

## ***Implantable Sinus Devices for Postoperative Use Following Endoscopic Sinus Surgery and for Recurrent Sinonasal Polyposis***

**Effective:** November 1, 2023

**Next Review:** August 2024

**Last Review:** September 1, 2023

### **IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### **DESCRIPTION**

Implantable sinus stents are inserted following endoscopic sinus surgery to maintain postoperative patency of the sinus opening and have the capability of being infused with medication that can be delivered topically over an extended period of time.

### **MEDICAL POLICY CRITERIA**

The use of implantable sinus devices for postoperative treatment following endoscopic sinus surgery and for treatment of recurrent sinonasal polyposis is considered **investigational**.

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

### **CROSS REFERENCES**

1. [Balloon Ostial Dilatation for Treatment of Sinusitis](#), Surgery, Policy No. 153
2. [Cryoablation for Chronic Rhinitis](#), Surgery, Policy No. 224

## BACKGROUND

Endoscopic sinus surgery (ESS) is typically performed in patients with chronic rhinosinusitis unresponsive to conservative treatment. ESS involves the removal of small pieces of bone, polyps, and debridement of tissue within the sinus cavities. These procedures can be done either in the physician's office under local anesthesia or in the hospital setting under general anesthesia. The surgery is generally associated with improvements in symptoms in appropriately selected patients.

There is a substantial amount of postoperative inflammation and swelling, and postoperative care is therefore a crucial component of ESS. There are a number of postoperative treatment regimens, and the optimal regimen is not certain. Options include saline irrigation, nasal packs, topical steroids, systemic steroids, topical decongestants, oral antibiotics, and/or sinus cavity debridement. Some form of sinus packing is generally performed postoperatively. Simple dressings moistened with saline can be inserted manually following surgery. Foam dressings are polysaccharide substances that form a gel when hydrated and can be used as nasal packs for a variety of indications. Middle meatal spacers are splint-like devices that prop open the sinus cavities post-ESS, but are not capable of drug delivery. Middle meatal spacers are being investigated as a method to reduce the formation of synechiae following ESS.

Implantable sinus stents are inserted following ESS surgery under endoscopic guidance. They are intended to improve post-ESS patency of the sinus meatus by stabilizing the sinus openings and the turbinates, reducing edema, and/or preventing obstruction by adhesions. These stents also have the capability of being infused with medication that can be delivered topically over an extended period of time as an alternative to topical application in the postoperative setting. They are distinguished from sinus or nasal packing and variations on packing devices that are routinely employed post sinus surgery such as foam dressings (e.g., SinuFoam™). These stents also differ from middle meatal spacers that are splint-like devices inserted post-ESS by direct visualization rather than under endoscopic guidance; spacers/splints are not capable of delivering local medication.

Recently, implantable sinus stents have been used to treat recurrent sinonasal polyposis in patients who have undergone ESS surgery previously.

## REGULATORY STATUS

Sinuva® Sinus Implant is made from bioabsorbable polymers designed to soften over time. Placed during a routine physician office visit, Sinuva expands into the sinus cavity and delivers an anti-inflammatory steroid directly to the site of polyp disease. As the implant softens and polyps decrease, the implant may be expelled out of the nose on its own or with actions such as sneezing or forceful nose blowing. The implant can be removed 90 days after placement or earlier at the physician's discretion. In December 2017, the U.S. Food and Drug Administration (FDA) approved mometasone furoate sinus implant (Sinuva) for the treatment of nasal polyps in patients 18 years of age and older who have had ethmoid sinus surgery.

The PROPEL® Contour Sinus Implant (Intersect ENT) was granted approval from the U.S. Food and Drug Administration (FDA) under the premarketing approval (PMA) program in August 2011. This device is a self-expanding, bioabsorbable, steroid-eluting stent that is intended for use in the ethmoid sinus. It is placed via endoscopic guidance using a plunger that is included with the device. Steroids (mometasone furoate) are embedded in a polyethylene glycol polymer, which allows sustained release of the drug over an approximate duration of 30

days. The device is dissolvable over a period of several weeks, and therefore does not require removal. In September 2012, a shortened version of the PROPEL® device, the PROPEL® Mini Sinus Implant, was approved for use in patients older than age 18 years following ethmoid sinus surgery.

