Molina Clinical Policy
Steroid-Eluting Sinus Stents and Implants (PROPEL, SINUVA): Policy No. 333

Last Approval: 4/13/2023
Next Review Due By: April 2024

Ohio Medicaid Addendum: All cases will be reviewed on a case-by-case basis for medical necessity. Repeat administration may be medically necessary if patient receives functional endoscopic sinus surgery again and medical necessity is met.

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 become swollen and inflamed, resulting in 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 (CRSwNP) and CRS without nasal polyps, but there is significant clinical overlap. The diagnosis of CRS is based on the presentation of signs and symptoms and a clinical examination using an anterior rhinoscopy or nasal endoscopy. A CT scan is the standard radiologic examination obtained when ethmoid sinus surgery (ESS) is being considered. Treatment of CRS is focused on reducing mucosal inflammation, promoting sinus drainage, and eradicating infections that may be present. First-line treatment for CRS is typically conservative medical therapy to alleviate symptoms, which includes the following: 1) oral antibiotics, 2) saline nasal irrigation, 3) topical and/or systemic decongestants (if not contraindicated), 4) topical steroids in the form of nasal sprays for controlling inflammation and/or systemic steroids, or 5) treatment of concomitant allergic rhinitis, including avoidance measures, pharmacotherapy, and/or immunotherapy. If medical and pharmaceutical therapy do not provide adequate relief, surgical interventions may be required. The common surgical treatment for unresponsive CRS is functional endoscopic sinus surgery (FESS), a set of minimally invasive surgical techniques. FESS is intended to open closed sinus ostia to allow proper drainage and air flow and prevent recurrent sinus infections. Complications from sinus surgery (e.g., inflammation, polyp recurrence, stenosis of the surgically enlarged sinus ostia, adhesions, and middle turbinate lateralization) can result in suboptimal outcomes and increased revision rates (Huang et al., 2015). The standard of care following FESS typically involves saline irrigation, nasal packs (packing, sponges, or gels to provide a barrier to adhesion development and facilitate hemostasis), foam dressings, topical steroids, systemic steroids, topical decongestants, oral antibiotics, and/or sinus cavity debridement. Bioabsorbable sinus implants that elute corticosteroids, were designed to address these limitations, and improve surgical outcomes for CRSwNP when used in the immediate postoperative period. Although the precise anti-inflammatory mechanism is unknown, corticosteroids have a wide range of effects on several inflammatory cell types (including mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) and mediators (including histamine, eicosanoids, leukotrienes, and cytokines) (SINUVA Prescribing Information, 2020).

Corticosteroid-eluting sinus stents are devices used postoperatively following ESS or to treat of recurrent sinonasal polyposis following ESS. These devices maintain the patency of the sinus openings during the postoperative period and/or serve as vehicles for local drug delivery. Reducing postoperative inflammation and maintaining the patency of the sinuses may be important in achieving optimal sinus drainage and may impact recovery from surgery and/or reduce the need for additional surgery. The PROPEL sinus stent and SINUVA sinus implant (mometasone furoate) are corticosteroid-eluting implants indicated for patients 18 and older who have undergone ethmoid surgery.

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- The **PROPEL sinus implants** are bioabsorbable, drug-eluting sinus stents intended to maintain patency of the ethmoid or frontal sinus opening after sinus surgery for CRS: PROPEL is indicated for the ethmoid sinus; PROPEL Mini is indicated for the ethmoid and frontal sinuses; and PROPEL Contour is indicated for the frontal and maxillary sinuses. Implantation of the Propel device into the ethmoid sinus ostia is performed by a physician under endoscopic visualization. Upon insertion, the implant expands radially to conform to the surgically enlarged sinus ostium following FESS, and the corticosteroid is released into the local area surrounding the stent. Mometasone furoate is embedded in a polyethylene glycol polymer, allowing for sustained drug release over a 30-day period. The device is dissolvable over a period of several weeks and therefore does not require removal. Each steroid-releasing implant contains 370 ug of mometasone furoate.

