Subject: SINUVA (Mometasone Furoate Sinus Implant)	**Original Effective Date:** 12/19/2018
Policy Number: MCP-333	**Revision Date(s):** 6/2021
Review Date(s): 12/19/2018; Q4 2019; Q3 2020, 6/29/21	
MCPC Approval Date: 12/19/2018	
P&T Approval Date: Q4 2019	

Contents

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.

The intent of the policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical studies, nationally recognized authoritative references, and current peer-reviewed scientific literature. 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. The information outlined in the MCP includes but is not limited to a review of evidence-based information obtained from the following sources Evaluation of New and Existing Technologies (UM 10). This policy is intended to address coverage criteria that are appropriate for the majority of individuals/members with a particular disease, illness, or condition. Each member's unique clinical circumstances may warrant individual consideration, based on review of applicable medical records.

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.

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Chronic rhinosinusitis (CRS) is a common inflammatory condition in which the nasal and paranasal sinus mucosa becomes swollen and inflamed leading to debilitating and persistent symptoms for at least 12 weeks. The exact etiology of CRS remains unknown (World Allergy Organization 2021). 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. Treatment of CRS is focused on reducing mucosal inflammation, promote sinus drainage, and eradicate infections that may be present. In patients with mild CRS symptoms, first line therapy is medical management involving saline irrigation, anti-inflammatory steroids, and decongestants. 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. For patients with moderate to severe CRS or when first-line treatment is unsuccessful, a short course of oral steroids and/or antibiotics may be prescribed. Alternative treatment options are particularly needed for CRS with nasal polyps (CRSwNP), which is associated with higher symptom burden and increased medication use compared to CRS without nasal polyps. Bioabsorbable sinus implants, which elute corticosteroids, were designed to address these limitations and improve surgical outcomes for CRSwNP when used in the immediate postoperative period.

SINUVA (mometasone furoate) is a corticosteroid-releasing sinus implant that gradually releases the corticosteroid mometasone furoate (MF) over a 90-day period, for treatment of nasal polyps in adults who have had ethmoid sinus surgery (ESS)**.** Mometasone furoate is a corticosteroid possessing potent anti-inflammatory activity. The precise mechanism of corticosteroid action on inflammation is not known; however, corticosteroids demonstrated to have a wide range of effects on multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, and cytokines) involved in inflammation. One SINUVA implant system contains 1350 mcg of MF and a sterile delivery system. The implant is made of bioabsorbable polymers designed to gradually soften over time, must be implanted under endoscopic visualization, and can be endoscopically removed at 90 days or earlier. As it softens and polyps decrease in number and size, the implant may be expelled on its own or after a sneeze or forceful nose blowing. The FDA determined that the drug had more of an effect than the device and approved SINUVA as a drug as opposed to a drug/device system (e.g. Propel). FDA approval of SINUVA was based on the results of two randomized, sham-controlled trials in adults with refractory CRSwNP who were candidates for repeat ESS (RESOLVE and RESOLVE II). 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.

FDA INDICATIONS

FDA-approved indication does not alone 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.

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 ALL of the following criteria are required. May include chart notes from the member's medical records, relevant labs and/or tests, and other relevant clinical information.

   - ❒ 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]

- ❒ Inadequate response, clinically significant adverse effects, or contraindication to intranasal corticosteroids after at least a three (3) month trial at the maximum recommended dose [i.e. mometasone, fluticasone, budesonide, or triamcinolone]
  - *First-line management usually consists of saline nasal rinses and topical intranasal corticosteroid sprays. Compared to traditional nasal spray, large-volume corticosteroid irrigation (budesonide or mometasone) provides improved distribution and penetration, resulting in improvement of subjective sino-nasal symptoms and quality of life as well as objective radiographic and endoscopic disease severity (World Allergy Organization, 2021).*

- ❒ Inadequate response, clinically significant adverse effects, or contraindication to oral corticosteroids within the last six months [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). A 10- to 15-day course of oral corticosteroids is usually adequate. A typical adult regimen is prednisone 40 mg for five days, followed by 20 mg daily for five days (UTD 2021).*

- ❒ SINUVA nasal implant will be used in conjunction with mometasone furoate nasal spray once daily
  - *All patients in the RESOLVE I and RESOLVE II trials were required to use a MF nasal spray once daily.*

5. Contraindications/Exclusions

**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 has not been evaluated.*

Route of Administration

- ❒ SINUVA 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 MF over 90 days. The implant may be removed on day 90 or sooner at the physician's discretion. Refer to product labeling for 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