The Relieva Stratus® MicroFlow spacer (Acclarent®) was cleared for marketing under the 510(k) program in October 2011 but is no longer cleared for marketing in the United States. This balloon-based device acted as a postoperative medication delivery system and spacer to maintain an opening to the sinuses within the first 14 days postoperatively. This was a temporary device that required manual removal after 30 days, with implantation of a new device if needed. It was approved for infusion with saline, but not for use with other medications such as steroids. However, despite rejected approval for infusion of medications, the device was marketed for those uses. In 2016, the manufacturer settled a lawsuit with the FDA for marketing the device for uses that were not approved by the FDA. These devices no longer have 510(k) approval in any capacity and should not be used for medical purposes.

## EVIDENCE SUMMARY

ESS has a high rate of success for symptom improvement in appropriately selected patients. Therefore, assessment of the impact of post-ESS sinus stents requires randomized comparison to ESS with standard packing, saline irrigation, and/or intranasal steroids.

### STENTS AS AN ADJUNCT TO ENDOSCOPIC SINUS SURGERY

#### Systematic Reviews

A 2015 Cochrane systematic review of randomized controlled trials (RCTs) comparing steroid-eluting sinus stents with non-steroid-eluting sinus stents, nasal packing, or no treatment in adults undergoing ESS.<sup>[1]</sup> No RCTs met the inclusion criteria. Therefore, an evidence review of potential advantages or disadvantages of steroid-eluting stents was not possible. In addition, the systematic review concluded that more high-quality RCTs are needed comparing sinus stents with surgery alone.

A systematic review of early postoperative care following ESS was published in 2011.<sup>[2]</sup> This review evaluated a number of different postoperative regimens including stents. The review included one RCT by Cote (2010).<sup>[3]</sup> and two nonrandomized studies. Some of the devices included in these studies are considered middle meatal spacers and are outside the scope of this evidence review for this policy. The overall level of evidence was judged as B (RCT with limitations). The authors concluded that topical steroids delivered by the “nonstandard” route required further study and that the results of current studies could not be extrapolated to larger populations. Based on this evidence, they did not recommend use of stents, but considered them an “option” for postoperative care.

Han (2012) published a meta-analysis of the two published RCTs of the PROPEL® implant, both of which compared a steroid-eluting stent with a non-steroid-eluting stent.<sup>[4]</sup> The results of the two RCTs were combined at the patient level, with reanalysis of the endoscopy videos by a panel of three independent ear, nose, and throat experts. The combined results were that the steroid-eluting device reduced postoperative interventions by 35% ( $p < 0.001$ ), reduced lysis of adhesions by 51% ( $p < 0.001$ ) and reduced the need for oral steroids by 46% ( $p < 0.001$ ).

In 2023, a systematic review and meta-analysis of 16 studies was conducted by Hwang examining the effect of corticosteroid-eluting spacers compared to conventional management (control).<sup>[5]</sup> These authors concluded that corticosteroid-eluting stents can improve surgical outcomes of ESS including edema, ethmoid inflammation, polypoid changes, and polyposis among other items. Specifically, mucosal edema was significantly lower in the corticosteroid-eluting stent group compared to control ( $p=0.0029$ ). Ethmoid inflammation and polypoid changes one month postoperatively were also significantly lower in the corticosteroid-eluting stent group compared to control ( $p<0.0001$  and  $p<0.0001$ , respectively). These findings are limited due to multiple spacer types being utilized as well as varying postoperative treatment. Future research is needed that controls for participant baseline characteristics, spacer type, and postoperative treatment.

In 2022, Shah published a retrospective study examining postoperative infection rates following endoscopic sinus surgery.<sup>[6]</sup> These authors examined 378 endoscopic sinus surgery cases with and without nasal polyposis between 2015-2018. Of the included 378 patients, 245 (64.8%) had received a steroid-eluting stent and of the 38 patients diagnosed with a postoperative infection, 28 of those patients had a steroid-eluting stent (73.7%). As a retrospective study, these findings are limited, and the exact cause of postoperative infection rates cannot be determined. Further research is needed to determine how steroid-eluting stents may increase risk of postoperative infection.

### **Randomized Controlled Trials**

Two small RCTs for the PROPEL<sup>®</sup> sinus implant were of similar design and were sponsored by the manufacturer (Intersect ENT). Both compared an implant that was steroid-eluting to an identical implant that was not steroid-eluting. Thus, these trials tested the value of drug delivery via a stent, but do not test the value of a stent itself versus treatment without a stent.

