Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery and for Recurrent Sinus Disease

**DISCLAIMER**

Our medical policies are designed for informational purposes only and are not an authorization, explanation of benefits or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the coverage. Medical technology is constantly changing, and we reserve the right to review and update our policies periodically.

**POLICY**

The use of implantable sinus stents for postoperative treatment following endoscopic sinus surgery and for treatment of recurrent sinus disease is considered investigational.

**POLICY GUIDELINES**

Sinus stents are defined as implantable devices specifically designed to improve patency and/or deliver local medication. These devices are inserted under endoscopic guidance and are distinguished from sinus packing and variations on packing devices routinely employed after sinus surgery.

Foam dressings, such as Sinu-Foam™, are used as nasal packs for a variety of conditions, including nosebleeds, and have also been used after endoscopic sinus surgery. They are considered different types of nasal packing.

Middle meatal spacers are related but separate devices intended to maintain sinus patency post-endoscopic sinus surgery. They are splint-like devices inserted directly rather than under endoscopic guidance, and do not have the capability of delivering local medication.

**CODING**

There are CPT category III codes for the insertion of these devices into the ethmoid sinus:

0406T Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant;
0407T Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant; with biopsy, polypectomy or debridement.

There is a HCPCS code for the Propel device:

S1090: Mometasone furoate sinus implant, 370 micrograms.

**BENEFIT APPLICATION**
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BLUECARD/NATIONAL ACCOUNT ISSUES
State or federal mandates (eg, Federal Employee Program) may dictate that certain U.S. Food and Drug Administration–approved devices, drugs, or biologics may not be considered investigational, and thus these devices may be assessed only by their medical necessity.

BACKGROUND

CHRONIC RHINOSINUSITIS
Chronic rhinosinusitis is an inflammatory sinus condition that has a prevalence between 1% and 5% in the U.S. population.  

Treatment
Endoscopic sinus surgery (ESS) is typically performed on patients with chronic rhinosinusitis unresponsive to conservative treatment. The surgery is associated with high rates of improvement in up to 90% of more appropriately selected patients. However, there are no high-quality randomized controlled trials comparing functional ESS with continued medical management or alternative treatment approaches. Because of the high success rates and minimally invasive approach, these procedures have rapidly increased in frequency, with an estimated 250,000 procedures performed annually in the United States. They can be done either in the physician’s office under local anesthesia or in the hospital setting under general anesthesia.

ESS involves the removal of small pieces of bone, polyps, and débridement of tissue within sinus cavities. There are a number of variations on the specific approach, depending on the disorders being treated and the preferences of the treating surgeon. For all procedures, there is substantial 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 uncertain. Options include saline irrigation, nasal packs, topical steroids, systemic steroids, topical decongestants, oral antibiotics, and/or sinus cavity débridement. Several randomized controlled trials have evaluated treatment options, but not all strategies have been rigorously evaluated. A 2011 systematic review has evaluated the evidence for these therapies. Reviewers concluded that the evidence was not strong for any of these treatments but that some clinical trial evidence supported improvements in outcomes. The strongest evidence supported use of nasal saline irrigation, topical nasal steroid spray, and sinus cavity débridement.

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 designed for drug delivery. There is some randomized controlled trial evidence that middle meatal spacers may reduce the formation of synechiae following ESS, although the available studies have significant heterogeneity in this outcome.

Implantable Sinus Stents
Implantable sinus stents are another option for postoperative management following ESS. These implants are intended to stabilize the sinus openings and the turbinates, reduce edema, and/or prevent obstruction by adhesions. They can also be infused with medication delivered topically over an extended
period of time, and this local delivery of medications may be superior to topical application in the postoperative setting.

REGULATORY STATUS
In 2011, the PROPEL™ system (Intersect ENT, Palo Alto, CA) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. This device is a self-expanding, bioabsorbable, steroid-eluting stent intended for use in the ethmoid sinus. It is placed via endoscopic guidance using a plunger 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 dissolves over several weeks, and therefore does not require removal. In 2012, a smaller 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. FDA product code: OWO

In 2009, the Relieva Stratus™ MicroFlow spacer, and in 2011, the Relieva Stratus™ Pro MicroFlow Spacer, both balloon-based devices, were cleared for marketing by FDA through the 510(k) process for use as a postoperative spacer to maintain an opening in the frontal sinus for 14 days after surgery. The labeling for the second device included that safety and effectiveness of injecting solutions other than saline had not been established. The devices were to be placed via a catheter under endoscopic guidance and required manual removal after 30 days, In May 2013, the manufacturer discontinued all sales of the Stratus™ and the company agreed to withdraw all FDA marketing clearances for the device, which is no longer commercially available in the United States.⑨

