

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 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 cardinal symptoms of chronic rhinosinusitis are: nasal obstruction, facial congestion, anterior and/or posterior mucopurulent drainage, and hyposmia (decreased ability to smell). Cough may be present 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 and regulated as a device. The PROPEL stent is not medically indicated to maintain sinus patency after balloon sinuplasty.

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 and regulated as a drug.

COVERAGE POLICY

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

1. Member is 18 years of age or older
2. Diagnosis of recurrent nasal polyp disease
3. History of endoscopic sinus surgery with documented date of surgery
4. Inadequate response, clinically significant adverse effects, or contraindication to ALL the following treatments:
 - 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 one-time post-operative intervention for chronic sinusitis surgery may be **considered medically necessary** when ALL the following clinical criteria are met with documentation:

1. Member is 18 years of age or older
2. Diagnosis of chronic sinusitis confirmed by CT scan and clinical symptoms lasting longer than 12 consecutive weeks with inflammation of the mucosa of the nose and paranasal sinuses
3. Primary or revision endoscopic sinus surgery (excluding balloon sinuplasty) is indicated with documented date of surgery
4. Prescribed to maintain patency of ONE OR MORE of the following:
 - a. Ethmoid sinus opening
 - b. Frontal sinus opening
 - c. Maxillary sinus opening
5. 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).

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

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Steroid-Eluting Sinus Stents and Implants (PROPEL, SINUVA):
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DRUG CLASS: Corticosteroid, Nasal

QUANTITY LIMITATIONS: ONE implant per nostril per lifetime

DOSING CONSIDERATIONS:

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

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

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 (mometasone furoate) implant: 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 endoscopic sinus surgery .

COMPENDIAL APPROVED OFF-LABELED USES: None

SUMMARY OF MEDICAL EVIDENCE

Steroid-Eluting Stents

Randomized Controlled Trials

Wang et al. (2023) conducted a short-term, multicenter, prospective, randomized, inpatient-controlled trial to assess the postoperative efficacy of steroid-eluting stents in patients with eosinophilic chronic rhinosinusitis with nasal polyps (CRSwNP). The primary outcome measured was the Lund-Kennedy endoscopic score within 12 weeks post-surgery. Secondary outcomes included assessment of nasal symptom scores, nasal resistance, acoustic rhinometry, nasal nitric oxide levels, three-dimensional volumetric computed tomography scores, and eosinophil counts in the ethmoid mucosa. The study enrolled 98-patients, each of whom received an absorbable steroid-eluting stent containing mometasone furoate in one sinus, while the other sinus served as a control. All patients received standard postoperative care and follow-up, with 95 completing the study after three patients were lost to follow-up. At postoperative weeks 4, 8, and 12, the Lund-Kennedy scores were significantly lower on the treated side compared to the control side (all $p < 0.01$). Additionally, at week 4, the control side exhibited greater tissue eosinophilia ($p = 0.011$), while at week 8, it showed higher volumetric, nasal obstruction, and total nasal symptom scores ($p = 0.011$, $p < 0.01$, and $p = 0.001$, respectively). No cases of adrenal cortical suppression or serious adverse effects were reported. The authors concluded that steroid-eluting stents are a beneficial adjunctive postsurgical treatment for CRSwNP, effectively reducing sinus edema and inflammation with effects lasting beyond 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 compared to absorbable Nasopore packs following endoscopic sinus surgery (ESS) for the treatment of chronic rhinosinusitis (CRS). The study included 181 patients with CRS who underwent ESS. Each patient received a steroid-eluting sinus stent in one ethmoid sinus cavity, while the contralateral side served as a control and was treated with a Nasopore pack. Endoscopic evaluations were conducted at 14-, 30-, and 90-days post-surgery, assessing postoperative intervention, polyp formation, adhesions, and middle turbinate positions. At 30 days postoperative, the need for surgical intervention was significantly lower in the stent-treated sinuses compared to the Nasopore-treated side ($p < 0.0001$). Additionally, the percentage of cases with polyp formation was significantly lower on the stent side at all three time points ($p < 0.0001$). By day 90, severe

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adhesions were also significantly reduced in the stent-treated sinuses compared to the Nasopore side ($p = 0.0003$), though no significant differences were observed at days 14 and 30. There were no significant differences in middle turbinate lateralization rates between treatment groups. No device-related adverse events were reported. The study concluded that steroid-eluting stents significantly improve early postoperative outcomes by reducing the need for additional surgical intervention and minimizing polyp formation compared to absorbable Nasopore packs.