The first RCT of this implant was published by Murr (2011).<sup>[7]</sup> A total of 38 patients with refractory chronic rhinosinusitis were included in the efficacy evaluation, and an additional five patients were enrolled for a safety evaluation. An inpatient control design was used in which each patient received a drug-eluting stent on one side and a non-drug-eluting stent on the other side via random assignment. Patients were not permitted to use topical or oral steroids for 30 days following the procedure. A 14-day course of antibiotics was given to all patients. The primary endpoint was the degree of inflammation recorded on follow-up endoscopy at day 21 postprocedure, as scored by a 100-mm visual analog scale (VAS). There were also semiquantitative gradings performed for polypoid changes, middle turbinate position, and adhesions/synechiae. The clinicians recording the outcomes were the same physicians who were treating the patients. One patient withdrew prior to study completion. The difference in inflammation scores at 21 days was significant in favor of the steroid-eluting group. The estimated difference in scores from graphical representation was approximately 18 units on the 0 to 100 VAS. The percent of patients having polypoid changes was 18.4% in the steroid-eluting group versus 36.8% in the non-steroid-eluting group ( $p=0.039$ ). Adhesions were also significantly less common in the steroid-eluting group (5.3% vs 21.1%,  $p=0.03$ ). There were no significant differences in the appearance or position of the middle turbinate.

The Advance II trial was an RCT of the PROPEL<sup>™</sup> sinus implant for 105 patients with chronic rhinosinusitis refractory to medical management.<sup>[8]</sup> This study also used an inpatient control design with each patient receiving a drug-eluting stent on one side and a non-drug-eluting stent on the other via random assignment. Patients were not permitted to use topical or oral

steroids for 30 days following the procedure. A 14-day course of antibiotics was given to all patients. The primary efficacy outcome was reduction in the need for postoperative interventions at day 30 following the procedure. A panel of three independent experts, who were blinded to treatment assignment and clinical information, viewed the endoscopy results and determined whether an intervention was indicated. The primary safety endpoint was the absence of clinically significant increased ocular pressure through day 90. Three patients were lost to follow-up (2.9%), and nine patients (8.6%) could not be evaluated because the video of the endoscopy could not be graded. Two patients had the device removed within 30 days of placement. Of the remaining patients, the need for postoperative intervention by expert judgment was found in 33.3% of patients in the steroid-eluting arm versus 46.9% in the non-steroid-eluting arm ( $p=0.028$ ). According to the judgments of the clinical investigators who were treating the patients, intervention was required in 21.9% of the steroid-eluting group and 31.4% of the non-steroid-eluting group ( $p=0.068$ ). The reduction in interventions was primarily driven by a 52% reduction in lysis of adhesions ( $p=0.005$ ). The primary safety hypothesis was met, as there were no cases of clinically significant increases in ocular pressure recorded over the 90-day period following the procedure.

## **Nonrandomized Studies**

The largest nonrandomized study identified was reported by Xu (2015). It evaluated post-ESS synechiae formation among 146 patients (252 nasal cavities) treated with a steroid-eluting absorbable spacer and 128 patients (233 nasal cavities) treated with a nonabsorbable spacer.<sup>[9]</sup> Eligible patients included those who underwent ESS (at minimum, maxillary antrostomy and anterior ethmoidectomy) for chronic rhinosinusitis with or without nasal polyps and were treated with a sinus spacer. Synechiae-related outcomes were unavailable for 10 subjects in the absorbable spacer group (6.8%) and nine subjects in the nonabsorbable spacer group (7.0%) due to lack of one-month follow-up. Rates of synechiae formation at one month postoperatively did not differ significantly between groups (5 [2.0%] nasal cavities in the absorbable stent group vs. 13 [5.6%] nasal cavities in the nonabsorbable spacer group).

A number of nonrandomized single-arm case series were identified that reported feasibility but did not study the effectiveness of sinus stents compared to standard care.<sup>[10-12]</sup> Only one of these studies had at least 50 participants. The ADVANCE study was a prospective, multicenter single-arm trial of placement of a mometasone-eluting absorbable stent in 50 patients who were scheduled to undergo ESS.<sup>[10]</sup> The end points evaluated on follow-up endoscopies were the degree of inflammation scored on a 100-mm VAS and semiquantitative grading for polypoid changes, middle turbinate position, and adhesions. By day seven postprocedure, the inflammation scores were in the “minimal” range and remained there for the rest of the time points. At one-month, polypoid lesions were present in 10% of patients, adhesions in 1.1%, and middle turbinate lateralization in 4.4%. Scores on the Sino-Nasal Outcome Test–22 (SNOT-22) and the Rhinosinusitis Disability Index improved significantly in the first month postprocedure. This short-term study does not permit conclusions due to methodological limitations including small sample size, the lack of a control group, and the lack of mid- to long-term follow-up.