RATIONALE
This evidence review was created in July 2012 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through December 11, 2017.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

RCTs are important in the evaluation of sinus implants as an adjunct to endoscopic sinus surgery (ESS) to adequately compare implantable stents with alternative treatment regimens and to minimize the effects of confounders on outcomes. Case series and trials without control groups offer little in the way of relevant evidence, because improvement in symptoms is expected after ESS and because there are multiple clinical and treatment variables that may confound outcomes.
The most relevant comparison for sinus stents is unclear because there is no standardized optimal postoperative treatment regimen. Ideally, the “standard care” comparison group should include some form of packing, intranasal steroids, and irrigation. An important consideration in evaluating controlled trials is that the control arm may not be treated with optimal intensity, thereby leading to a bias in favor of the device. For example, a study design that compares a steroid-eluting stent with a non-steroid-eluting stent will primarily evaluate the efficacy of steroids when delivered by the device, but will not evaluate the efficacy of a stent itself. If the control group does not receive topical or oral steroids postoperatively, then this might constitute undertreatment in the control group and result in a bias favoring the treatment group. Another concern is comparison of the efficacy of a drug with the efficacy of a drug delivery system. For example, if a steroid-eluting spacer is compared with a control of saline irrigation alone, it will be difficult to separate the efficacy of the drug itself (steroids) from the drug delivery system (stent).

The literature consists of a few, small randomized trials, single-arm case series, and systematic reviews of these studies. The following is a summary of the key findings to date.

**STEROID-ELUTING STENTS AS AN ADJUNCT TO ESS**

**Systematic Reviews**

A 2015 Cochrane review addressed steroid-eluting sinus stents for improving chronic rhinosinusitis (CRS) symptoms in individuals undergoing ESS. Study eligibility criteria were RCTs that compared the effects of steroid-eluting sinus stents with non-steroid-eluting sinus stents, nasal packing, or no treatment in adults with CRS who underwent ESS. After an initial search, 21 RCTs were identified, including the RCTs reported by Murr et al (2011) and Marple et al (2012) and colleagues (described above). None of the trials met authors’ inclusion criteria. Reviewers concluded that there was no evidence from high-quality RCTs to demonstrate the benefits of steroid-eluting stents.

A systematic review of early postoperative care following ESS was published in 2011. Reviewers evaluated a number of postoperative regimens, including stents. Reviewers included an RCT by Cote et al (2010) and 2 nonrandomized studies. Some devices included in these studies are considered middle meatal spacers and are outside the scope of this evidence review. The overall level of evidence was judged as B (RCT with limitations). Reviewers 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, reviewers did not recommend use of stents, but considered them an option for postoperative care.

Han et al (2012) performed a meta-analysis of the 2 published RCTs assessing the PROPEL implant, both of which compared a steroid-eluting stent with a non-steroid-eluting stent. Trial results were combined at the patient level, with reanalysis of the endoscopy videos by a panel of 3 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).

**Randomized Controlled Trials**

As noted, there are 2 RCTs of the steroid-eluting sinus implant (PROPEL). Both trials had similar designs and both were sponsored by the device manufacturer (Intersect ENT). Both compared an implant that is steroid-eluting with an identical non-steroid-eluting implant. Thus these trials tested the value of drug delivery via a stent, but did not test the value of a stent itself vs treatment without a stent.
The first RCT was published by Murr et al (2011). Thirty-eight patients with refractory CRS were included in the efficacy evaluation, and an additional 5 patients were enrolled for a safety evaluation. An intrapatient control design was used, meaning that each patient received a drug-eluting stent on 1 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 end point was the degree of inflammation recorded on follow-up endoscopy at day 21 postprocedure, as scored by a 100-mm visual analog scale (VAS). Semiquantitative grading was also performed for polypoid changes, middle turbinate position, and adhesions/synechiae. The clinicians recording the outcomes were the same physicians who treated the patients. One patient withdrew prior to study completion.

The difference in inflammation scores at 21 days significantly favored the steroid-eluting group. The estimated difference in scores from graphical representation was approximately 18 units on the 0 to 100 VAS. The percentage of patients having polypoid changes was 18.4% in the steroid-eluting group and 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.