- **SINUVA (mometasone furoate)** is a corticosteroid-releasing sinus implant that gradually releases mometasone furoate over a 90-day period for the treatment of nasal polyps in adults who have had ESS. One SINUVA implant system contains 1350 mcg of mometasone furoate and a sterile delivery system. The implant is made of bioabsorbable polymers that gradually soften over time. It must be implanted under endoscopic visualization and can be removed endoscopically after 90 days. The implant may be expelled on its own as it softens and polyps decrease in number and size, or after a sneeze or forceful nose blowing. SINUVA is not biodegradable (as is the PROPEL device) and is removed 90 days after placement or earlier at the physician's discretion. Repeat administration of SINUVA has not been studied. The FDA determined that SINUVA was more effective than the device and approved it as a drug rather than a drug/device system like PROPEL.

PROPEL implant is regulated as a device, whereas the SINUVA implant is regulated as a drug.

RELATED POLICIES / PROCEDURES

MCP-408: Balloon Sinus Ostial Dilation (Balloon Sinuplasty)

COVERAGE POLICY

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

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** 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

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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 mometasone furoate nasal spray once daily.

PROPEL/PROPEL Mini/PROPEL Contour (mometasone furoate) for post-operative intervention for chronic sinusitis surgery **may be considered medically necessary** when **ALL** the following clinical criteria are met with documentation:

1. Diagnosis of CRS confirmed by CT scan and defined as symptoms lasting longer than 12 consecutive weeks in duration with inflammation of the mucosa of the nose and paranasal sinuses; **AND**

2. Primary or revision endoscopic sinus surgery is indicated. Documentation of date of sinus surgery required; **AND**

3. Prescribed to maintain patency of **ONE** of the following:
   a. Ethmoid sinus opening
   b. Frontal sinus opening
   c. Maxillary sinus opening

AND

4. Inadequate response, clinically significant adverse effects, or contraindication to **ALL** the following:
   a. Intranasal corticosteroids: at least a 3-month trial at the maximum recommended dose (e.g., mometasone, fluticasone, budesonide, or triamcinolone); **AND**
   b. Oral corticosteroids within the last 6 months (e.g., prednisone, methylprednisolone, or dexamethasone).

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 any component of the formulation (i.e., the copolymers of the SINUVA sinus implant or bioabsorbable polymers of the PROPEL implant including lactide, glycolide or caprolactone copolymers)

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

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DOSING CONSIDERATIONS
SINUVA Implant: ONE implant contains 1350 mcg of mometasone furoate released over 90 days

PROPEL / PROPEL MINI / PROPEL CONTOUR: Each implant contains 370mcg of mometasone furoate released continuously over 30 days

QUANTITY LIMITATIONS
ONE implant per nostril per lifetime
Informational Note: The SINUVA 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 corticosteroid is released over 90 days and the bioabsorbable polymers soften over this time. The implant is removed at Day 90 or earlier (at the physician's discretion) using standard surgical instruments. Refer to product labeling for a detailed description of the implant and instructions for implant insertion; **AND**
2. The Propel sinus implant is inserted into the ethmoid sinus cavity by a physician under endoscopic visualization. Upon insertion, the implant expands radially to conform to the sinus cavity. The delivery system is then removed and discarded. Mometasone furoate is released over an approximate duration of 30 days. The device dissolves over several weeks and therefore does not require removal. Each steroid-releasing implant contains 370 ug of mometasone furoate; **AND**
3. Refer to MHI Policy & Procedure *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:
Propel delivers sustained steroid medication localized into the ethmoid cavity after surgery approved, with several versions available depending on the placement location in the sinus area. SINUVA is a longer lasting product, specifically created for patients suffering from recurring nasal polyps.

PROPEL implants are regulated as devices by the FDA, while the SINUVA implant is regulated as a drug. SINUVA was developed by the manufacturer of the FDA-approved PROPEL product line of steroid-releasing implants.

PROPEL (mometasone furoate) implant *FDA approved through the premarket approval process (P100044) (product code OWO)*
Post-operative intervention for chronic sinusitis surgery
Bioabsorbable sinus implant indicated for patients ≥ 18 years of age following ESS to maintain sinus patency; prevents sinus obstruction from adhesions, reduces inflammation, and reduces the need for postoperative intervention (e.g., adhesion lysis, oral corticosteroids)
- Propel: Ethmoid sinus *August 11, 2011*

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- Propel Mini: Ethmoid and frontal sinuses *September 21, 2012*
- Propel Contour: Frontal and maxillary sinuses *February 23, 2017*

SINUVA (mometasone furoate) sinus implant
Nasal polyps: For the treatment of nasal polyps in patients ≥ 18 years of age who have had ESS.
SINUVA Sinus Implant (Intersect ENT) was initially approved in 1987. In 2017, the SINUVA Sinus Implant was approved with a new dose (1350 µg mometasone furoate) under a New Drug Application (NDA 209310).

