus to gradually release the corticosteroid over 90 days. The implant can be removed at Day 90 or earlier at the physician's discretion using standard surgical instruments. • To be inserted by physicians trained in otolaryngology. • Repeat administration has not been studied.	1,350 mcg/90 days

VI. Product Availability

Sinus implant: 1,350 mcg mometasone furoate

VII. References

1. Sinuva Prescribing Information. Menlo Park, CA; Intersect ENT, Inc..; December 2017. Available at: https://www.sinuva.com/hcp/. Accessed November 18, 2019.
2. Newton JR, Ah-see KW. A review of nasal polyposis. Ther Clin Risk Manag 2008;4(2):507-12. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2504067/. Accessed November 18,

2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.15.21	05.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.