Marple et al (2012) published results of the ADVANCE II trial, an RCT of the PROPEL sinus implant for 105 patients with CRS refractory to medical management. This trial also used an intrapatient control design, with each patient receiving a drug-eluting stent on 1 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 postprocedure. A panel of 3 independent experts, blinded to treatment assignment and clinical information, viewed the endoscopic results and determined whether an intervention was indicated. The primary safety end point was the absence of clinically significant increased ocular pressure through day 90.

Three (2.9%) patients were lost to follow-up, and 9 (8.6%) patients 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, need for postoperative intervention by expert judgment was found in 33.3% of patients in the steroid-eluting arm and in 46.9% in the non-steroid-eluting arm (p=0.028). According to the judgments of the clinical investigators 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, because there were no cases of clinically significant increases in ocular pressure recorded over the 90-day period postprocedure.

Nonrandomized Comparative Studies
The largest nonrandomized study identified was reported by Xu et al (2016). 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. Eligible patients included those who underwent ESS (at minimum, maxillary antrostomy and anterior ethmoidectomy) for CRS with or without nasal polyps and were treated with a sinus spacer. Synechiae-related outcomes were unavailable for 10 (6.8%) subjects in the absorbable spacer group and 9 (7.0%) subjects in the nonabsorbable spacer group due to lack of 1-month follow-up. Rates of synechiae formation at 1 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).
Noncomparative Studies
Matheny et al (2014) reported on results from a single-arm case series that evaluated use of office-based placement of a mometasone-eluting absorbable stent (PROPEL device) within 7 days of ESS including bilateral ethmoidectomy. Eligible patients had CRS with or without nasal polyps and were treated by 1 of 3 surgeons. The surgical procedure was ESS with complete ethmoidectomy, followed by packing with a chitosan-polyethylene glycol absorbable dressing. At outpatient follow-up scheduled five to seven days postsurgery, patients underwent débridement of the ethmoid cavity with placement of the steroid-eluting stent. Twenty patients who underwent 40 stent placements were included. Complications included acute sinusitis in 2 patients between 2 and 4 weeks postsurgery. Sinuses were evaluated using video endoscopy by an independent reviewer using a 100-mm VAS and a standardized case report form described by Murr et al (2011). Ethmoid sinus inflammation was reduced from 25.6 at baseline to 18.9 at week 4 (p=0.034). The mean total Sino-Nasal Outcome Test–20 (SNOT-20) score was reduced (improved) from 42.8 at baseline to 18.4 at week 2 and 8.9 at week 4. The procedure was generally well tolerated.

ADVANCE was a prospective, multicenter, single-arm trial of placement of a mometasone-eluting absorbable stent in 50 patients scheduled to undergo ESS. As reported by Forwith et al (2011), 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 7 postprocedure, the inflammation scores were in the “minimal” range and remained there for the rest of the time points. At 1 month, polypoid lesions were present in 10% of patients, adhesions in 1.1%, and middle turbinate lateralization in 4.4%. Scores on the SNOT-22 and the Rhinosinusitis Disability Index improved significantly in the first month postprocedure.

A 2011 case series reported on 23 patients with refractory rhinosinusitis who underwent ESS and were treated postoperatively with the Relieva Stratus MicroFlow Spacer Device infused with triamcinolone. Over 6 months, there were significant improvements on multiple sinus-related outcome measures such as the SNOT-20 and the Lund-MacKay Staging System for computed tomography. No significant intraoperative or postoperative complications were reported.

Section Summary: Steroid-Eluting Stents as an Adjunct to ESS
The most direct evidence relating to use of steroid-eluting nasal stents as an adjunct to ESS comes from 2 RCTs comparing steroid-eluting stents with a non-steroid-eluting stent. One trial used blinded assessors to evaluate postimplantation sinus changes, an important strength, but the trials had potentials for bias. In addition, to most accurately evaluate the benefit from the PROPEL device, ensuring that the comparison group is not undertreated (ie, receives some form of packing, intranasal steroids, and irrigation) is important.

STEROID-ELUTING STENTS FOR RECURRENT POLYPOSIS
A relatively small body of literature has addressed outcomes after placement of steroid-eluting absorbable sinus stents in the office setting as a planned procedure post-ESS or due to recurrent or persistent nasal polyposis after ESS.

Han et al (2014) reported on results from RESOLVE, a sham-controlled randomized trial evaluating the use of office-based placement of a mometasone-eluting nasal stent for patients with recurrent nasal polyposis after ESS. Eligible patients had CRS, had undergone prior bilateral total ethmoidectomy more than 3 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 trial 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), both respectively. For patient-reported outcomes, there were no significant differences in change in nasal obstruction/congestion scores 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 3 months based on established criteria (47% vs 77%), although statistical comparisons were not reported.

