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Medical Policy Manual

**Topic:** Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery and for Recurrent Sinonasal Polyposis

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**Section:** Surgery

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**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**

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 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 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 are starting to be used to treat recurrent sinonasal polyposis in patients who have undergone ESS surgery previously.

REGULATORY STATUS

The PROPEL® system (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 marketed 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.

MEDICAL POLICY CRITERIA

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

SCIENTIFIC EVIDENCE

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.

Literature Appraisal

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.[1] 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.[2] This review evaluated a number of different postoperative regimens including stents. The review included one RCT by Cote et al.[3] 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 et al. performed 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.[4] 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).

Randomized Controlled Trials

Two small RCTs for the PROPEL® 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 in 2011 by Murr et al.[5] 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 intrapatient 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 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). There were also semiquantitative grading 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™ sinus implant for 105 patients with chronic rhinosinusitis refractory to medical management. This study also used an intrapatient 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 end point 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 et al in 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. 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 9 subjects in the nonabsorbable spacer group (7.0%) 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).

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. 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. 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 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
In 2014, Han et al. 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.[11] 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 blinding 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 3 months based on established criteria (47% vs 77%), although statistical comparisons were not reported.

Nonrandomized Studies

In 2014, Lavigne et al. 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.[12] Eligible patients had chronic sinusitis 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. 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 et al.[13] Plasma mometasone concentrations were in the undetectable range in 26 of 32 samples at 3, 7, 14, 21, and 30 days post-implant, and undetectable in all samples at 21 and 30 days post-implant.

Clinical Practice Guidelines

No clinical practice guidelines were identified that recommend the use of sinus stents, including the 2015 update of the 2007 guideline from the American Academy of Otolaryngology-Head and Neck Surgery Foundation.[14]

Summary

The current evidence is insufficient to draw conclusions regarding the effectiveness and safety of postoperative sinus stents, with and without drug-eluting capability, compared to standard postoperative care following sinus surgery such as packing and saline irrigation. The most direct evidence comes from the two published randomized controlled trials comparing steroid-eluting sinus stents with non-steroid-
eluting stents, both of which showed some benefit with steroid-eluting stents. However, the studies had some limitations. These trials primarily evaluate the efficacy of topical steroids when delivered by an implanted device, but do not evaluate the efficacy of the device versus standard care. In addition, there are no clinical practice guidelines that recommend the use of postoperative sinus stents. Therefore, the use of sinus stents with or without drug-eluting capability is considered investigational.

The current evidence is insufficient to draw conclusions regarding the effectiveness and safety of implantable sinus stents, with and without drug-eluting capability, in individuals who have recurrent sinonasal polyposis. In addition, there are no clinical practice guidelines that recommend the use of sinus stents for the treatment of recurrent sinonasal polyposis. Therefore, the use of sinus stents with or without drug-eluting capability, is considered investigational for the treatment of recurrent sinonasal polyposis.

REFERENCES


**CROSS REFERENCES**

[Balloon Ostial Dilation for Treatment of Sinusitis](#), Surgery, Policy No. 153

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