MEDICAL POLICY – 7.01.134
Steroid-Eluting Sinus Stents

BCBSA Ref. Policy: 7.01.134
Effective Date: May 1, 2020
Last Revised: April 7, 2020
Replaces: N/A

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Introduction

Endoscopic sinus surgery (ESS) is a surgery where a thin tube is inserted through the nose to find and remove blockages in the nose and sinuses. After ESS, common treatments used to reduce swelling and prevent further blockages include: salt solution rinses, nasal packs, nasal sprays or oral drugs that reduce swelling and infection, and sinus suctioning. Another treatment option is the use of sinus stents that are implanted during ESS. These devices contain steroids or other drugs that are released directly into the tissues of the nasal passages or sinuses to help them heal and stay open over an extended period of time. The use of sinus stents containing steroids or other drugs for ESS is unproven (investigational). More studies are needed to see if this treatment is as good or better than proven methods.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria
<table>
<thead>
<tr>
<th>Device</th>
<th>Investigational</th>
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<tbody>
<tr>
<td>Steroid-eluting sinus stents</td>
<td>The use of steroid-eluting sinus stents* for postoperative treatment following</td>
</tr>
<tr>
<td></td>
<td>endoscopic sinus surgery and for treatment of recurrent sinonasal polyposis is</td>
</tr>
<tr>
<td></td>
<td>considered investigational.</td>
</tr>
<tr>
<td></td>
<td>*Note: Sinus stents are defined as implantable devices specifically designed to</td>
</tr>
<tr>
<td></td>
<td>improve patency and/or deliver local medication. These devices are inserted</td>
</tr>
<tr>
<td></td>
<td>under endoscopic guidance and are distinguished from sinus packing and variations</td>
</tr>
<tr>
<td></td>
<td>on packing devices routinely employed after sinus surgery.</td>
</tr>
<tr>
<td>Drug-eluting sinus stents</td>
<td>The use of drug-eluting sinus stents is considered investigational in all other</td>
</tr>
<tr>
<td></td>
<td>conditions.</td>
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**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
<td>31299</td>
<td>Unlisted procedure, accessory sinuses</td>
</tr>
<tr>
<td>HCPCS</td>
<td>J3490</td>
<td>Unclassified drugs</td>
</tr>
<tr>
<td></td>
<td>J7401</td>
<td>Mometasone furoate sinus implant, 10 micrograms (new code effective 10/1/19)</td>
</tr>
</tbody>
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**Related Information**

Foam dressings, such as Sinu-Foam™, are used as nasal packs for a variety of conditions, including nosebleeds, and have also been used after endoscopic sinus surgery. They are considered different types of nasal packing.
Middle meatal spacers are related but separate devices intended to maintain sinus patency post-endoscopic sinus surgery. They are splint-like devices inserted directly rather than under endoscopic guidance, and do not have the capability of delivering local medication.

Evidence Review

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.

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 (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.\(^2\) 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 débridement. 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 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 they 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.

**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.

**Summary of Evidence**

For individuals who have chronic rhinosinusitis who have undergone ESS who receive implantable steroid-eluting sinus stents, the evidence includes: randomized controlled trials (RCTs). The 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 postimplantation 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 (ie, 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. The 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.

Ongoing and Unpublished Clinical Trials

A search of clinicaltrials.gov in December 2019 did not identify any trials that would likely influence this review.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.
In response to requests, input was received from 1 physician specialty society and 4 academic medical centers while this policy was under review in 2012. Input overall was mixed, without consensus among respondents. Some reviewers expressed support for use of these devices after endoscopic sinus surgery. Reviewers who supported use cited the randomized controlled trials reviewed in this review as the main source of evidence. Other reviewers did not support use in general following endoscopic sinus surgery, arguing that a subset of patients may benefit, but there was no consensus on which populations this subgroup would include.

**Practice Guidelines and Position Statements**

No guidelines or statements were identified.

**Medicare National Coverage**

There is no national coverage determination.

**Regulatory Status**

*Intraoperative Steroid-Eluting Sinus Stents*

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 (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® device, the PROPEL® 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® 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™ 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.

FDA product code: OWO

References

12. Smith, TT, Singh, AA, Luong, AA, Ow, RR, Shotts, SS, Sautter, NN, Han, JJ, Stambaugh, JJ, Raman, AA. Randomized controlled trial of a bioabsorbable steroid-releasing implant in the frontal sinus opening. Laryngoscope, 2016 Jul 2;126(12). PMID 27363723


**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/01/19</td>
<td>New policy, approved August 13, 2019, effective December 5, 2019. Add to Surgery section. This policy was previously archived but is now being reinstated. Policy created with literature review through December 2018. The use of steroid-eluting or drug-eluting sinus stents is considered investigational.</td>
</tr>
<tr>
<td>05/01/20</td>
<td>Annual Review, approved April 7, 2020. Policy updated with literature review through December 2019; no referenced added. Policy statements unchanged.</td>
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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
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