Also, Lavigne et al (2014) reported on 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. Eligible patients had CRS and had undergone bilateral ethmoidectomy more than 90 days before enrollment, but had refractory polyposis on at least 1 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 7 (p<0.027), and continued to demonstrate improvements by the 6-month follow-up. Mean bilateral polyp grade (clinician-assessed) improved from 4.5 at baseline to 2.8 at day 7 (p<0.003), with continued improvements through 6-month follow-up. No significant adverse events were reported.

Ow et al (2014) reported on plasma mometasone and cortisol concentrations for 5 patients with recurrent polyposis after bilateral total ethmoidectomy who underwent placement of the same investigational device described by Lavigne (2014). 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 postimplant.

Section Summary: Steroid-Eluting Stents for Recurrent Polyposis

One RCT was identified evaluating the use of steroid-eluting nasal stents for recurrent or persistent nasal polyposis after ESS, which demonstrated improvements in polyp grade and ethmoid obstruction. Strengths of this trial included use of a sham control and adequate power for its primary outcome. However, the trial had a high risk of bias due to unblinded outcome assessment. Although avoidance of repeat ESS and oral steroids may be relevant outcomes for this indication, it would be more important if decisions about repeat ESS or other treatments were standardized and, in the trial setting, if decisions were prespecified or made by a clinician blinded to treatment group. Sinus stents may prove to have a role in nasal polyposis; however, additional positive results from well-designed RCTs are needed to confirm the results of the single available RCT.

SUMMARY OF EVIDENCE

For individuals who have chronic rhinosinusitis who have undergone ESS who receive implantable steroid-eluting sinus stents, the evidence includes 2 RCTs, a number of observational studies, and systematic reviews of these studies. Relevant outcomes are symptoms, change in disease status, morbid events, and treatment-related morbidity. The most direct evidence comes from 2 RCTs comparing steroid-eluting sinus stents with non-steroid-eluting stents, both of which showed some benefit with steroid-eluting stents. However, these trials had some limitations, including risk of bias. In addition,
because of the comparison groups used in both, these trials primarily evaluated the efficacy of topical steroids when delivered by an implanted device, and not the efficacy of the device vs standard care. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have recurrent sinonasal polyposis who have undergone endoscopic sinus surgery who receive implantable steroid-eluting sinus stents, the evidence includes an RCT and a single-arm study. Relevant outcomes are symptoms, change in disease status, morbid events, and treatment-related morbidity. The most direct evidence comes from the available RCT, which compared steroid-eluting stents plus topical steroids with steroids alone for individuals with recurrent polyposis after ESS. This trial had a high risk of bias due to unblinded outcome assessment. Although avoidance of repeat ESS and oral steroids may be a relevant outcome for this indication, it would be important for decisions about repeat ESS or other treatments to be standardized and prespecified or be made by a clinician blinded to treatment group. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

CLINICAL INPUT FROM PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 1 physician specialty society and 4 academic medical centers while this policy was under review in 2012. Input overall was mixed, without consensus among respondents. Some reviewers expressed support for use of these devices after endoscopic sinus surgery. Reviewers who supported use cited the randomized controlled trials reviewed in this review as the main source of evidence. Other reviewers did not support use in general following endoscopic sinus surgery, arguing that a subset of patients may benefit, but there was no consensus on which populations this subgroup would include.

PRACTICE GUIDELINES AND POSITION STATEMENTS
No guidelines or statements were identified.

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS
Not applicable.

MEDICARE NATIONAL COVERAGE
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

ONGOING AND UNPUBLISHED CLINICAL TRIALS
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

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of the Steroid-Releasing S8 Sinus Implant in Chronic Sinusitis Patients With Recurrent Sinus Obstruction (completed)

NCT02266810a The PROGRESS Study: Safety and Efficacy of the Propel Mini and Propel Nova Steroid-Eluting Sinus Implants Following Surgical Opening of the Frontal Sinus for Chronic Sinusitis: A Randomized Blinded Controlled Stud 160 Oct 2016 (completed)

NCT: national clinical trial.

*a Denotes industry-sponsored or cosponsored trial.

REFERENCES


Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery and for Recurrent Sinus Disease


**CODES**

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<td>ICD-10-CM</td>
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**POLICY HISTORY**

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Policy statement unchanged.