

Protocol

Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery

(701134)

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

Medical Benefit		Effective Date: 04/01/14	Next Review Date: 01/15
Preauthorization	No	Review Dates: 01/13, 01/14	

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required but recommended if, despite this Protocol position, you feel this service is medically necessary; supporting documentation must be submitted to Utilization Management.** 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.*

Description

Sinus stents are devices that are used postoperatively following endoscopic sinus surgery (ESS). The intent of these devices is to maintain patency of the sinus openings in the postoperative period, and/or to 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.

Background

Endoscopic sinus surgery (ESS) is typically performed in patients with chronic rhinosinusitis unresponsive to conservative treatment. The surgery is associated with improvements in symptoms in up to 90% of more appropriately selected patients. 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 U.S. (1) 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 the sinus cavities. There are a number of variations on the specific approach, depending on the disorders that are being treated and the preferences of the treating surgeon. For all procedures, 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. There have been a number of randomized controlled trials (RCTs) that have evaluated various treatment options, but all different strategies have not been rigorously evaluated. (2-5) A systematic review evaluated the evidence for these therapies. (1) The authors of this review 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 was for 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. (1) Middle meatal spacers are splint-like

devices that prop open the sinus cavities post-ESS, but are not capable of 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. (6)

Implantable sinus stents are another option for postoperative management following ESS. These implants are inserted via catheters under endoscopic guidance. These devices may stabilize the sinus openings and the turbinates, reduce edema, and/or prevent obstruction by adhesions. They also have the capability of being infused with medication that can be 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

The PROPEL™ system was granted U.S. Food and Drug Administration (FDA) approval 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 thereby does not require removal.

The Relieva Stratus™ MicroFlow spacer is a balloon-based device that acts as a spacer and medication delivery system. It was FDA approved under the 510(k) program in October 2011. It is indicated for use as a postoperative spacer to maintain an opening to the sinuses within the first 14 days postoperatively. It is placed via a catheter under endoscopic guidance. This device is temporary and requires manual removal after 30 days, with implantation of a new device if needed. It is approved for infusion with saline, but not for use with other medications such as steroids. This device is no longer marketed in the U.S.

Related Protocol

Balloon Ostial Dilation for Treatment of Chronic Sinusitis

Policy (Formerly Corporate Medical Guideline)

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

Policy Guideline

Sinus stents are defined as implantable devices that are specifically designed to improve patency and/or deliver local medication. These are distinguished from sinus packing and variations on packing devices that are routinely employed post-sinus surgery.

Foam dressings, such as SinuFoam™, are used as nasal packs for a variety of conditions, including nosebleeds, and have also been used post-ESS. These are considered different types of nasal packing.

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

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are

considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment 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.

1. Rudmik L, Mace J, Mechor B. Effect of a dexamethasone SinuFoam™ middle meatal spacer on endoscopic sinus surgery outcomes: A randomized, double-blind, placebo-controlled trial. *Int Forum Allergy Rhinol* 2012; 2(3):248-51.
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3. Cote DW, Wright ED. Triamcinolone-impregnated nasal dressing following endoscopic sinus surgery: a randomized, double-blind, placebo-controlled study. *Laryngoscope* 2010; 120(6):1269-73.
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8. Murr AH, Smith TL, Hwang PH et al. Safety and efficacy of a novel bioabsorbable, steroid-eluting sinus stent. *Int Forum Allergy Rhinol* 2011; 1(1):23-32.
9. Forwith KD, Chandra RK, Yun PT et al. ADVANCE: a multisite trial of bioabsorbable steroid-eluting sinus implants. *Laryngoscope* 2011; 121(11):2473-80.
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12. Han JK, Marple BF, Smith TL. Effect of steroid-releasing sinus implants on postoperative medical and surgical interventions: an efficacy meta-analysis. *Int Forum Allergy Rhinol* 2012; 2(4):271-9.