Clinical Policy: Mometasone Furoate (Sinuva)

Reference Number: CP.PHAR.448
Effective Date: 03.01.20
Last Review Date: 08.25
Line of Business: Commercial, HIM-Medical Benefit, Medicaid

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 chronic rhinosinusitis with nasal polyps (CRSwNP) in adult 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. Chronic Rhinosinusitis with Nasal Polyps (must meet all)**:**

1. Diagnosis of CRSwNP;
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):*
   **For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395*
   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);*
   **For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
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 (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Chronic Rhinosinusitis with Nasal Polyps (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
CRSwNP: chronic rhinosinusitis with nasal polyps

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
CRSwNP	• 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	1,350 mcg/90 days

Indication	Dosing Regimen	Maximum Dose
	removed at Day 90 or earlier at the physician's discretion using standard surgical instruments. • To be inserted by physicians trained in otolaryngology.	

VI. Product Availability

Sinus implant: 1,350 mcg

VII. References

1. Sinuva Prescribing Information. Menlo Park, CA; Intersect ENT, Inc.; January 2023. Available at: https://www.sinuva.com/hcp. Accessed April 17, 2025.
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 May 9, 2024.
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 May 9, 2024.
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 May 9, 2024.
5. Rank MA, Chu DK, Bognanni A, et al. The Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis. J Allergy Clin Immunol. 2023; 151(2): 386-392.

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
J7402	Mometasone furoate sinus implant, (sinuva), 10 mcg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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	09.13.21	02.22

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2021 consensus panel treatment algorithm; references reviewed and updated.		
Template changes applied to other diagnoses/indications and continued therapy section.	09.27.22	
1Q 2023 annual review: no significant changes; updated HCPCS code; references reviewed and updated.	11.03.22	02.23
RT4: clarified diagnosis from "nasal polyps" to "CRSwNP" per updated language in FDA approved indication.	02.10.23	
3Q 2023 annual review: no significant changes; references reviewed and updated.	04.18.23	08.23
3Q 2024 annual review: no significant changes; references reviewed and updated.	05.09.24	08.24
3Q 2025 annual review: no significant changes; references reviewed and updated. Added step therapy bypass for IL HIM per IL HB 5395.	06.24.25	08.25

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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.