Molina Clinical Policy
Sinuva (mometasone furoate)
Policy No. 333

Last Approval: 6/7/2021
Next Review Due By: June 2022

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. 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 (e.g., 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 and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

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 over a 90-day period for treatment of nasal polyps in adults who have had ethmoid sinus surgery (ESS). Although the exact anti-inflammatory mechanism is unknown, corticosteroids have a wide range of effects on various cell types (including mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) and mediators (including histamine, eicosanoids, leukotrienes, and cytokines) involved in inflammation (Product Information, 2020). One Sinuva implant system contains 1350 mcg of mometasone furoate 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.

COVERAGE POLICY

Sinuva (mometasone furoate) for the treatment of nasal polyps **may be considered medically necessary** when **ALL** of the following clinical criteria are met:

1. Diagnosis of recurrent nasal polyp disease

AND
2. History of ethmoid sinus surgery. Documentation of date of ethmoid sinus surgery required.

AND
3. Inadequate response, clinically significant adverse effects, or contraindication to **ALL** of the following:
    a. Intranasal corticosteroids: at least a 3-month trial at the maximum recommended dose [e.g., mometasone, fluticasone, budesonide, or triamcinolone]
        Informational Note: 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).
    AND
    b. Oral corticosteroids within the last six months [e.g., prednisone, methylprednisolone, or dexamethasone]
        Informational Note: 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).

AND
4. Sinuva nasal implant will be used in conjunction with mometasone furoate nasal spray once daily
    Informational Note: All patients in the RESOLVE I and RESOLVE II trials were required to use a MF nasal spray once daily.

CONTINUATION OF THERAPY
Reauthorization is not allowed for this one-time implant treatment.
The safety and efficacy of repeat administration of SINUVA has not been evaluated.

LIMITATIONS AND EXCLUSIONS
The following are considered **contraindications/exclusions** based on insufficient evidence:
1. Hypersensitivity to mometasone furoate, or to any of the copolymers of the Sinuva sinus implant

The following are considered **experimental, investigational and unproven** based on insufficient evidence:
1. Any indications other than those listed above

DURATION OF APPROVAL: ONE time authorization

PRESCRIBER REQUIREMENTS: Prescribed and administered by a physician specializing in otolaryngology (ENT)

AGE RESTRICTIONS: 18 years of age or older

DOSING CONSIDERATIONS
1 implant (1350 mcg) inserted in the ethmoid sinus via endoscopic visualization; remove by day 90 or earlier

QUANTITY LIMITATIONS
ONE implant per nostril per lifetime
Informational Note: The labeling states that repeat administration has not been studied.

ADMINISTRATION:
1. The 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; **AND**
2. Refer to MHI Policy & Procedure (P&P): Specialty Medication Administration Site of Care Policy: MHI Pharm 11

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DRUG INFORMATION

ROUTE OF ADMINISTRATION: Sinus Implant

DRUG CLASS: Corticosteroid, Nasal

FDA-APPROVED USES: Nasal polyps: Treatment of nasal polyps in patients ≥18 years
Note: Implant is for patients who have had ethmoid sinus surgery.

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

COMPENDIAL APPROVED OFF-LABELED USES: None

SUMMARY OF MEDICAL 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 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.

Professional Society Guidelines

The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS, 2015) 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.

The American Rhinologic Society (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) 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.

SUPPLEMENTAL INFORMATION

N/A

CODING & BILLING INFORMATION

CPT	Description

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

AVAILABLE DOSAGE FORMS: Single-use, bioabsorbable implant, coated with a formulation of 1350 mcg mometasone furoate

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper

billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

6/7/2021	MCPC	Policy reviewed and updated, no changes in coverage criteria, updated references.
Q3 2020	P&T	Policy reviewed and updated, no changes in coverage criteria, updated references.
Q4 2019	P&T	Policy reviewed and updated, no changes in coverage criteria, updated references.
12/13/2018	MCPC	New policy. IRO Peer Review. 10/23/2018. Practicing Physician. Board certified in otolaryngology

REFERENCES

Government Agency

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Prescribing Information and Drug Compendia

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APPENDIX

Reserved for State specific information *(to be provided by the individual States, not Corporate). Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*