Systematic Review and Meta-Analyses

Goshtasbi et al. (2019) conducted an updated meta-analysis to assess the effectiveness of steroid-eluting stents in managing chronic rhinosinusitis after ESS. Seven studies encompassing 444 sinuses implanted with steroid-eluting stents and 444 corresponding control sinuses in the frontal or ethmoid regions were included in the analysis. Among patients who received steroid-eluting stents compared to controls, the pooled odds ratios (ORs) for postoperative intervention, additional surgery, and oral steroid use were 0.45 ($p < 0.001$), 0.30 ($p < 0.001$), and 0.58 ($p = 0.004$), respectively. Additionally, the pooled ORs for frontal sinus ostia (FSO) patency, moderate-to-severe adhesion or scarring, and increased polyp scores were 2.53 ($p < 0.001$), 0.28 ($p < 0.001$), and 0.42 ($p = 0.002$), respectively. Mean differences for FSO/ethmoid inflammation and FSO diameter were -10.86 mm ($p < 0.001$) and +1.34 mm ($p < 0.001$), respectively. A significant limitation of the evidence was that all included studies were industry-sponsored, making it difficult to eliminate potential publication bias. Despite this, the findings suggest that steroid-eluting stents may enhance ESS outcomes by reducing postoperative interventions, recurrent polyposis, and inflammation while promoting FSO patency.

PROPEL Implant

Randomized Controlled Trials

Forwith et al. (2011) published findings from the ADVANCE study, a non-randomized, open-label, multicenter, single-arm trial assessing the placement of the PROPEL implant in 50 CRS patients undergoing ESS (90 sinuses). Participants received either bilateral or unilateral steroid-eluting sinus implants at the end surgery, with oral and intranasal steroids withheld for the first 60 days postoperatively. Patients were monitored endoscopically 60 days post-surgery, while patient-reported outcomes were tracked for six months (Sinonasal Outcomes Test 22, Rhinosinusitis Disability Index, and Total Nasal Symptom Scoring). Implants were successfully placed in all 90 sinuses. At 60 days and six months, self-reported survey results showed statistically significant improvements from baseline. Minimal inflammation and adhesions were observed at one month, with consistently low inflammation scores at all time points. No significant changes in intraocular pressure (IOP) occurred, despite concerns that topical ophthalmic corticosteroids could potentially elevate IOP and lead to ocular hypertension. The study concluded that the PROPEL stent may enhance surgical outcomes by reducing inflammation, adhesions, and polypoid tissue formation, with minimal ocular side effects. However, no evidence supports its ability to maintain long-term sinus patency. Limitations of the study include its small sample size ($n = 50$), short-term objective follow-up, and lack of randomization.

Murr et al. (2011) reported results from the CONSENSUS II trial, which evaluated the safety, effectiveness, and performance of the PROPEL device in 50 patients with when ethmoid CRS following functional endoscopic sinus surgery (FESS). Of these participants, 43 received the 23-mm PROPEL sinus implant, while seven received a shorter version. Patients and providers were blinded implant placement through block randomization. All participants began a 14-day course of antibiotics one day prior to surgery, and no additional steroids, including nasal steroids, were allowed for the first postoperative month. Findings showed a statistically significant reduction in ethmoid sinus inflammation with the PROPEL implant compared to the control implant at day 21, with continued reductions observed at days 30 and 45. The PROPEL device also lowered the incidence of medial turbinate lateralization, significant adhesions, and polypoid formation at day 30 compared to the control implant.

