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

Last Approval: 04/10/2024
Next Review Due By: April 2025

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

Rhinosinusitis, also known as sinusitis, is an inflammation of the paranasal sinuses and nasal mucosa in all age groups. It can be caused by infection, airborne allergens (such as dust mites, mold, pollen), or autoimmune deficiency. There are two main types of sinusitis: acute and chronic.

Chronic rhinosinusitis (CRS) is an inflammatory condition involving the paranasal sinuses and the lining of the nasal passages, lasting 12 weeks or longer, despite attempts at medical management, and is associated with sinus edema and impaired mucociliary clearance. The diagnosis of chronic rhinosinusitis requires objective evidence of mucosal inflammation, with or without nasal polyps, based on clinical presentation and examination using anterior rhinoscopy, or nasal endoscopy. The four cardinal symptoms of chronic rhinosinusitis are: nasal obstruction, facial congestion, anterior and/or posterior mucopurulent drainage, and hyposmia (decreased ability to smell). The fourth cardinal symptom may be cough in pediatric patients. First-line treatment for chronic rhinosinusitis is usually conservative medical therapy to resolve the symptoms, such as oral antibiotics, saline nasal irrigation, topical and/or systemic decongestants, topical steroids in the form of nasal sprays for controlling inflammation and/or systemic steroids, and/or treatment of concomitant allergic rhinitis, including avoidance measures, pharmacotherapy, and/or immunotherapy. For patients who do not experience adequate relief with medical and pharmaceutical therapy, surgical interventions may be necessary. Radiologic imaging must be obtained, of which a CT scan is the gold standard, when surgery is being considered. The typical surgical treatment for chronic rhinosinusitis is functional endoscopic sinus surgery (FESS) in which soft tissue and/or bone is removed to create openings from the sinuses into the nose.

Corticosteroid-eluting sinus stents are devices used postoperatively following endoscopic sinus surgery (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 is important in achieving optimal sinus drainage and surgical recovery, and may reduce the need for additional surgery.

Regulatory Status
The PROPEL sinus stents are bioabsorbable, drug-eluting sinus stents intended to maintain patency of the ethmoid or frontal sinus opening after sinus surgery. Upon insertion, the implant expands radially to conform to the surgically enlarged sinus ostium following ESS, 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. Originally FDA approved through the Premarket Approval clearance process on August 11, 2011, under PMA number P100044 and product code OWO. It is classified as a drug – eluting sinus stent.

The SINUVA sinus implant (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. 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. FDA approved at new dose on December 8, 2017, through New Drug Application clearance process under NDA number 209310. It is classified as a mometasone furoate – implant.

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
2. History of endoscopic sinus surgery, with date of surgery documentation
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]
    b. Oral corticosteroids within the last six months [e.g., prednisone, methylprednisolone, or dexamethasone]
4. Sinuva nasal implant will be used in conjunction with mometasone furoate nasal spray once daily

PROPEL/PROPEL Mini/PROPEL Contour (mometasone furoate) as a 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 chronic sinusitis 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
2. Primary or revision endoscopic sinus surgery is indicated, with date of surgery documentation
3. Prescribed to maintain patency of **ONE** of the following:
    a. Ethmoid sinus opening
    b. Frontal sinus opening
    c. Maxillary sinus opening
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)
    b. Oral corticosteroids within the last 6 months (e.g., prednisone, methylprednisolone, or dexamethasone).

CONTINUATION OF THERAPY: These are one – time use implant treatments. Reauthorization is not allowed.
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

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

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**.**
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**.**
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*
- 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

Wang et al. (2023) conducted a short term prospective, multicenter, randomized, intrapatient-controlled trial to evaluate the postoperative efficacy of steroid-eluting stents for eosinophilic chronic rhinosinusitis with nasal polyps (CRSwNP). The primary outcome was assessing the Lund-Kennedy endoscopic score within 12 weeks post-surgery. Secondary outcomes were evaluating nasal symptoms scores, nasal resistance, acoustic rhinometry, nasal nitric oxide levels, 3-dimensional volumetric computed tomography scores, and eosinophil counts in the ethmoid mucosa. Ninety-eight patients were enrolled and randomly implanted with absorbable steroid-eluting stents containing mometasone furoate in one sinus at the end of endoscopic sinus surgery (ESS), leaving the other sinus as the control. All patients received standard postoperative care and follow-up. Three patients were lost in follow up, leaving 95 patients who completed the trial. At postoperative weeks 4, 8, and 12, the Lund-Kennedy scores were significantly lower on the treatment side than on the control side (all $p < 0.01$). Compared with the treatment side, the control side exhibited higher tissue eosinophilia at week 4 and higher volumetric, nasal obstruction, and total nasal symptom scores at postoperative week 8 ($p = 0.011$, $p = 0.011$, $p < 0.01$, and $p = 0.001$, respectively). No adrenal cortical suppression or serious side effects were observed. The authors concluded that steroid-eluting stents are a good supplementary postsurgical treatment in patients with CRSwNP, as they reduce sinus edema and inflammation with effects persisting past stent disintegration.