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

Background/Summary of Evidence

RESOLVE I is a multicenter patient-blind RCT evaluating the effectiveness and safety of the SINUVA sinus implant in adult pts with refractory CRSwNP. The study included 100 subjects with CRS who were scheduled to undergo revision ESS following prior ethmoidectomy due to recurrent obstruction related to polyposis (Han, 2014). 100 patients were randomized to undergo bilateral placement of SINUVA implants (n=53) or a sham procedure (n=47) and followed for 90 days. SINUVA implants were bilaterally inserted into the ethmoid sinuses and implants were removed on day 60 to eliminate risk of spontaneous dislodgement and unblinding. The mean percentage of implants remaining in place at 30, 45 and 60 days was 92.5%, 86.5% and 56.7%, respectively. No serious adverse events were reported. At 90 days, compared to the control group, the SINUVA group had significantly better bilateral polyp grade and less ethmoid obstruction. The authors reported a significant improvement in patient-reported nasal obstruction and congestion scores and Nasal Obstruction Symptom Evaluation (NOSE), with a two-fold reduction seen in the SINUVA group vs. sham treatment. However, no validated tool was used to make this assessment, so these results are of uncertain value. During the post-operative period, fewer SINUVA group subjects required oral steroids for ethmoid obstruction (11% vs. 26%), and fewer SINUVA group subjects met the criteria for ESS (47% vs. 77%). The limitations of this study include single-blinded trial design, relatively small study population, and limited follow-up duration.

The RESOLVE II study provided supportive safety and efficacy data for FDA approval of SINUVA. RESOLVE II is a multicenter, randomized, sham-controlled, double-blind trial evaluating the effectiveness and safety of the SINUVA sinus implant in adult pts w/refractory CRSwNP (Kern et al. 2018). The study 300 chronic sinusitis adult patients who had prior ESS but present with recurrent sinus obstruction. All patients enrolled in the randomized trials were considered by their clinicians to be candidates for revision sinus surgery. Patients were randomized to undergo bilateral placement of SINUVA implants or a sham procedure. On day 90, the mean bilateral polyp grade was significantly lower in patients treated with SINUVA compared to controls and the mean patient-reported score for nasal obstruction/congestion was statistically significantly lower on days 30 and 90 with the implants compared to sham treatment. Both co-primary efficacy endpoints were met as patients receiving SINUVA demonstrated a reduction in polyps, nasal obstruction/congestion, a reduction in need for repeat sinus surgery, and an improvement in impaired sense of smell. The 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. 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, as well as a reduction from baseline NOSE score.

Results suggest that the SINUVA implant may statistically significantly improve nasal obstruction/congestion and bilateral polyp grade and reduce the need for repeat sinus surgery compared with sham procedure at 90 days follow-up in adult pts with refractory CRSwNP. 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) and a statistically significant reduction in bilateral polyp grade vs. placebo-treated patients (-0.56 vs. -0.15, respectively).

All patients in both trials were required to use a mometasone furoate nasal spray daily. Implants were removed within 60 days after insertion to allow for blinded grading at day 90. Clinical studies did not include sufficient numbers of subjects age ≥ 65 years to determine if they responded differently from subjects ages 18–64 years. Repeat administration has not been studied. 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.

Hayes

A Health Technology Assessment assigned a 'potential but unproven benefit' rating for use of the SINUVA sinus implant plus daily MF intranasal spray for the treatment of patients with nasal polyps after ESS (Dec 2019). The overall quality of the body of evidence for the SINUVA steroid-releasing sinus implant plus daily MF intranasal spray for the treatment of nasal polyps after ESS was rated as low. The low-quality body of evidence evaluated suggests the SINUVA sinus implant plus daily MF intranasal spray may improve endoscopic and patient-reported outcomes after ESS and reduce the need for additional sinus surgery compared with sham procedure plus daily MF intranasal spray. This Rating also reflects uncertainty due to a small body of evidence and lack of long-term follow-up to assess the durability of benefit. Overall quality was based on the balance of benefits and harms and was assessed taking into consideration the quality of individual studies; the precision, directness, and consistency of data; and the applicability of the data to general practice.

The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS, 2015)
The AAO-HNS evidence-based Clinical Practice Guideline for adult sinusitis recommends that sinus surgery may be considered in patients with recurrent acute rhinosinusitis or CRS (Rosenfeld et al., 2015). There is no recommendation for use of steroid-releasing implants after ESS for the treatment of nasal polyps.

American Rhinologic Society (ARS)
The ARS issued a position statement endorsing the use of drug-eluting implants in the sinus cavities, noting that there have been a number of well-controlled studies on steroid-eluting implants in the paranasal sinuses (ARS, 2016). According to the ARS, these studies have demonstrated improvement of patient outcomes by reducing polyp burden and inflammation, decreasing the need for systemic steroids, and delaying revision sinus surgery.

National Institute for Health and Care Excellence (NICE)
NICE issued an interventional procedures guidance on corticosteroid-eluting stent or spacer insertion during ESS to treat CRS (NICE, 2016). NICE stated that current evidence regarding efficacy is limited; there are currently no major safety concerns. There was no mention of use of steroid-releasing implants after ESS for the treatment of nasal polyps.

DEFINITIONS

N/A

APPENDIX

N/A

CODING INFORMATION

The codes listed in this 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.
KEO June 3, 2021

CPT	Description
NA	

HCPCS	Description
J7402	Mometasone furoate sinus implant, (SINUVA), 10 micrograms. *Effective April 1, 2021

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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
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 Q4 2019 P&T Q3 2020 MCPC 6/7/2021

**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.*