Marple et al. (2012) conducted ADVANCE II study, a multicenter, prospective, randomized, double-blind, intra-patient-controlled trial evaluating the safety and efficacy of the PROPEL device following bilateral ethmoidectomy in 105 CRS patients (210 sinuses). Participants were randomly assigned to receive either the drug-eluting implant in one ethmoid sinus or an identical non-drug-eluting stent in the contralateral sinus. No additional steroids were administered for 30 days postoperatively. The study met its primary safety endpoint, demonstrating no clinically significant increase in ocular pressure through 90 days post-surgery. The steroid-releasing implant was associated with a 29% relative reduction in the need for post-operative interventions, a 52% decrease in adhesion lysis procedures, and a 44.9% relative reduction in frank polyposis compared to control sinuses. A key limitation of this study was its intra-patient trial design, in which both sinuses received implants, one with a steroid and one without,

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preventing a direct comparison of post-operative between the device and standard postoperative care.

PROPEL Mini and Contour

Randomized Controlled Trials

Smith et al. (2016) the PROGRESS study, a prospective, multicenter, randomized, blinded trial using an inpatient control design to evaluate the safety and efficacy of the PROPEL Mini steroid-releasing implant following ESS. The study included 80 participants, each receiving the implant in one sinus ostium, while the contralateral ostium served as the control without a steroid-eluting stent. Both sinuses underwent standard post-operative care. Endoscopic assessments were performed 30 days after ESS, with real-time grading by clinical investigators and an independent, blinded sinus surgeon to determine the need for postoperative interventions in the FSO. Results demonstrated that the PROPEL Mini led to a statistically significant 38.1% relative reduction in postoperative interventions compared to surgery alone, as determined by an independent reviewer. Additional findings at 30- and 90-days post-ESS included a 55.6% reduction in oral steroid use, a 75% decrease in the need for surgical interventions, a 16.7% reduction in inflammation scores, a 54.3% reduction in restenosis rate, and a 32.2% larger FSO diameter on treated sides compared to the control. No device-related adverse events were reported.

Luong et al. (2018) evaluated the effectiveness and safety of the PROPEL Contour implant in enhancing postoperative outcomes when placed in the FSO after ESS in adult with CRS. Similar to the study by Smith et al. (2016), patients underwent bilateral frontal sinusotomies, with a steroid-releasing sinus implant randomly placed in one sinus. The study's primary objective was to determine whether the implant reduced the need for postoperative interventions – defined as either surgical intervention or an oral steroid trial) – within 30 days. An independent, blinded reviewer conducted video endoscopic evaluations, showing that steroid-releasing implants significantly lowered the rate of postoperative interventions to 11.5% compared to 32.8% in patients who underwent surgery alone. The study concluded that the PROPEL Contour implant was both safer and more effective than surgery alone in maintaining FSO patency and optimizing surgical outcomes when no other immediate postoperative corticosteroids were administered.

SINUVA (mometasone furoate) sinus implant

Randomized Controlled Trials

Han et al. (2014) presented findings from the RESOLVE trial, a randomized, sham-controlled study assessing the safety and efficacy of the SINUVA steroid-eluting nasal implant (mometasone furoate 1350 µg) in (SINUVA) in 100 adults with recurrent nasal polyposis after prior ESS who were candidates for revision 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,

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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.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Hayes (2023) published a health technology assessment to evaluate the effectiveness of the Sinuva implant in patients with nasal polyps following endoscopic sinus surgery (ESS). This review included two randomized controlled trials (RCTs) and one pretest/posttest study, all examining the impact of bilateral Sinuva implantation combined with daily mometasone furoate (MF) intranasal spray. Compared to a sham procedure, the Sinuva implant significantly improved endoscopic and patient-reported outcomes, including reductions in bilateral polyp grade, ethmoid sinus obstruction, and nasal congestion. The treatment also decreased the need for repeat ESS, with fewer Sinuva-treated patients requiring surgery at follow-up than those in the sham group. Adverse event rates varied, with sinusitis being the most reported complication. The primary limitations of the assessment include a small sample size, which may limit generalizability and omit relevant safety data, and the absence of long-term follow-up, making it difficult to determine the implant's sustained effectiveness beyond six months. While the Sinuva implant shows potential for improving nasal polyp symptoms and reducing surgical interventions, further research is necessary to establish its long-term safety, efficacy, and optimal patient selection criteria.