Huang et al. (2022) conducted a multicenter, randomized, controlled, single-blinded clinical trial to compare the efficacy of bioabsorbable steroid-eluting sinus stents versus absorbable Nasopore packs after ESS for the treatment of chronic rhinosinusitis (CRS). The authors state that the primary goal of medical and surgical management of CRS is to achieve symptom control. ESS improves ventilation and drainage, as well as increased access for targeted local anti-inflammatory treatment; however, poor adherence to medical management often contribute to the failure of primary ESS. Postoperative intranasal corticosteroids have been shown to improve the endoscopic scores yet were found to be prescribed at low rates indicating low patient use; therefore steroid-eluting stent maybe a solution for the problem of compliance. One hundred eighty-one patients with CRS who underwent ESS were randomly assigned to receive a steroid-eluting sinus stent in one ethmoid sinus cavity, whereas the contralateral control side received a Nasopore pack. Endoscopic evaluations were performed 14, 30, and 90 days after the ESS. Postoperative intervention, polyp formation, adhesions, and middle turbinate position were assessed as efficacy outcomes. Thirty days after the ESS, the stents significantly reduced the need for surgical intervention compared to the Nasopore ($P < .0001$). The percentage of cases with polyp formation was significantly lower on the stent sides compared with the Nasopore sides ($P < .0001$) at 14, 30, and 90 days after ESS. The percentage of severe adhesion was significantly lower on the stent sides than on the Nasopore sides at postoperative day 90 ($P = .0003$), whereas they were not significantly lower at postoperative days 14 and 30. There were no significant differences between the stent sides and the Nasopore sides regarding the frequency of middle turbinate lateralization at all end points. There were no device related adverse events reported. The authors concluded the study demonstrated significant improvement in the early postoperative outcomes by reducing the need for postoperative surgical intervention and polyp formation using steroid-eluting stents when compared with absorbable Nasopore packs.

Goshtasbi et al. (2019) conducted an updated meta-analysis evaluating the efficacy of steroid-eluting stents in management of chronic rhinosinusitis after ESS. Of 78 published studies, nine met inclusion criteria for qualitative analysis. Two studies included did not provide compatible data for meta-analysis, instead they were utilized for descriptive reports in the discussion. Seven of the studies provided quantifiable data for analysis, resulting in 444 sinuses implanted with steroid eluting stents, and 444 controlled frontal or ethmoid sinuses. In patients who received steroid eluting stents vs controls, collective odds ratios (ORs) for postoperative need for intervention, surgery, and oral steroid were 0.45 (95% confidence interval [CI], 0.33-0.62; $p < 0.001$), 0.30 (95% CI, 0.18-0.52; $p < 0.001$), and 0.58 (95% CI, 0.40-0.84; $p = 0.004$), respectively. In addition, collective ORs for frontal sinus ostia (FSO) patency, moderate-to-severe adhesion/scarring, and increase in polyp score were 2.53 (95% CI, 1.61-3.97; $p < 0.001$), 0.28 (95% CI, 0.13-0.59; $p < 0.001$), and 0.42 (95% CI, 0.25-0.74; $p = 0.002$), respectively. Collective mean differences for FSO/ethmoid inflammation and FSO diameter were -10.86 mm ($p < 0.001$) and +1.34 mm ($p < 0.001$),

respectively. The results led the authors to conclude that evidence suggests that steroid eluting stents can improve ESS outcomes by reducing rates of postoperative intervention and recurrent polyposis and inflammation, while promoting FSO patency; however, a major limitation to all evidence is that all studies analyzed were industry-sponsored and ruling-out publication bias was not possible.

PROPEL Implant

The efficacy and safety of the PROPEL implant in adult patients with CRS undergoing ESS were evaluated in three foundational prospective clinical trials.

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. 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.

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.

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 PROPEL implant reduced the frequency of medial turbinate lateralization, the development of significant adhesions, and polypoid formation at day 30 compared to the control implant.

PROPEL Mini and Contour

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. Like 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.

Smith et al. (2016) conducted a prospective, multicenter, randomized, blinded trial using an intrapatient control design to assess the safety and efficacy of the PROPEL mini steroid-releasing implant following ESS (PROGRESS study). Eighty participants were included in the study, and each subject had one sinus ostia treated with the PROPEL Mini device, and the other sinus ostia did not receive the steroid eluting stent implant. All patients received standard post-operative care in both sinuses. Endoscopic evaluations recorded at 30-days post0-ESS were graded real time by clinical investigators, in addition to an independent, blinded sinus surgeon to assess the need for postoperative interventions in the FSO. 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. There were no device related adverse events reported.

SINUVA (mometasone furoate) sinus implant

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% 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.

National and Specialty Organizations

The **American Rhinologic Society** published the International Consensus statement on Allergy and Rhinology: Rhinosinusitis (Orlandi et al. 2021) recommended post-operative drug eluting stents for postoperative care following ESS for CRS, noting the harm potential lies in misplacement and local reaction, the cost is variable depending on stents and medication, and summates the recommendation that there is a preponderance of benefit over harm.
The consensus statement also recommended steroid eluting implants for CRSwNP highlighting the benefits of reduction in ethmoid obstruction and polyp grade, decreased need for revision ESS, and reduced nasal obstruction scores.

The **American Academy of Otolaryngology-Head and Neck Surgery** (2023) published a position statement supporting the use of drug eluting sinus implants. The statement sited that clinical evidence demonstrates that using the drug eluting sinus implants reduces inflammation, relieves obstruction of sinuses, improves the sinonasal symptoms and quality of life of affected patients, all while also reducing systemic corticosteroid burden.

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.

The **National Institute for Health and Care Excellence (NICE)** (2016) 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.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Code

Code	Description
31299	Unlisted procedure, accessory sinuses (if specified as endoscopic placement of a drug-eluting implant)

HCPCS (Healthcare Common Procedure Coding System Codes

Code	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

04/10/2024	Policy reviewed. No changes to coverage criteria.
04/13/2023	Policy reviewed. No changes in coverage criteria. Updated 'Summary of Evidence' section and references.
04/13/2022	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.
06/07/2021	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	New policy. IRO Peer Review. 10/23/2018. Practicing Physician. Board certified in otolaryngology.

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