Medical Coverage Policy | Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery and for Recurrent Sinus Disease

EFFECTIVE DATE: 09|18|2012
POLICY LAST UPDATED: 12|06|2016

OVERVIEW

This policy documents coverage for implantable sinus stents for postoperative use following endoscopic sinus surgery and recurrent sinus disease for Commercial products. 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.

PRIOR AUTHORIZATION

Prior Authorization is not required

POLICY STATEMENT

Commercial Products:

Implantable sinus stents for postoperative use following endoscopic sinus surgery and for treatment of recurrent sinonasal polyposis is considered not medically necessary as there is insufficient published peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

MEDICAL CRITERIA

None

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. 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. 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 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 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 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.

The PROPEL™ system (Intersect ENT, Palo Alto, CA) was granted 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 therefore does not require removal.

In September 2012, a shortened 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. The Relieva Stratus™ MicroFlow spacer, a balloon-based device that acts as a spacer and medication delivery system, was cleared for marketing 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 United States.

The evidence for implantable steroid-eluting sinus stents in individuals who have chronic rhinosinusitis who have undergone endoscopic sinus surgery (ESS) includes 2 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 2 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 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 1 RCT and 1 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. Therefore, implantable sinus stents are considered not medically necessary for Commercial products as there is no proven efficacy.

COVERAGE

Coverage may vary among groups/contracts. Please refer to the appropriate Benefit Booklet or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

CODING

Commercial Products:

The following codes are not medically necessary:

S1090 0406T 0407T

RELATED POLICIES

BlueCHiP for Medicare National and Local Coverage Determinations Policy

PUBLISHED

Provider Update, January 2017
Provider Update, April 2015
Provider Update, December 2013
Provider Update, January 2013

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