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

(701134)
(Formerly Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery)

<table>
<thead>
<tr>
<th>Medical Benefit</th>
<th>Effective Date: 04/01/17</th>
<th>Next Review Date: 01/18</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preauthorization</td>
<td>No</td>
<td>Review Dates: 01/13, 01/14, 01/15, 01/16, 01/17</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Individuals:</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>With chronic rhinosinusitis who have undergone endoscopic sinus surgery</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td></td>
<td>• Implantable steroid-eluting sinus stents</td>
<td>• Standard management (including topical steroid, packing, and irrigation)</td>
<td>• Symptoms</td>
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<td></td>
<td></td>
<td></td>
<td>• Change in disease status</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Morbid events</td>
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<td></td>
<td></td>
<td></td>
<td>• Treatment-related morbidity</td>
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<tr>
<td>With recurrent sinonasal polyposis</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td></td>
<td>• Implantable steroid-eluting sinus stents</td>
<td>• Topical steroids alone</td>
<td>• Symptoms</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Change in disease status</td>
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</table>

### Description

Sinus stents are devices used postoperatively following endoscopic sinus surgery (ESS). These devices are used 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.

### Summary of Evidence

The evidence for implantable steroid-eluting sinus stents in individuals who have chronic rhinosinusitis who have undergone ESS includes two randomized controlled trials (RCTs), a number of observational studies, and systematic reviews of these studies. Relevant outcomes include symptoms, change in disease status, morbid events, and treatment-related morbidity. The most direct evidence comes from the two available RCTs 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, including risk of bias. In addition, because of the comparison group used in both, these trials primarily evaluate the efficacy of topical steroids when delivered by
Protocol

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Last Review Date: 01/17

an implanted device, but do not evaluate the efficacy of the device versus standard care. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for implantable steroid-eluting sinus stents in individuals who have recurrent sinonasal polyposis includes one RCT and one single-arm study. Relevant outcomes include 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 is at 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.

Policy

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

Policy Guidelines

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 after sinus surgery.

Foam dressings, such as SinuFoam™, are used as nasal packs for a variety of conditions, including nosebleeds, and have also been used after 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 inserted directly rather than under endoscopic guidance, and they do not have the capability of delivering local medication.

Background

ESS is typically performed in 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 RCTs comparing functional ESS to 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 the 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. A number of RCTs have evaluated various treatment options, but all different strategies have not been rigorously evaluated. A systematic review evaluated the evidence for these therapies. 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 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. 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 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 August 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 that is 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 a period of several weeks, and therefore does not require removal. In September 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: OW0

In October 2011, the Relieva Stratus™ MicroFlow spacer, a balloon-based device that acts as a spacer and medication delivery system, was cleared for marketing by FDA through the 510(k) program for use postoperatively to maintain an opening to the sinuses for 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 (e.g., steroids). This device is no longer marketed in the United States.

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 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.