Clinical Policy: Mometasone Furoate (Sinuva)

Reference Number: CP.PHAR.448
Effective Date: 03.01.20
Last Review Date: 02.22
Line of Business: Commercial, Medicaid, HIM-Medical Benefit

Coding Implications
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 is 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.

It is the policy of health plans affiliated with Centene Corporation® 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 all of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, and c):
   a. Mometasone nasal spray;
   b. Xhance®;
   c. One additional formulary intranasal steroid (e.g., budesonide);
6. Medical justification why Sinuva will work despite inadequate response to generic mometasone nasal spray (e.g., contraindications to excipients);
7. Sinuva will be inserted by an otolaryngologist;
8. Dose does not exceed 1,350 mcg (1 implant) per sinus per 90 days.

Approval duration: 4 months (1 implant per sinus)

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): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid and HIM-Medical Benefit.

II. Continued Therapy

A. 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 (e.g., improvement in nasal congestion or obstruction, reduction of bilateral polyp grade);
3. Ethmoid sinus polyps grade ≥ 1 on the sinus(es) receiving the implant(s);
4. If request is for a dose increase, new dose does not exceed 1,350 mcg (1 implant) per sinus per 90 days.

Approval duration: 4 months (1 implant per sinus)

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): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid and HIM-Medical Benefit.

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 – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid and HIM-Medical Benefit 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	Dosing Regimen	Dose Limit/ Maximum Dose
mometasone furoate (Nasonex®)	2 sprays/nostril (50 mcg/spray) IN BID (400 mcg/day)	400 mcg/day
fluticasone propionate (Flonase®)	2-4 sprays/nostril (50 mcg/spray) IN QD or BID (200 - 800 mcg)	800 mcg/day
budesonide (Rhinocort®)	2 sprays/nostril (32 mcg/spray) IN QD (128 mcg)	128 mcg/day
Xhance™ (fluticasone propionate)	1 to 2 sprays (93 mcg/spray) to nostril IN BID	744 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 (1,350 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.	1,350 mcg/90 days

VI. Product Availability

Sinus implant: 1,350 mcg

VII. References

1. Sinuva Prescribing Information. Menlo Park, CA; Intersect ENT, Inc..; April 2020. Available at: https://www.sinuva.com/hcp/. Accessed September 13, 2021.
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 September 13, 2021.
3. Intersect ENT. Safety evaluation of repeat placement of the S8 sinus implant in chronic sinusitis patients with nasal polyps (ENCORE). ClinicalTrials.gov Identifier: NCT03358329. Available at: https://clinicaltrials.gov/ct2/show/study/NCT03358329. Accessed September 13, 2021.
4. Han JK, Bosson JV, Cho SH, et al. Multidisciplinary consensus on a stepwise treatment algorithm for management of chronic rhinosinusitis with nasal polyps. Int Forum Allergy Rhinol. 2021;1-10. Available at: https://onlinelibrary.wiley.com/doi/10.1002/alr.22851. Accessed September 13, 2021.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J7401	Mometasone furoate sinus implant, 10 mcg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	12.03.19	02.20
1Q 2021 annual review: clarified that 1 implant may be placed per sinus per PI; added re-authorization criteria based on results of a repeat administration study in patients with ethmoid sinus polyps grade ≥ 1 per PI; references reviewed and updated.	10.09.20	02.21
1Q 2022 annual review: per previously approved clinical guidance, specified that one of the tried intranasal steroids must be Xhance per 2021 consensus panel treatment algorithm; references reviewed and updated.	09.13.21	02.22

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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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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