COMPENDIAL APPROVED OFF-LABELED USES: None

SUMMARY OF MEDICAL EVIDENCE

PROPEL Implant
The Propel sinus implant, the Propel Mini Steroid-Releasing Implant, and the Propel Contour devices were FDA-approved through the premarket approval process. The efficacy and safety of the PROPEL implant in adult patients with CRS undergoing FESS were reported in 3 prospective clinical trials that included 205 patients in the U.S. The ADVANCE II clinical trial is derived from and supported by the ADVANCE clinical trial and the CONSENSUS II pilot study.

Forwith et al. (2011) published the results of the ADVANCE study, a non-randomized, open-label, multicenter, single-arm trial that evaluated the placement of the PROPEL implant in 50 patients with CRS who were scheduled to undergo ESS (n = 50 patients; 90 sinuses). The participants received bilateral or unilateral steroid-eluting sinus implants at the end of the ESS procedure. Oral or intranasal steroids were withheld during the first 60 days postoperatively. The patients received endoscopic follow-up to 60 days post-operation, and patient-reported outcomes continued for 6 months (Sinonasal Outcomes Test 22, Rhinosinusitis Disability Index, and Total Nasal Symptom Scoring). Implants were successfully placed in all 90 sinuses. Three self-reported surveys reported statistically significant mean changes from baseline to days 60 and 6 months. Minimal degrees of inflammation and adhesions were observed at 1 month and mean inflammation scores were minimal at all time points. No clinically significant changes in baseline intraocular pressure (IOP) occurred despite the likely possibility of topical ophthalmic corticosteroids causing increased IOP and ocular hypertension. The authors concluded that the stent appears to optimize surgical results by minimizing the occurrence of inflammation, adhesions, and polypoid tissue formation, with negligible potential for ocular adverse effects (AEs). There is no evidence available to suggest that this absorbable sinus stent maintains sinus patency over time. The limitations noted for this study include its small sample size (n = 50), short-term objective follow-up, and lack of randomization.

The efficacy and safety of the PROPEL implant have been studied in two prospective double-blinded randomized controlled trials (RCTs) (Murr et al., 2011; CONSENSUS II; Marple et al. (2012); ADVANCE II). Both studies utilized an intrapatient control design and compared a steroid-eluting implant with an identical control implant. The primary efficacy outcome in CONSENSUS II is the degree of inflammation rated by the treating physician, whereas the primary outcome in ADVANCE II is the reduction in the need for postoperative interventions at day 30 post-procedure.

- Murr et al. (2011) reported the results of the CONSENSUS II trial, which assessed the safety, effectiveness, and performance of the PROPEL device when used following FESS in patients with ethmoid CRS in 50 participants (n = 50). Forty-three patients received the 23-mm PROPEL Sinus Implant, and seven patients received a shorter version. Patients and providers were blinded to which stent was placed via block randomization. All patients were placed on a 14-day course of antibiotics the day prior to surgery, and no additional steroids (including nasal steroids) were allowed for the first month following surgery. The authors reported a statistically significant reduction in ethmoid sinus inflammation compared to the control implant at day 21 and statistically significant reductions in inflammation were also observed at days 30 and 45. The SINUVA implant reduced the frequency of medial turbinate lateralization, the development of significant adhesions, and polypoid formation at day 30 compared to the control implant.

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- Marple et al. (2012) assessed the safety and effectiveness of the PROPEL device following bilateral ethmoidectomy for patients with CRS in ADVANCE II. The study is a multi-center, prospective, randomized, double-blind, intra-patient-controlled trial with 105 patients (n = 105 / 210 sinuses). Participants were randomly assigned to either the treatment device in one ethmoid sinus or an identical non-drug-eluting stent device in the contralateral ethmoid sinus. No additional steroids were administered for 30 days after the procedure. The primary safety endpoint of the absence of clinically significant increase in ocular pressure through day 90 following the procedure was met. The drug-releasing implant noted a 29.0% relative reduction in post-operative interventions, a 52% decrease in lysis of adhesions, and a relative reduction in frank polyposis of 44.9% compared to control sinuses with non-drug-releasing implants. Study limitations include an intra-patient trial design where both sinuses had implants, one with steroid and the other without drug, which does not allow for a comparison of post-operative outcomes of the device with outcomes with standard of care.

