Subject: SINUVA (Mometasone Furoate Sinus Implant)	Original Effective Date: 12/19/2018
Policy Number: MCP-333	Revision Date(s):
Review Date(s): 12/19/2018; Q4 2019; Q3 2020	
MCPC Approval Date: 12/19/2018	
P&T Approval Date: Q4 2019, Q3 2020	

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP document and provide the directive for all Medicare members.

RECOMMENDATIONS

This policy addresses **SINUVA (mometasone furoate)**, a corticosteroid-eluting implant indicated for the treatment of nasal polyps in patients 18 years of age and older who have had ethmoid sinus surgery.

Molina Healthcare reserves the right to update this Policy and revise coverage criteria to include or omit any off-label condition(s) as necessary based on medical literature and clinical studies that may become available.

FDA INDICATIONS

- **SINUVA (mometasone furoate)** is a corticosteroid-eluting (mometasone furoate) implant indicated for the treatment of nasal polyps in patients ≥ 18 years of age who have had ethmoid sinus surgery

Available as: Single-use, bioabsorbable implant, coated with a formulation of 1350 mcg mometasone furoate

FDA Approved: December 8, 2017
Developed by the manufacturer of the FDA-approved Propel product line of steroid-releasing implants. The Sinuva implant was previously known as the S8 sinus implant and, more recently, the Resolve implant. ***Propel implants are regulated as devices by the FDA, while the agency is regulating the Sinuva implant as a drug.***

Black Box Warnings/REMS: None at the time of this writing
CLASSIFICATION: Bioabsorbable steroid-releasing sinus implant

RECOMMENDATIONS/COVERAGE CRITERIA

SINUVA (mometasone furoate) may be authorized for members who meet **ALL** the following criteria **[ALL]**

1. Prescriber specialty [ONE]

- ❒ Prescribed and administered by a physician specializing in otolaryngology (ENT)

2. Diagnosis/Indication [ALL]
Documentation of diagnosis required and may include clinical notes from the member's medical records including any relevant labs and/or tests, supporting the diagnosis **[ONE]**

- ❒ Diagnosis of recurrent nasal polyp disease
- ❒ History of ethmoid sinus surgery. Documentation of date of ethmoid sinus surgery required.

3. Age/Gender/Restrictions [ALL]

- ❒ 18 years of age or older
  - *The safety and effectiveness of the SINUVA Sinus Implant have not been established in children or adolescents less than 18 years of age.*

4. Conventional Therapy/Concurrent Therapy/Other Requirements [ALL]

- ❒ Failure of intranasal corticosteroids after at least a three (3) month trial at the maximum recommended dose (if not contraindicated) [i.e. mometasone, fluticasone, budesonide, or triamcinolone]
  - *First-line management consists of saline nasal rinses and standard, topical intranasal corticosteroid sprays (International Consensus Statement on Allergy and Rhinology: Rhinosinusitis, 2016).*
  - *Topical intranasal corticosteroid sprays are standard treatment for nasal polyps, but their efficacy is reduced by poor patient compliance and impaired access of drug to the sinus mucosa. (Kern RC, 2018)*
- ❒ Failure of oral corticosteroids within the last six months (if not contraindicated) [i.e. prednisone, methylprednisolone, or dexamethasone]
  - *Systemic corticosteroids are effective, acutely shrinking polyps, but the efficacy is transient and limited by dose-dependent side effects. (Head K, 2016)*
- ❒ SINUVA nasal implant will be used in conjunction with mometasone furoate nasal spray once daily
  - *All patients in both trials (RESOLVE I and RESOLVE II) were required to use a mometasone furoate nasal spray once daily. Implants were removed within 60 days after insertion to allow for blinded grading at day 90.*

5. **Contraindications/Exclusions**

**There are no contraindications listed in the manufacturer's labeling. Formal drug-drug interaction studies have not been conducted with the SINUVA Sinus Implant.*

Authorization will not be granted if ANY of the following conditions apply [ANY]

- ❒ Non-FDA approved indications
- ❒ Hypersensitivity to mometasone furoate, or to any of the copolymers of the SINUVA Sinus Implant

6. **Labs/Reports/Documentation required [ALL]**

All documentation for determination of medical necessity must be submitted for review. Prescriber to submit documentation as indicated in the criteria above, including but not limited to chart notes, applicable lab values and/or tests, adverse outcomes, treatment failures, or any other additional clinical information or clinical notes from the member's medical records supporting the diagnosis. Letters of support and/or explanation are often useful but are not sufficient documentation unless ALL specific information required by this MCP is included.

NOTE: Additional documentation, rationale, and/or supporting evidence may be requested for review as deemed necessary or appropriate by Molina Medical/Pharmacy staff.

