Clinical Policy: Mometasone Furoate (Sinuva)

Reference Number: IL.PHAR.448
Effective Date: 1.1.20
Last Review Date: 3.30.23
Line of Business: 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 sinus implant 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 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 sinus per 90 days.

Approval duration: 4 months (1 implant)

B. Other diagnoses/indications

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 PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: 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.PMN.53 for Medicaid.

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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 1350 mcg (1 implant) per sinus per 90 days.

Approval duration: 12 months (4 implants)

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 PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the or PDL (Medicaid), the non-formulary policy for the relevant line of business: 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.PMN.53 for Medicaid.
   Approval duration: Duration of request or 12 months (whichever is less); or
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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.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
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
CRSwNP	• 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.	1350 mcg/90 days

VI. Product Availability

Sinus implant: 1350 mcg mometasone furoate

VII. References

1. Sinuva Prescribing Information. Menlo Park, CA; Intersect ENT, Inc..; January 2023. Available at: https://www.sinuva.com/hcp/. Accessed February 10, 2023.
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 October 9, 2020.
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 October 9, 2020.
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 November 3, 2022.

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, 10 mcg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created for migration to HFS PDL. Adapted from CP.PHAR.448.	12.30.19	1.7.20
2Q 2021 Annual Review and Changes: 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.	4.14.2021	
2Q 2022 annual review: references reviewed	4.28.22	
2Q 2023 Annual review and RT4: clarified diagnosis from "nasal polyps" to "CRSwNP" per updated language in FDA approved indication; updated HCPCS code; applied template changes.	3.29.23	

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.