A meta-analysis of the two trials conducted by Murr et al. and Marple et al. found a significant reduction in postoperative interventions (35%), adhesion and lysis (51%), and the need for oral steroids in treated sinuses (40%), in the 143 patients who received a steroid-releasing implant compared to control sinuses that received a nondrug implant (Han et al. 2012).

An evidence-based peer review on “Chronic rhinosinusitis: Management” lists glucocorticoid-eluting sinus implants as a medical adjunct to sinus surgery; however, the "Summary and Recommendations" section of the review omits any recommendation of glucocorticoid-eluting sinus implants (Holbrook, 2023). The review summarizes the following regarding mometasone-eluting sinus implants: “…approved by the US Food and Drug Administration to maintain the patency of the ethmoid or frontal sinus openings following endoscopic surgery. The approved implants deliver 370 mcg of mometasone furoate from a biodegradable, bioabsorbable polymer matrix over 30 days. Several published studies and a meta-analysis have examined the utility of these devices. The meta-analysis included two randomized trials with a total of 143 patients and found that drug-eluting implants, compared with nondrug implants, significantly reduced postoperative interventions, lysis of adhesions, and the need for oral corticosteroids by 35, 51, and 40 percent, respectively. Another study demonstrated that the implants could be inserted in-office into the ethmoid cavity for treatment of recurrent polyposis following endoscopic sinus surgery with resultant reduction in NP size, ethmoid sinus obstruction, and improvement in nasal obstruction symptom scores achieved for six months.”

PROPEL Mini and Contour

Smith et al. (2016) and Luong et al. (2017) conducted two identical trials of prospective, randomized, blinded design using an intra-patient control involving 160 adults diagnosed with CRS (80 patients in each trial). After successful bilateral frontal sinusotomy (using balloons and/or traditional instruments), each patient was randomized to receive 1 steroid-releasing implant (PROPEL Mini or PROPEL Contour) in 1 FSO (treatment side), while the contralateral FSO served as the control. A 10-day course of antibiotics was required 1 day prior to surgery. Intranasal steroid sprays starting at 14 days post-ESS were permitted, and oral steroids were prescribed, if warranted, by the investigator. No implant-related adverse events were reported in either study. Limitations of the studies include the intrapatient study design and the removal of the implant at day 21 (the potential of the implant removal procedure causing additional trauma to the adjacent mucosa and affecting normal healing on the treatment side). The primary efficacy endpoint for both RCTs was reduction in the need for postoperative interventions (steroid or surgical) at 30 days based on a centralized, blinded video-endoscopy review by the same independent sinus surgeon.

- Smith et al. (2016) assessed the safety and efficacy of the PROPEL mini steroid-releasing implant following ESS (PROGRESS study). Each subject had one sinus ostia treated with the PROPEL Mini device, and the other received standard care. At 30 days post-ESS, the PROPEL Mini provided a statistically significant relative reduction of 38.1% in the need for postoperative interventions compared to surgery alone, as assessed by an independent reviewer. A statistically significant reduction in this measure at 30 days and 90 days was reported, with a 55.6% reduction in the need for oral steroid interventions, a 75% reduction in the need for surgical interventions, a 16.7% reduction in the inflammation score, 54.3% reduction in restenosis rate, and a 32.2% greater diameter of the FSO on treated sides compared to the control at 30 days.

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- Luong et al. (2018) evaluated the efficacy and safety of the PROPEL Contour implant in improving postoperative outcomes when placed in the FSO following ESS in adult patients with CRS. Similar to the study conducted by Smith et al. (2016), patients underwent bilateral frontal sinusotomies, followed by random placement of a steroid-releasing sinus implant. The primary outcome of the study was the reduction in need for postoperative interventions (defined as surgical intervention or oral steroid trial) at 30 days. The data showed that, based on video endoscopic evaluation by an independent, blinded reviewer, steroid-releasing implants significantly reduced the need for postoperative interventions to 11.5% compared to 32.8% with surgery alone. The authors concluded that the PROPEL Contour steroid-releasing sinus implant was safer and more effective than surgery alone in maintaining FSO patency and improving surgical outcomes when no other immediate postoperative corticosteroids were administered.

