

Protocol

Steroid-Eluting Sinus Stents

(701134)

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

Medical Benefit		Effective Date: 10/01/19	Next Review Date: 01/21
Preauthorization	No	Review Dates: 01/13, 01/14, 01/15, 01/16, 01/17, 01/18, 01/19, 07/19, 01/20	

This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none">• With chronic rhinosinusitis who have undergone endoscopic sinus surgery	Interventions of interest are: <ul style="list-style-type: none">• Implantable steroid-eluting sinus stents	Comparators of interest are: <ul style="list-style-type: none">• Standard management (including topical steroid, packing, and irrigation)	Relevant outcomes include: <ul style="list-style-type: none">• Symptoms• Change in disease status• Morbid events• Treatment-related morbidity
Individuals: <ul style="list-style-type: none">• With recurrent sinonasal polyposis who have undergone endoscopic sinus surgery	Interventions of interest are: <ul style="list-style-type: none">• Implantable steroid-eluting sinus stents	Comparators of interest are: <ul style="list-style-type: none">• Topical steroids alone	Relevant outcomes include: <ul style="list-style-type: none">• Symptoms• Change in disease status• Morbid events• Treatment-related morbidity

DESCRIPTION

Steroid-eluting sinus stents are devices used postoperatively following endoscopic sinus surgery (ESS) 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.

SUMMARY OF EVIDENCE

For individuals who have chronic rhinosinusitis who have undergone ESS who receive implantable steroid-eluting sinus stents, the evidence includes 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 four 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). 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 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 stents for recurrent or persistent nasal polyposis after ESS, which demonstrated improvements in polyp grade and ethmoid obstruction. Strengths of these trials included use of a 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. Sinus stents may prove to have a role in nasal polyposis; however, further follow-up is needed to evaluate the durability of the results. The evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY

The use of steroid-eluting sinus stents for postoperative treatment following endoscopic sinus surgery and for treatment of recurrent sinonasal polyposis is considered **investigational**.

The use of drug-eluting sinus stents is considered **investigational** in all other conditions.

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 ESS. They are considered different types of nasal packing.

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

BACKGROUND

CHRONIC RHINOSINUSITIS

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

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.² 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 debridement. Several randomized controlled trials have evaluated treatment options, but not all strategies have been rigorously evaluated.³⁻⁶ A 2011 systematic review has evaluated the evidence for these therapies.² 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.⁷ 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.⁸

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

INTRAOPERATIVE STEROID-ELUTING SINUS STENTS

In 2011, the PROPEL(R) system (Intersect ENT, Menlo Park, CA) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process (P100044). 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(R) device, the PROPEL(R) mini Sinus Implant, was approved for use in patients older than age 18 years following ethmoid sinus surgery. In 2017, the PROPEL Contour was approved through a PMA supplement. The PROPEL(R) Contour Sinus Implant is an adaptable implant that is designed to maximize drug delivery to the frontal and maxillary sinus.

Postoperative Steroid-Eluting Sinus Stents

SINUVA(TM) Sinus Implant (Intersect ENT, Inc., Menlo Park, CA) was initially approved in 1987. In 2017, the SINUVA(TM) 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.

FDA product code: OWO

RELATED PROTOCOL

Balloon Ostial Dilation for Treatment of Chronic Sinusitis

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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