

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



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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

0407T Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant; with biopsy, polypectomy or debridement

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

REFERENCES

1. Sedaghat AR. Chronic rhinosinusitis. *Am Fam Physician*. Oct 15 2017;96(8):500-506. PMID 29094889
2. Rudmik L, Soler ZM, Orlandi RR, et al. Early postoperative care following endoscopic sinus surgery: an evidence-based review with recommendations. *Int Forum Allergy Rhinol*. Nov-Dec 2011;1(6):417-430. PMID 22144050
3. Berlucchi M, Castelnovo P, Vincenzi A, et al. Endoscopic outcomes of resorbable nasal packing after functional endoscopic sinus surgery: a multicenter prospective randomized controlled study. *Eur Arch Otorhinolaryngol*. Jun 2009;266(6):839-845. PMID 18946677
4. Cote DW, Wright ED. Triamcinolone-impregnated nasal dressing following endoscopic sinus surgery: a randomized, double-blind, placebo-controlled study. *Laryngoscope*. Jun 2010;120(6):1269-1273. PMID 20513050
5. Freeman SR, Sivayoham ES, Jepson K, et al. A preliminary randomised controlled trial evaluating the efficacy of saline douching following endoscopic sinus surgery. *Clin Otolaryngol*. Oct 2008;33(5):462-465. PMID 18983380
6. Rotenberg BW, Zhang I, Arra I, et al. Postoperative care for Samter's triad patients undergoing endoscopic sinus surgery: a double-blinded, randomized controlled trial. *Laryngoscope*. Dec 2011;121(12):2702-2705. PMID 21997904
7. Rudmik L, Mace J, Mechor B. Effect of a dexamethasone Sinu-Foam™ middle meatal spacer on endoscopic sinus surgery outcomes: a randomized, double-blind, placebo-controlled trial. *Int Forum Allergy Rhinol*. Jan 17 2012;2(3):248-251. PMID 22253199
8. Lee JM, Grewal A. Middle meatal spacers for the prevention of synechiae following endoscopic sinus surgery: a systematic review and meta-analysis of randomized controlled trials. *Int Forum Allergy Rhinol*. Nov 2012;2(6):477-486. PMID 22648984

9. Food & Drug Administration, Office of Criminal Investigations. July 22, 2016: Medical Device Manufacturer Acclarent Inc. to Pay \$18 Million to Settle False Claims Act Allegations. 2016; <https://www.fda.gov/iceci/criminalinvestigations/ucm512838.htm>. Accessed January 18, 2018.
10. Huang Z, Hwang P, Sun Y, et al. Steroid-eluting sinus stents for improving symptoms in chronic rhinosinusitis patients undergoing functional endoscopic sinus surgery. *Cochrane Database Syst Rev*. Jun 10 2015;6(6):CD010436. PMID 26068957
11. Murr AH, Smith TL, Hwang PH, et al. Safety and efficacy of a novel bioabsorbable, steroid-eluting sinus stent. *Int Forum Allergy Rhinol*. Jan-Feb 2011;1(1):23-32. PMID 22287304
12. Marple BF, Smith TL, Han JK, et al. Advance II: a prospective, randomized study assessing safety and efficacy of bioabsorbable steroid-releasing sinus implants. *Otolaryngol Head Neck Surg*. Jun 2012;146(6):1004-1011. PMID 22301107
13. Han JK, Marple BF, Smith TL, et al. Effect of steroid-releasing sinus implants on postoperative medical and surgical interventions: an efficacy meta-analysis. *Int Forum Allergy Rhinol*. Jul-Aug 2012;2(4):271-279. PMID 22550039
14. Xu JJ, Busato GM, McKnight C, et al. Absorbable steroid-impregnated spacer after endoscopic sinus surgery to reduce synechiae formation. *Ann Otol Rhinol Laryngol*. Mar 2016;125(3):195-198. PMID 26391092
15. Matheny KE, Carter KB, Jr., Tseng EY, et al. Safety, feasibility, and efficacy of placement of steroid-eluting bioabsorbable sinus implants in the office setting: a prospective case series. *Int Forum Allergy Rhinol*. Oct 2014;4(10):808-815. PMID 25224654
16. Forwith KD, Chandra RK, Yun PT, et al. ADVANCE: a multisite trial of bioabsorbable steroid-eluting sinus implants. *Laryngoscope*. Nov 2011;121(11):2473-2480. PMID 22020898
17. Catalano PJ, Thong M, Weiss R, et al. The MicroFlow Spacer: A drug-eluting stent for the ethmoid sinus. *Indian J Otolaryngol Head Neck Surg*. May 28 2011;63(3):279-284. PMID 22754810
18. Han JK, Forwith KD, Smith TL, et al. RESOLVE: a randomized, controlled, blinded study of bioabsorbable steroid-eluting sinus implants for in-office treatment of recurrent sinonasal polyposis. *Int Forum Allergy Rhinol*. Nov 2014;4(11):861-870. PMID 25266981
19. Lavigne F, Miller SK, Gould AR, et al. Steroid-eluting sinus implant for in-office treatment of recurrent nasal polyposis: a prospective, multicenter study. *Int Forum Allergy Rhinol*. May 2014;4(5):381-389. PMID 24599580
20. Ow R, Groppo E, Clutter D, et al. Steroid-eluting sinus implant for in-office treatment of recurrent polyposis: a pharmacokinetic study. *Int Forum Allergy Rhinol*. Oct 2014;4(10):816-822. PMID 25256638

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