Singh et al. (2019) published an analysis that evaluated the effect of the PROPEL implants on frontal outcomes in various patient subgroups with chronic CRS using pooled data from of two RCTs (Smith et al. 2016 and Luong et al. 2017). Data from the two studies were pooled through day 90, and subgroup analyses were performed. The subgroup analysis revealed that the implant group had better outcomes for frontal sinus surgery through 90 days, regardless of asthma status, previous endoscopic sinus surgery, extent of surgery, extent of polyps, or LundMackay computed tomography stage. Furthermore, when compared to surgery alone, the implants significantly reduced the rate of restenosis/occlusion and the need for postoperative interventions after 90 days.

Rizan et al. (2016) conducted a systematic review to evaluate the efficacy and safety of bioabsorbable steroid-eluting intranasal devices. Seven studies met the inclusion criteria, including five RCTs that followed patients from 2 to 6 months after receiving steroid-eluting intranasal devices. Six studies found stent efficacy to be statistically significant. Adhesion formation, polyp formation, inflammation, Lund-Kennedy scores, and perioperative sinus endoscopy scores were reduced by steroid-eluting bioabsorbable intranasal devices. The devices improved patient-reported outcomes and olfaction while reducing the number of postoperative interventions. According to the authors, there is a lack of data, and more research is needed to determine whether they are safe and effective post-ESS adjuncts. The study conclude that additional studies are required to optimize the dosing regimen, compare devices, and provide long-term outcomes.

Huang et al. (2015), in a Cochrane systematic review, identified 21 trials (from the 159 retrieved) that studied the effects of steroid-eluting stents (SES) compared to nonsteroid-eluting sinus stents, nasal packing, or no treatment in adult patients with CRS who underwent FESS. However, these trials had to be excluded because they met some but not all the inclusion criteria. Therefore, no trials could be included, and an evidence review of the potential advantages or disadvantages of SES was not possible. The authors were unable to provide evidence to establish whether steroid-eluting sinus stents have potential advantages and disadvantages for patients with CRS undergoing FESS. The systematic review concluded that high-quality RCTs comparing SES with surgery alone were needed to assess whether SES confer any beneficial effects (Cochrane 2015).

SINUVA (mometasone furoate) sinus implant

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). Bronchitis, nasopharyngitis, otitis media, headache, presyncope, asthma, and epistaxis were the most common AEs observed in clinical trials in patients who received SINUVA implants.

Han et al. (2014) reported the results of RESOLVE, a sham-controlled randomized trial, to evaluate the safety and efficacy of a steroid-eluting nasal implant of mometasone furoate 1350 µg (SINUVA) in 100 adults (n=100) with recurrent nasal polyposis after ESS who are considered candidates for revised ESS. Enrolled participants had bilateral total ethmoidectomy more than 3 months prior and were randomly assigned to SINUVA (n=53) or control (n=47) treatment. Follow-up duration was 90 days after SINUVA implants were bilaterally inserted into the ethmoid sinuses. Implants were removed on day 60 to eliminate the possibility of spontaneous dislodgement and unblinding. During the post-operative period, fewer SINUVA-treated patients required oral steroids for ethmoid obstruction (11%

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vs. 26%). At 90 days of follow-up, the SINUVA group had significantly better grades of bilateral polyps and less ethmoid obstruction compared to the control group. The treatment group experienced a 2-fold reduction in nasal obstruction and congestion score at day 90 compared to the control group and 53% of treated patients (compared to 23% of the controls) were no longer indicated for repeat ESS at 90 days. Statistically significant reduction in both polyp grade and ethmoid sinus obstruction reported from this trial supports the efficacy of the SINUVA implant for the treatment of patients with CRSwNP refractory to medical therapy and considered candidates for revision ESS. Limitations of this study include the single-blind trial design (treatment assignment was not blinded to the clinicians involved in endoscopic grading), the relatively small study size, and the short follow-up time.