ADMINISTRATION, QUANTITY LIMITATIONS, AND AUTHORIZATION PERIOD

Consult the manufacturer's labeling for more detailed information on dosage and administration of this drug, cautions, precautions, contraindications, potential drug interactions, laboratory test interferences, and monitoring.

Authorization Limit [ALL]

- ❒ Quantity limit: One implant per nostril per lifetime
  - *The labeling states that repeat administration has not been studied.*

- ❒ Reauthorization is not allowed for this one-time implant treatment. There are no studies evaluating repeat implantation of the SINUVA Sinus Implant
  - *The safety and efficacy of repeat administration of SINUVA (mometasone furoate) has not been evaluated.*

Route of Administration

- ❒ SINUVA (mometasone furoate) sinus implant is a **provider-administered** and to be placed in the ethmoid sinuses during a routine office visit by an otolaryngologist. The implant expands in the sinus where it remains for the elution of mometasone furoate over 90 days. The Sinuva implant may be removed on day 90 or sooner at the physician's discretion. The Sinuva product label contains a detailed description of the implant and instructions for implant insertion.

- ❒ Refer to MHI Policy & Procedure (P&P): Specialty Medication Administration Site of Care Policy: MHI Pharm 11

Coverage Exclusions

This policy addresses SINUVA (mometasone furoate), a corticosteroid-eluting implant indicated for the treatment of nasal polyps in patients 18 years of age and older who have had ethmoid sinus surgery.

All other uses of SINUVA (mometasone furoate) sinus implant that are not an FDA-approved indication or not included in the 'Coverage Criteria' section of this policy are considered not medically necessary. This is subject to change based on research and medical literature, or at the discretion of Molina Healthcare.

*Pharmaceutical samples: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition, prior prescription history, or as continuation of therapy.

**FDA-approved indication does not, in itself, dictate coverage. Molina Clinical Policy may not recommend coverage for all FDA-approved indications. Please review this Policy in its entirety for indications covered by Molina Healthcare.*

Background/Summary of Evidence

Chronic rhinosinusitis (CRS) is a broad, inflammatory syndrome, characterized by persistent nasal obstruction, drainage, facial pressure, and loss of smell. CRS is often divided into 2 phenotypes based on nasal endoscopy, CRS with nasal polyps and CRS without nasal polyps, but there is significant clinical overlap.

- First-line management consists of saline nasal rinses and standard, topical intranasal corticosteroid sprays for both phenotypes. Symptoms fluctuate, and patients are subject to frequent viral, allergic, and bacterial exacerbations. In resistant cases, extended courses of systemic corticosteroids are used to reduce symptom burden and avoid sinus surgery.
- Alternative treatment options are particularly needed for CRS with nasal polyps, which is associated with higher symptom burden, increased medication use, greater revision rate, and higher costs compared to CRS without nasal polyps.
- Bioabsorbable sinus implants, which elute corticosteroids, were designed to address these limitations and improve surgical outcomes for CRS with nasal polyps when used in the immediate postoperative period.

SINUVA (mometasone furoate)

- A second-generation, bioabsorbable corticosteroid-releasing sinus implant that gradually releases the corticosteroid mometasone furoate over a 90-day period, for treatment of nasal polyps in adults who have had ethmoid sinus surgery
- FDA approval of Sinuva was based on the results of two randomized, sham-controlled trials **(RESOLVE and RESOLVE II)** in adults with refractory chronic rhinosinusitis develop nasal polyps who were candidates for repeat ethmoid sinus surgery.
- **RESOLVE II** a randomized, single blind, parallel arm, study of chronic sinusitis patients who had prior endoscopic sinus surgery but presented with recurrent sinus obstruction (RESOLVE II). The efficacy of Sinuva was primarily based on a placebo-controlled study of 300 patients, ≥ 18 years of age, with nasal polyps and a history of ethmoid sinus surgery. The co-primary efficacy endpoints were change from baseline to day 30 in nasal obstruction/ congestion score and change from baseline to day 90 in bilateral polyp grade.
    - Sinuva-treated patients experienced a statistically significant reduction in nasal obstruction/congestion score vs. placebo-treated patients (-0.80 vs. -0.56, respectively; difference: -0.23 [95% CI: -0.39, -0.06]).

- Sinuva-treated patients experienced a statistically significant reduction in bilateral polyp grade vs. placebo-treated patients (-0.56 vs. -0.15, respectively; difference: -0.35 [95% CI: 0.60, -0.09])
- The co-primary efficacy endpoints were met, which included a 63% statistically significant relative reduction in bilateral polyp grade for patients who were given Sinuva compared to control (P=0.007), as well as a reduction from baseline Nasal Obstruction/Congestion score (P=0.007).

