Medical Coverage Policy | Steroid-Eluting Sinus Stents and Implants

EFFECTIVE DATE: 09|18|2012
POLICY LAST UPDATED: 04|20|2022

OVERVIEW
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.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
The use of steroid-eluting sinus stents for postoperative treatment following endoscopic sinus surgery and for treatment of recurrent sinonasal polyposis is not covered as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

The use of steroid-eluting sinus stents is not covered in all other conditions as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Commercial Products:
The use of steroid-eluting sinus stents for postoperative treatment following endoscopic sinus surgery and for treatment of recurrent sinonasal polyposis is not medically necessary, as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

The use of steroid-eluting sinus stents is not medically necessary in all other conditions, as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

BACKGROUND
Chronic rhinosinusitis is an inflammatory sinus condition that has a prevalence between 1% and 5% in the U.S. population.

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 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 randomized controlled trials (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 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.

Sinus Stents and Implants

Implantable sinus stents and implants 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 applications in the postoperative setting.

REGULATORY STATUS

In 2011, the PROPEL(R) 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(R) device, the PROPEL(R) mini Sinus Implant, was approved for use in patients older than age 18 years following ethmoid sinus surgery to maintain patency. In 2017, the PROPEL Contour was approved through a premarket approval supplement. The PROPEL(R) Contour Sinus Implant is an adaptable implant that is designed to maximize drug delivery to the frontal and maxillary sinus.

SINUVA(TM) Sinus Implant (Intersect ENT, Inc., Menlo Park, CA) was initially approved in 1987. In 2017, the SINUVA(TM) 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.

For individuals who have chronic rhinosinusitis who have undergone ESS who receive implantable steroid-eluting sinus stents, the evidence includes RCTs. 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 4 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 post implantation 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 that the technology results in an improvement in the net health outcome.

For individuals who have recurrent sinonasal polyposis who have undergone endoscopic sinus surgery who receive steroid-eluting sinus implants, the evidence includes RCTs. 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 implants 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Therefore, this service is not covered for Medicare Advantage Plans and not medically necessary for Commercial products.

CODING

The following codes are not covered for Medicare Advantage Plans and not medically necessary for Commercial products:

J7402 Mometasone furoate sinus implant, (Sinuva), 10 micrograms (New Code Effective 4/1/2021)
S1091 Stent, non-coronary, temporary, with delivery system (Propel) (New Code Effective 4/1/2021)

The following codes should be used for claims for dates of service prior to 4/1/2021. These codes were deleted as of 4/1/2021 and the codes above must be used for dates of service on or after 4/1/2021.

C9122 Mometasone furoate sinus implant, 10 micrograms (Sinuva)
J7401 Mometasone furoate sinus implant, 10 mcg

To report endoscopic placement of a drug-eluting implant in the ethmoid sinus without any other nasal/sinus endoscopic surgical services, use unlisted CPT code 31299.

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, June 2022
Provider Update, April 2021
Provider Update, May 2020
Provider Update, June 2019
Provider Update, November 2018x

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 evidencebased review with recommendations. Int Forum Allergy Rhinol. Nov-Dec 2011; 1(6): 417-30. PMID 22144050
3. Berlucchi M, Castelnuovo 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): 839-45. 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): 1269-73. 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): 462-5. 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): 2702-5. 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. May-Jun 2012; 2(3): 248-51. 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): 477-86. PMID 22648984
9. 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): CD010436. PMID 26068957
10. 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
11. 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): 1004-11. PMID 22301107
12. Smith TL, Singh A, Luong A, et al. Randomized controlled trial of a bioabsorbable steroid-releasing implant in the frontal sinus opening. Laryngoscope. Dec 2016; 126(12): 2659-2664. PMID 27363723
13. Luong A, Ow RA, Singh A, et al. Safety and Effectiveness of a Bioabsorbable Steroid-Releasing Implant for the Paranasal Sinus Ostia: A Randomized Clinical Trial. JAMA Otolaryngol Head Neck Surg. Jan 2018; 144(1): 28-35. PMID 29098299
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): 195-8. PMID 26391092
15. Han JK, Forwith KD, Smith TL, et al. RESOLVE: a randomized, controlled, blinded study of bioabsorbable steroideluting sinus implants for in-office treatment of recurrent sinonasal polyposis. Int Forum Allergy Rhinol. Nov 2014; 4(11): 861-70. PMID 25266981
16. Kern RC, Stolovitzky JP, Silvers SL, et al. A phase 3 trial of mometasone furoate sinus implants for chronic sinusitis with recurrent nasal polyps. Int Forum Allergy Rhinol. Apr 2018; 8(4): 471-481. PMID 29350840
17. Forwith KD, Han JK, Stolovitzky JP, et al. RESOLVE: bioabsorbable steroid-eluting sinus implants for in-office treatment of recurrent sinonasal polyposis after sinus surgery: 6-month outcomes from a randomized, controlled, blinded study. Int Forum Allergy Rhinol. Jun 2016; 6(6): 573-81. PMID 26992115

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