National and Specialty Organizations

The **American Rhinologic Society's International Consensus statement on Allergy and Rhinology: Rhinosinusitis** guideline endorses the use of post-operative drug-eluting stents for postoperative care following ESS for CRS (Orlandi et al. 2021). The recommendation acknowledges potential risks, such as stent misplacement and localized reactions, while also noting that costs vary based on the type of stent and medication used. The statement concludes that the benefits outweigh the risks. The consensus supports the use of steroid-eluting implants for patients with CRSwNP. These implants have been shown to improve outcomes by reducing ethmoid obstruction and polyp size, lowering the need for revision ESS, and decreasing 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 cited clinical evidence that demonstrates their effectiveness in reducing inflammation, alleviating sinus obstruction, and improving sinonasal symptoms and overall quality for patients while also reducing the need for systemic corticosteroid.

The **American Rhinologic Society (ARS)** (2023) issued a position statement endorsing the use of drug-eluting implants in the sinus cavities, emphasizing their role in maintaining ostial patency and reducing sinonasal inflammation. The ARS highlighted a growing body of high-quality evidence supporting the safety and effectiveness of these implants in the paranasal sinuses, citing multiple well-controlled studies demonstrating their benefits. These include reduced polyp burden and inflammation, decreased reliance on systemic steroids, prevention of middle turbinate lateralization, and a delayed need for revision sinus surgery. Additionally, the ARS emphasized the cost-effectiveness and positive impact of these implants on patient-centered outcomes, reinforcing that drug-eluting implants should not be considered investigational and should be made available to patients at the physician's discretion.

The **National Institute for Health and Care Excellence (NICE)** (2016) published interventional procedures guidance on the use of corticosteroid-eluting stents or spacers during ESS to for treating CRS. The guidance acknowledged that while evidence on efficacy remains limited, no major safety concerns were identified. NICE recommended further research, particularly controlled studies focusing on between-patient comparisons rather than within-patient analyses. The use of steroid-releasing implants following ESS to treat nasal polyps was not addressed in the guidance.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

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

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HCPCS (Healthcare Common Procedure Coding System)

Code	Description
J7402	Mometasone furoate sinus implant, (Sinuva), 10 micrograms.
S1091	Stent, non-coronary, temporary, with delivery system (Propel)

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

04/09/2025	Policy reviewed. No changes to coverage criteria. IRO Peer Review on March 23, 2025, by a practicing physician board-certified in Otolaryngology - Head and Neck Surgery.
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.