- All patients in both trials were required to use a mometasone furoate nasal spray once daily. Implants were removed within 60 days after insertion to allow for blinded grading at day 90.
- The most common adverse effects that occurred in clinical trials in patients who received Sinuva implants were bronchitis, nasopharyngitis, otitis media, headache, presyncope, asthma, and epistaxis. Some patients treated with Sinuva had measurable plasma concentrations of mometasone furoate; whether use of the implant could result in hypothalamic-pituitary-adrenal (HPA) axis suppression or other systemic corticosteroid adverse effects has not been established.

HAYES

Hayes concluded that sufficient published evidence to evaluate the Sinuva Sinus Implant for the treatment of nasal polyps after ethmoid sinus surgery was identified. The results presented in the majority of the study abstracts report overall positive findings for health outcomes for the Sinuva implant. No full-text articles were reviewed, and a comprehensive Health Technology Assessment is not available.

CLINICAL PRACTICE GUIDELINES No practice guidelines specifically pertaining to the Sinuva implant were identified at the time of this review (September 2019). However, a search for other relevant guidelines revealed the following guidelines address the use of "biomaterials."

Both the **American Rhinologic Society (ARS, 2014)** and the **American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS, 2015)** have published position statements regarding the use of "biomaterials."

- The ARS does not supply any citations to support their statement, which does not allow sufficient evaluation of the evidentiary basis of their position.
- The AAO-HNS statement does include citations, but they do not include any studies not previously discussed above. As stated above, these studies do not sufficiently demonstrate the safety and efficacy of these devices. The ARS also published a position statement on drug-eluting implants in 2016. This document specified support for the use of such devices based upon "demonstrated improvement of patient outcomes by reducing inflammation, decreasing scarring and middle turbinate lateralization and limiting the need for oral steroids."

DEFINITIONS

N/A

APPENDIX

N/A

CODING INFORMATION

**CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).*

The codes listed in the policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is covered or non-covered. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

CPT	Description
NA	

HCPCS	Description
S1090	Mometasone furoate sinus implant, 370 micrograms [Propel sinus implant]
J3490	Unclassified drugs [when specified as SINUVA sinus implant]

REFERENCES

Package Insert, FDA, Drug Compendia

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Clinical Trials, Definitions, Peer-Reviewed Publications

Adriaensen GFJPM, Lim KH, Fokkens WJ. Safety and efficacy of a bioabsorbable fluticasone propionate-eluting sinus dressing in postoperative management of endoscopic sinus surgery: a randomized clinical trial. Int Forum Allergy Rhinol. 2017; 7(8):813-820.

Forwith KD, Han JK, Stolovitzky JP, et al. **RESOLVE**: bioabsorbable steroid-eluting sinus implants for in-office treatment of recurrent sinonasal polyposis after sinus surgery: 6-month outcomes from a randomized, controlled, blinded study. Int Forum Allergy Rhinol. 2016; 6(6):573-581.

Han JK, Forwith KD, Smith TL, et al. **RESOLVE:** a randomized, controlled, blinded study of bioabsorbable steroid-eluting sinus implants for in-office treatment of recurrent sinonasal polyposis. Int Forum Allergy Rhinol. 2014; 4(11):861-870.

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Head K, Chong LY, Piromchai P, et al. Systemic and topical antibiotics for chronic rhinosinusitis. **Cochrane Database Syst Rev.** 2016;4:CD011994.

Kern RC, et al.; **RESOLVE II** study investigators. A phase 3 trial of mometasone furoate sinus implants for chronic sinusitis with recurrent nasal polyps. Int Forum Allergy Rhinol. 2018; 8(4):471-481.

Government Agencies, Professional Societies, and Other Authoritative Publications

American Academy of Otolaryngology-Head and Neck Surgery. Position statement: The use of Biomaterials in Sinonasal Procedures. 9/26/2015. Available at: http://www.entnet.org/content/position-statement-use-biomaterials-sinonasal-procedures. Accessed on May 2020.

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Policy History	Approval
Policy Developed Peer Review: AMR Peer Review Network. 10/23/2018. Practicing Physician. Board certified in otolaryngology	MCPC 12/13/2018
Reviewed: Q4 2019	P&T Q4 2019
Annual Review* No coverage criteria changes with this annual review. Minor revisions, including clarification and addition of language, however no change to intent.	P&T Q3 2020

**Policy Revisions and Annual Reviews: All content, clinical evidence, coverage criteria, practice guidelines, appendices and reference sections were reviewed and revised with the most recent medical literature and available evidence for both 'Annual Reviews' and 'Revisions.' Revisions include notable content updates or revisions that which may have affected criteria or requires review by a practicing specialist, Peer Reviewer. The revisions noted below but may not be all-inclusive of all revised criteria and content in each policy; refer to MCP for all revisions and complete context.*