## **STENTS AS POST-ESS TREATMENT OF RECURRENT POLYPOSIS**

### **Randomized Controlled Trials**

Kern (2018) published results of the RESOLVE II trial, a sham-controlled RCT evaluating the use of a mometasone-eluting nasal stent with recurrence of nasal polyposis after ESS.<sup>[13]</sup> Two

hundred subjects were randomized to treatment or control in a 2:1 ratio and underwent bilateral placement of two implants in the treatment group whereas the control group received a sham procedure. The efficacy endpoints were change in nasal obstruction/congestion and bilateral polyp grade from baseline to follow-up. Patients who were treated with the implants showed significant reduction in the primary efficacy endpoints compared to the control group. At 90 days follow-up, the treatment group also showed significant reduction in secondary endpoints compared to controls including repeat sinus procedures, percent ethmoid obstruction, and decreased sense of smell.

Han (2014) reported results of the RESOLVE trial, a sham-controlled RCT evaluating the use of office-based placement of a mometasone-eluting nasal stent for patients with recurrence of nasal polyposis after ESS.<sup>[14]</sup> Eligible patients had chronic rhinosinusitis, had undergone prior bilateral total ethmoidectomy more than three months earlier, had endoscopically confirmed recurrent bilateral ethmoid sinus obstruction due to polyposis that was refractory to medical therapy, and were considered candidates for repeat surgery based on the judgment of the surgeon and patient. Patients and those who administered symptom questionnaires at follow-up visits were blinded to treatment group. The study was powered to detect a between-group difference of at least a 0.6-point change in polyp grade from baseline, and at least a 1.0-point change in nasal obstruction/congestion score. One hundred subjects were randomized to treatment (n=53) or control (n=47). For endoscopically measured outcomes, at 90 days of follow-up, the treatment group had a greater reduction in polyp grade than the control group (-1.0 vs. -0.1; p=0.016) and a greater reduction in percent ethmoid obstruction on a 100-mm VAS (-21.5 mm vs. 1.3 mm; p=0.001). For patient-reported outcomes, there were no significant differences in change in nasal obstruction/congestion score between groups. Compared with controls, fewer treatment-group patients required oral steroids for ethmoid obstruction (11% vs 26%) and fewer treatment-group patients were indicated for sinus surgery at three months based on established criteria (47% vs 77%), although statistical comparisons were not reported.

### **Nonrandomized Studies**

Lavigne (2014) reported results from a case series of 12 patients who underwent placement of an investigational mometasone-eluting absorbable stent described as similar to the PROPEL device, but with differences in stent structure to target obstructed sinuses, for recurrent nasal polyposis after ESS.<sup>[15]</sup> Eligible patients had chronic sinusitis and had undergone bilateral ethmoidectomy more than 90 days before enrollment, but had refractory polyposis on at least one side that was at least grade 2 on a 0 to 4 point scale. All implants were placed in the office setting. Average SNOT-22 scores (reported as a normalized value with a total possible score that could range from 0-5) changed from 2.19 at baseline to 1.48 at day seven (p<0.027), and continued to demonstrate improvements by the six-month follow-up. Mean bilateral polyp grade (clinician-assessed) improved from 4.5 at baseline to 2.8 at day seven (p<0.003), with continued improvements through six-month follow-up. No significant adverse events were reported.

Ow (2014)<sup>[16]</sup> reported plasma mometasone and cortisol concentrations for five patients with recurrent polyposis after bilateral total ethmoidectomy who underwent placement of the same investigational device described by Lavigne (2014).<sup>[16]</sup> Plasma mometasone concentrations were in the undetectable range in 26 of 32 samples at 3, 7, 14, 21, and 30 days postimplant and undetectable in all samples at 21 and 30 days post-implant.

## PRACTICE GUIDELINE SUMMARY

No clinical practice guidelines were identified that recommend the use of sinus stents to improve post-ESS patency, reduce edema, or prevent obstruction including the 2015 update of the 2007 guideline from the American Academy of Otolaryngology-Head and Neck Surgery Foundation.<sup>[17]</sup>

## SUMMARY

There is not enough research to show that implantable sinus stents, with or without drug-eluting capability, can improve health outcomes for patients with recurrent polyposis or following sinus surgery compared to standard care, such as packing and saline irrigation. In addition, there are no clinical guidelines based on research that recommend the use of postoperative sinus stents. Therefore, the use of sinus stents with or without drug-eluting capability is considered investigational.

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## CODES

Codes	Number	Description
CPT	31299	Unlisted procedure, accessory sinuses
HCPCS	C2625	Stent, noncoronary, temporary, with delivery system
	J7402	Mometasone furoate sinus implant, (sinuva), 10 micrograms
	S1091	Stent, non-coronary, temporary, with delivery system (propel)

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