REFERENCES

1. American Academy of Otolaryngology-Head and Neck Surgery. Position Statement: Drug-Eluting Sinus Implants. Published January 17, 2023. Accessed March 4, 2025. <https://www.entnet.org/resource/position-statement-eluting-implants/>
2. American Rhinologic Society (ARS). ARS Position Statement: Criteria for Drug-Eluting Implants. Published January 28, 2023. Accessed March 4, 2025. <https://www.american-rhinologic.org>
3. Forwith KS, Chandra RK, Yun PT, Miller SK, Jampel HD. ADVANCE: A multisite trial of bioabsorbable steroid-eluting sinus implants. *Laryngoscope*. 2011;121(11):2473-2480. Doi: 10.1002/lary.22228.
4. Goshtasbi K, Abouzari M, Abiri A, Yasaka T, Sahyouni R, Bitner B, Tajudeen BA, Kuan EC. Efficacy of steroid-eluting stents in management of chronic rhinosinusitis after endoscopic sinus surgery: updated meta-analysis. *Int Forum Allergy Rhinol*. 2019 Dec;9(12):1443-1450. doi: 10.1002/alar.22443. PMID: 31539461; PMCID: PMC6901756.
5. Han JK, Forwith KD, Smith TL, et al. RESOLVE: A randomized, controlled, blinded study of bioabsorbable steroid-eluting sinus implants for in-office treatment of recurrent sinonasal polyposis. *Int Forum Allergy Rhinol*. 2014; 4(11):861-870. doi: 10.1002/alar.21426.
6. Hayes. Sinuva (Intersect ENT Inc.) steroid-releasing sinus implant for the treatment of nasal polyps after ethmoid sinus surgery. Published December 31, 2029. Updated March 24, 2023. Accessed March 15, 2025. <https://evidence.hayesinc.com/>.
7. Huang Z, Zhou B, Wang D, et al. Comparison of Bioabsorbable Steroid-Eluting Sinus Stents Versus Nasopore After Endoscopic Sinus Surgery: A Multicenter, Randomized, Controlled, Single-Blinded Clinical Trial. *Ear Nose Throat J*. 2022 May;101(4):260-267. doi: 10.1177/0145561320947632. PMID: 32845808.
8. Kern RC, Stolovitzky JP, Silvers SL, et al. RESOLVE II study investigators. A phase 3 trial of mometasone furoate sinus implants for chronic sinusitis with recurrent nasal polyps. *Int Forum Allergy Rhinol*. 2018 Apr;8(4):471-481. doi: 10.1002/alar.22084. (ClinicalTrials.gov Identifier: NCT022915490).
9. Luong A, Ow RA, Singh A, et al. Safety and effectiveness of a bioabsorbable steroid-releasing implant for the paranasal sinus ostia: a randomized clinical trial. *JAMA Otolaryngol Head Neck Surg*. 2018;144(1):28-35. doi: 10.1001/jamaoto.2017.1859. NCT02266810.
10. Marple BF, Smith TL, Han JK, et al. Advance II: A prospective, randomized study assessing safety and efficacy of bioabsorbable steroid-releasing sinus implants. *Otolaryngol Head Neck Surg*. 2012; 146:1004-11. PMID: 22301107.
11. Murr AH, Smith TL, Hwang PH, et al. Safety and efficacy of a novel bioabsorbable, steroid-eluting sinus stent. *Int Forum Allergy Rhinol*. 2011;1(1):23-32. doi: 10.1002/alar.20020. Erratum in: *Int Forum Allergy Rhinol*. 2019 Aug;9(8):945.
12. National Institute for Health and Care Excellence. Corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis. Interventional procedures guidance [IPG551]. Published 23 March 2016. Accessed March 4, 2025. <https://www.nice.org.uk>.
13. Orlandi RR, Kingdom TT, Smith TL, et al. International consensus statement on allergy and rhinology: rhinosinusitis 2021. *Int Forum Allergy Rhinol*. 2021 Mar;11(3):213-739. doi: 10.1002/alar.22741. Erratum in: *Int Forum Allergy Rhinol*. 2022 Jul;12(7):974. PMID: 33236525.
14. Smith TL, Singh A, Luong A, et al. Randomized controlled trial of a bioabsorbable steroid-releasing implant in the frontal sinus opening. *Laryngoscope*. 2016 Dec;126(12):2659-2664. doi: 10.1002/lary.26140. Erratum in: *Laryngoscope*. 2020 Mar;130(3):836.

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15. United States Food and Drug Administration (FDA). Premarket Approval. PROPEL. Product Code: OWO. PMA Number: P100044. Accessed March 4, 2025. <https://www.accessdata.fda.gov>.
16. United States Food and Drug Administration (FDA). New Drug Approval. SINUVA. NDA Number: 209310. Accessed March 4, 2025. <https://www.accessdata.fda.gov>.
17. Wang C, Yu L, Chu X, et al. Short-term postoperative efficacy of steroid-eluting stents for eosinophilic chronic rhinosinusitis with nasal polyps: A randomized clinical trial. *Int Forum Allergy Rhinol*. 2023 May;13(5):899-909. doi: 10.1002/alr.23085. PMID: 36086876.