Steroid – Eluting Sinus Stents and Implants

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This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

DESCRIPTION

Steroid-eluting sinus stents are devices used postoperatively following endoscopic sinus surgery (ESS) for the treatment of chronic rhinosinusitis (CRS) or for treatment of recurrent sinonasal polyposis following ESS. These devices maintain patency of the sinus openings in the postoperative period, and/or serve as a local drug delivery vehicle. Reducing postoperative inflammation and maintaining patency of the sinuses may be important in achieving optimal sinus drainage and may impact recovery from surgery and/or reduce the need for additional surgery.

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

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 (RCTs) 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 debridement of tissue within sinus cavities. There are several 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 several 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 debridement. Several RCTs 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 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 designed for drug delivery. There is some RCT 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 and implants 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 applications in the postoperative setting.

Steroid – Eluting Stents as an Adjunct to Endoscopic Sinus Surgery

Clinical Context and Therapy Purpose

The purpose of a steroid-eluting sinus stent in patients who have chronic rhinosinusitis (CRS) who have (ESS) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations

The population of interest is patients who have ESS for CRS.

Interventions
The therapy being considered is a bioabsorbable steroid-eluting sinus stent (eg, PROPEL Sinus Stent, PROPEL Mini Sinus Stent, PROPEL Countour Sinus Stent) for post-operative care following ESS.

Comparators
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).

Outcomes
The Perioperative Sinus Endoscopy score sums the combined scores determined from middle turbinate position, middle meatal status, ethmoid cavity appearance, as well as secondary sinus blockage (frontal and sphenoid). Each category is scored from 0-2, with 0 being not present, 1 as partially present, and 2 being fully present. The highest total score is 16, with scores ranging from 18-20 when the frontal and sphenoid sinuses are also included. The higher the score, the worse the status of the nasal cavity.

Post-ESS synechiae formation, the Sino-Nasal Outcome Test (SNOT-22) Questionnaire, and the Rhinosinusitis Disability Index may also be used to evaluate perioperative outcomes.

A beneficial outcome would be an improvement in symptoms.

A harmful outcome would be adverse events from the implantable stents.

The PROPEL series of sinus stents are bioabsorbable and elute steroids for 30 days. Therefore, outcomes should be assessed within 30 days.

Review of Evidence
The literature consists of randomized trials, single-arm case series, and systematic reviews.

Systematic Reviews
A 2015 Cochrane review addressed steroid-eluting sinus stents for improving chronic rhinosinusitis (CRS) symptoms in individuals undergoing endoscopic sinus surgery (ESS). Study eligibility criteria were randomized controlled trials (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). 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.

Randomized Controlled Trials
There are 4 randomized controlled trials (RCTs) of the PROPEL, PROPELMini, and PROPEL Contour steroid-eluting sinus stents, all sponsored by the device manufacturer (Intersect ENT). These trials used an intrapatient control design, with each patient receiving a drug-eluting stent on 1 side and a non-drug-eluting stent or medical treatment on the other via random assignment.

The 2 trials of PROPEL for the ethmoid sinus had similar designs. 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 versus treatment without a stent. The primary efficacy outcome in Murr et al. (2011) was degree of inflammation rated by the treating physician. In Marple et al (2012) the primary outcome was reduction in the need for postoperative interventions at day 30 post procedure. 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 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 ($p=0.028$). 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 post procedure.

The RCTs by Smith et al. (2016) and Luong et al. (2017), implanted either a PROPEL Mini Sinus Implant or a PROPEL Contour Sinus Implant in the frontal sinus with a control of surgery alone on the contralateral side. The primary outcome was the need for post-operative intervention (e.g., surgery or steroids) determined by an independent blinded physician. Both trials showed a reduction in the need for additional surgical intervention by approximately 22%, with no adverse effects of treatment. The number needed to treat was 4.7 to prevent 1 patient from undergoing postoperative intervention. No stent-related adverse events were noted.

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. 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).

Section Summary
The most direct evidence relating to use of steroid-eluting nasal stents as an adjunct to endoscopic sinus surgery (ESS) comes from 4 RCTs comparing steroid-eluting stents with either a non-steroid-eluting stent or medical management. The need for post-operative intervention at 30 days was reduced by 14% to 24%, translating to a number needed to treat of 4.7 or more. Three trials used blinded assessors to evaluate post implantation sinus changes, an important strength, but the trials had potentials for bias. To most accurately evaluate the benefit from PROPEL devices it is important to ensure that the comparison group is not undertreated (i.e., receives some form of packing, intranasal steroids, and irrigation).

Steroid – Eluting Implants for Recurrent Polyposis

Clinical Context and Therapy Purpose
The purpose of steroid-eluting implants in patients who have recurrent polyposis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations
The relevant population of interest is patients with recurrent polyposis after endoscopic sinus surgery (ESS).

Interventions
The therapy being considered is a steroid-eluting sinus implant (e.g., SINUVA). This implant is bioresorbable and softens over time, but needs to be removed by 90 days

Comparators
A sham treatment may be used to determine whether active treatment reduces the need for endoscopic sinus surgery (ESS).

Outcomes
The general outcomes of interest are symptoms, anatomic outcomes, and need for additional endoscopic sinus surgery (ESS). These outcomes may be measured by the nasal obstruction/congestion score change (scale 0–3), polyp grade change (scale 0 to 8),

ethmoid sinus obstruction change (scale 0–100), and the percentage of patients still indicated for repeat sinus surgery.

A beneficial outcome would be an improvement in symptoms and reduction in repeat ESS.