Kern et al. (2018) conducted a multicenter, randomized, sham-controlled, double-blind trial evaluating the effectiveness and safety of the SINUVA sinus implant in adult patients with refractory CRSwNP. The RESOLVE II phase 3 RCT provided supporting safety and efficacy data for the FDA approval of SINUVA. The study enrolled 300 adult patients with CRSwNP who had prior ESS but had recurrent sinus obstruction, and all were considered candidates for revision sinus surgery. Patients were assigned to either bilateral SINUVA implant placement or a sham procedure. Implants were removed within 60 days of insertion to allow for blinded grading at day 90. Both treatment and control groups were required to self-administer mometasone furoate nasal spray once daily during the 90-day follow-up. The primary efficacy endpoints were the change from baseline in nasal obstruction/congestion score (to day 30) and bilateral polyp grade (to day 90), as determined by an independent, blinded panel based on centralized, blinded video endoscopy review. SINUVA-treated patients had significantly lower nasal congestion/congestion scores (-0.80 and -0.56, respectively) and bilateral polyp grades (-0.56 vs. -0.15, respectively). Furthermore, there was a 61% reduction in the need for repeat sinus surgery at 90 days in the treatment group (37% in the placebo-treated patients). Repeat dosing has not been studied.

A Health Technology Assessment (HTA) assigned a 'potential but unproven benefit' rating for the use of the SINUVA sinus implant and daily mometasone furoate intranasal spray in the treatment of patients with nasal polyps following ESS (Hayes, reviewed December 2021). SINUVA plus daily mometasone furoate intranasal spray may improve endoscopic and patient-reported outcomes after ESS and reduce the need for additional sinus surgery, compared to a sham procedure plus daily mometasone furoate intranasal spray. The HTA concluded that the rating reflects low-quality evidence and uncertainty resulting from a small amount of evidence, as well as a lack of long-term follow-up to determine the durability of benefits.

National and Specialty Organizations

The **International Consensus statement on Allergy and Rhinology: Rhinosinusitis (ICAR-RS)** recommended steroid-eluting stents for ESS as optional (Orlandi, et al., 2016). In 2021, five years since the publication of the first ICAR-RS, in a compilation of evidence-based recommendations for medical and surgical treatment of the most common forms of RS, the ICAR-RS stated that for steroid eluting implants for CRSwNP, "corticosteroid eluting implants have been shown to have beneficial impact on ethmoid polyposis and obstruction, and 1 study has shown them to be cost-effective in preventing revision ESS. Experience is early and although evidence is high level, only short-term outcomes are currently available." The consensus conclude that corticosteroid-eluting implants can be considered as an option in a previously operated ethmoid cavity with recurrent nasal polyposis.

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

The **American Rhinologic Society (ARS)** (2023) issued a position statement supporting the use of drug-eluting implants in the sinus cavities and noted that there is a growing body of high-quality evidence on the safety and efficacy of drug-eluting implants in the paranasal sinuses. The ARS cites several well-controlled studies on steroid-eluting implants in the paranasal sinuses and that these studies have demonstrated improved patient outcomes by reducing polyp burden and inflammation, reducing the need for systemic steroids, and delaying revision sinus surgery.

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National Institute for Health and Care Excellence (NICE) published an interventional procedures guidance on the insertion of corticosteroid-eluting stent or spacer during ESS to treat CRS. The guidance stated that current evidence regarding efficacy is limited; however, no major safety concerns was cited. It is recommended that additional research be conducted on the insertion of corticosteroid-eluting bioabsorbable stents or spacers during ESS, specifically controlled studies designed for between-patient (rather than within-patient) comparisons. The use of steroid-releasing implants after ESS to treat nasal polyps was not mentioned in the guidance (NICE, 2016).

CODING & BILLING INFORMATION

CPT Code

CPT	Description
31299	Unlisted procedure, accessory sinuses

HCPCS Codes

HCPCS	Description
J7402	Mometasone furoate sinus implant, (SINUVA), 10 micrograms.
S1091	Stent, non-coronary, temporary, with delivery system (PROPEL) *For unilateral placement of a drug-eluting sinus implant, report 1 Unit* *For bilateral placement of a drug-eluting sinus implant, report 2 Units*

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 not 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

4/13/2023 MCPC	Policy reviewed and updated. No changes in coverage criteria. Updated 'Summary of Evidence' section and references.
4/13/2022 MCPC	Policy revised: Changed title from SINUVA (mometasone furoate) to Sinus Implants (PROPEL, SINUVA) due to addition of PROPEL clinical evidence and coverage criteria. Updated and added references. IRO Peer Review. 02/21/22. Practicing Physician. Board-certified in Otolaryngology - Head and Neck Surgery.
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.

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*