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: 09|04|2018

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). These devices 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.

This policy is applicable to Commercial Products only. For Blue CHiP for Medicare, see related policy section.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Commercial Products:

The Mometasone furoate sinus implant is not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

Implantable sinus stents for postoperative use following endoscopic sinus surgery and for treatment of recurrent sinonasal polyposis is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes. For BlueCHiP for Medicare, refer to the related policies section for the BlueCHiP for Medicare National and Local Coverage Determinations Policy.

COVERAGE

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

BACKGROUND

Endoscopic sinus surgery (ESS) is typically performed in patients with chronic rhinosinusitis unresponsive to conservative treatment. The surgery is associated with high rates of improvements in symptoms in up to 90% of more appropriately selected patients. However, there are no high-quality randomized controlled trials (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 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 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. Several RCTs have evaluated treatment options, but not all strategies have been rigorously evaluated. A 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 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 designed for 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 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 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 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.

In 2009, the Relieva Stratus™ MicroFlow spacer, and in 2011, the Relieva Stratus™ Pro MicroFlow Spacer, both balloon-based devices, were cleared for marketing by FDA through the 510(k) process for use as a postoperative spacer to maintain an opening in the frontal sinus for 14 days after surgery. The labeling for the second device included that safety and effectiveness of injecting solutions other than saline had not been established. The devices were to be placed via a catheter under endoscopic guidance and required manual removal after 30 days, In May 2013, the manufacturer discontinued all sales of the Stratus™ and the company agreed to withdraw all FDA marketing clearances for the device, which is no longer commercially available in the United States.

For individuals who have chronic rhinosinusitis who have undergone endoscopic sinus surgery (ESS) who receive implantable steroid-eluting sinus stents, the evidence includes 2 randomized controlled trials (RCTs), a number of observational studies, and systematic reviews of these studies. Relevant outcomes are symptoms, change in disease status, morbid events, and treatment-related morbidity. The most direct evidence comes from 2 RCTs comparing steroid-eluting sinus stents with non-steroid-eluting stents, both of which showed some benefit with steroid-eluting stents. However, these trials had some limitations, including risk of bias. In addition, because of the comparison groups used in both, these trials primarily evaluated the efficacy of topical steroids when delivered by an implanted device, and not the efficacy of the device versus standard care. 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 an RCT and a single-arm study.

Relevant outcomes are 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 had a 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, this service is not medically necessary for Commercial products.

CODING

Commercial Products:

The following codes are not medically necessary:

S1090 Mometasone furoate sinus implant, 370 micrograms.

0406T Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant (Code deleted 12/31/2018)

0407T Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant; with biopsy, polypectomy or debridement (Code deleted 12/31/2018)

RELATED POLICIES

BlueCHiP for Medicare National and Local Coverage Determinations Policy
New Technology

PUBLISHED

Provider Update, November 2018
Provider Update, August 2017
Provider Update, January 2017
Provider Update, April 2015
Provider Update, December 2013
Provider Update, January 2013

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