A harmful outcome would be adverse events from the implant.

The steroid-eluting implants are kept in place for up to 90 days. Relevant outcomes would be measured at 90 days to evaluate the short-term effects of the treatment and at 1 or 2 years to evaluate the durability of this treatment.

Review of Evidence
Two sham-controlled randomized controlled trials (RCTs), RESOLVE (A Randomized, Controlled, Blinded Study of Bioabsorbable Steroid-eluting Sinus Implants for In-office Treatment of Recurrent Sinonasal Polyposis) and RESOLVE II (A Phase 3 Trial of Mometasone Furoate Sinus Implants for Chronic Sinusitis with Recurrent Nasal Polyps) with a total of 400 patients have addressed outcomes after placement of steroid-eluting absorbable sinus stents in the office setting due to recurrent or persistent nasal polyposis after endoscopic sinus surgery (ESS).

In RESOLVE, 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. Six-month outcomes from RESOLVE were reported by Forwith et. al in 2016. Differences in polyp grade and ethmoid obstruction scores remained significantly improved in the intervention group at 6 months, but the difference between groups in patient-reported symptom scores was not statistically significant at 6 months (See Table 6). In RESOLVE II the implant group showed significant reductions in nasal congestion, polyp grade, and ethmoid obstruction at 90 days compared to sham controls. Out of 200 patients treated with the implant, 39% were indicated for sinus surgery at 3 months compared to 63.3% of controls (p<0.001).

Section Summary
Two randomized controlled trials (RCTs) evaluated the use of steroid-eluting nasal implants for recurrent or persistent nasal polyposis after ESS, which demonstrated improvements in polyp grade and ethmoid obstruction. Strengths of the trials included use of sham control and adequate power for the primary outcome. However, the trials 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.

Summary of Evidence
For individuals who have chronic rhinosinusitis (CRS) who have undergone endoscopic sinus surgery (ESS) who receive implantable steroid-eluting sinus stents, the evidence includes randomized controlled trials (RCTs). Relevant outcomes are symptoms, change in disease status, morbid events, and treatment-related morbidity. The most direct evidence relating to use of steroid-eluting nasal stents as an adjunct to ESS comes from 4 RCTs comparing steroid-eluting stents with either a non-steroid-eluting stent or medical management. The need for post-operative intervention at 30 days was reduced by 14% to 24%, translating to a number needed to treat of 4.7 or more. Three trials used blinded assessors to evaluate post-implantation sinus changes, an important strength, but the trials had potentials for bias. To evaluate the benefit most accurately from PROPEL devices it is important to ensure that the comparison group is not undertreated (i.e., receives some form of packing, intranasal steroids, and irrigation). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have recurrent sinonasal polyposis who have undergone endoscopic sinus surgery (ESS) who receive steroid-eluting sinus implants, the evidence includes randomized controlled trials (RCTs). Relevant outcomes are symptoms, change in disease status, morbid events, and treatment-related morbidity. Two RCTs were identified evaluating the use of steroid-eluting nasal implants for recurrent or persistent nasal polyposis after ESS, which demonstrated improvements in polyp grade and ethmoid obstruction. Strengths of these trials included use of sham control and adequate power for its primary outcome. However, the trials 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements
No guidelines or statements were identified.

Regulatory Status
In 2011, the PROPEL® system (Intersect ENT, Menlo Park, 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 released 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 to maintain patency. In 2017, the PROPEL Contour was approved through a premarket approval supplement. The PROPEL Contour sinus implant is an adaptable implant that is designed to maximize drug delivery to the frontal and maxillary sinus.

SINUVA™ Sinus Implant (Intersect ENT, Inc., Menlo Park, CA) was initially approved in 1987. In 2017, the SINUVA Sinus Implant was approved with a new dose (1350 µg mometasone furoate) under a New Drug Application (NDA 209310). The corticosteroid is released over 90 days and the bioabsorbable polymers soften over this time. The implant is removed at Day 90 or earlier using standard surgical instruments. The SINUVA™ Sinus Implant is indicated for the treatment of nasal polyps in adult patients who have had ethmoid sinus surgery.

PRIOR APPROVAL

Not applicable.

POLICY

See Related Medical Policies

- 07.01.31 Balloon Ostial Dilation (BOD)/Balloon Sinuplasty for the Treatment of Chronic and Recurrent Rhinosinusitis as a Stand-Alone Procedure or as an Adjunctive Procedure to Functional Endoscopic Sinus Surgery (FESS)
- 07.01.83 Nasal Implants for Nasal Vestibular Lateral Wall Stenosis or Collapse

The use of steroid-eluting sinus stents and implants including but not limited to the following: PROPEL, PROPEL Mini, PROPEL contour or SINUVA for postoperative treatment following endoscopic sinus surgery (ESS) for the treatment of chronic rhinosinusitis (CRS), recurrent sinonasal polyposis, and all other indications is considered **investigational**, because the evidence is insufficient to determine the effects of the technology on health outcomes.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 30999 Unlisted procedure, nose
- 31299 Unlisted procedure, accessory sinuses
- C1874 Stent, coated/covered, with delivery system
- C2625 Stent, noncoronary, temporary, with delivery system
- J7401 Mometasone furoate sinus implant, (sinuva), 10 micrograms
- S1091 Stent, non-coronary, temporary, with delivery system (propel)

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POLICY HISTORY		
Date	**Reason**	**Action**
October 2022	Annual Review	Policy Renewed
October 2021		New Policy Created – Content Moved and Revised

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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