Medical Coverage Policy | Implantable Sinus Stents For Postoperative Use Following Endoscopic Sinus Surgery

EFFECTIVE DATE: 09/18/2012
POLICY LAST UPDATED: 02/03/2015

OVERVIEW

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

BlueCHiP for Medicare

Implantable sinus stents for postoperative use following endoscopic sinus surgery is covered but not separately reimbursed.

Commercial Products:

Implantable sinus stents for postoperative use following endoscopic sinus surgery 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. (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 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. FDA product code: OWO 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.

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.

Two randomized controlled trials (RCTs) have compared the Propel™ device with steroids to the same device without steroids and reported that the steroid-eluting device reduced postoperative inflammation, the need for oral steroids, and the need for postoperative reinterventions. 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 improvements reported in these trials reflect the impact of local steroids, which were withheld in the control arm, as well as the impact of the stent device itself. These trial results are not adequate evidence to conclude that use of the Propel™ device is superior to standard postoperative care following ESS, because the control group did not receive standard postoperative care. In particular, the lack of postoperative steroids of any type in the control group may represent undertreatment compared with usual care.

This evidence is insufficient to determine whether sinus stents improve outcomes when used postoperatively following ESS. Further RCTs are needed that compare the devices to optimal postoperative care without the device to determine whether they can improve postoperative outcomes for patients undergoing ESS, therefore implantable sinus stents are considered not medically necessary as there is no proven efficacy.

COVERAGE

Coverage may vary among groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable not medical necessity benefits/coverage.

CODING

BlueCHiP for Medicare and Commercial.

The following HCPCS code is not separately reimbursed for BlueCHiP for Medicare and not medically necessary for Commercial:

S1090

RELATED POLICIES

None

PUBLISHED

Provider Update	Apr 2015
Provider Update	Dec 2013
Provider Update	Jan 2013

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