Medical Coverage Policy

Implantable Sinus Spacers and Stents for Postoperative Use Following Endoscopic Sinus Surgery

☒ Device/Equipment ☐ Drug ☐ Medical ☐ Surgery ☒ Test ☐ Other

Effective Date:	9/18/2012	Policy Last Updated:	9/18/2012

☐ **Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.**

☒ **Prospective review is not required.**

Description:
Endoscopic sinus surgery is typically performed in patients with chronic rhinosinusitis unresponsive to conservative treatment. Improvements are associated 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 yearly in the US. (1) They can be done either in the doctor's office under local anesthesia or in the hospital setting under general anesthesia.

Endoscopic sinus surgery 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 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 the surgery.

While there are a number of postoperative treatment regimens, 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 that have evaluated various treatment options, but not all different strategies have 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 supported the 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 may 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 surgery, but are not capable of drug delivery. There is some evidence that middle meatal spacers may reduce the formation of synechiae following surgery.

Sinus spacers/stents are devices used postoperatively following endoscopic sinus surgery. The intent of these devices is to maintain patency of the sinus openings in the postoperative period, and/or deliver local medication. Reducing postoperative inflammation and maintaining patency of the sinuses may be important in achieving optimal sinus drainage and may impact recovery from surgery. These are

distinguished from sinus packing and variations on packing devices that are routinely employed post-sinus surgery.
The PROPEL™ system was granted FDA approval under the PMA program in August 2011. This device is a self-expanding, bioabsorbable, steroid-eluting stent that is intended for use in the ethmoid sinus. 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 thereby does not require removal.

The Relieva Stratus™ MicroFlow spacer is a balloon-based device that acts as a spacer and medication delivery system. It was FDA approved 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. 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.

Currently there is insufficient evidence to determine whether sinus spacers and 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 spacers and stents for postoperative use following endoscopic sinus surgery is considered **not medically necessary.**

Medical Criteria:
None

Policy:
BlueCHiP for Medicare members:
Implantable sinus spacers and stents for postoperative use following endoscopic sinus surgery is covered but not separately reimbursed.

Commercial Products:
Implantable sinus spacers and stents for postoperative use following endoscopic sinus surgery is considered **not medically necessary** for as there is insufficient published, peer-reviewed scientific literature demonstrating the effectiveness of the procedure.

Coverage:
Coverage may vary among groups/contracts. Please refer to the appropriate Member Certificate, Subscriber Agreement, or Benefit Booklet for applicable not medical necessity benefits/coverage.

Coding:
There are no specific CPT codes for insertion of these devices.

The following HCPCS code for Propel device is not separately reimbursed for BlueCHiP for Medicare members and not medically necessary for all other members.:
S1090: Mometasone furoate sinus implant, 370 micrograms.

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References:

Berlucchi M, Castelnuovo P, Vincenzi A, Morra B, Pasquini E. Endoscopic outcomes of resorbable nasal packing after functional endoscopic sinus surgery: a multicenter prospective randomized controlled study. European Archives of Oto-Rhino-Laryngology;2009 Jun;266(6):839-45.

Cote DWJ, Wright ED. Triamcinolone-Impregnated Nasal Dressing Following Endoscopic Sinus Surgery: A Randomized, Double-Blind, Placebo-Controlled Study. Laryngoscope 120: June 2010:1269-73.

Forwith KD, Chandra RK, Yun PT, Miller SK, Jampel HD. ADVANCE: a multisite trial of bioabsorbable steroid-eluting sinus implants. Laryngoscope. 2011 Nov;121(11):2473-80.

Han JK, Marple BF; Smith TL; Murr AH; Lanier BJ;Stambaugh JW, Mugglin AS. Effect of steroid-releasing sinus implants on postoperative medical and surgical interventions: an efficacy meta-analysis. International Forum of Allergy & Rhinology,; 2(4)', July/August 2012;271-279.

Hansen FS, Djupesland PG, Fokkens WJ. Preliminary efficacy of fluticasone delivered by a novel device in recalcitrant chronic rhinosinusitis. Rhinology;48;2010:1-5.

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. International Forum of Allergy & Rhinology; Vol. 00;2012:1-10.

Marple BF, Smith TL, Han JK, Gould AR, Jampel HD, Stambaugh JW, Mugglin AS. Advance II: a prospective, randomized study assessing safety and efficacy of bioabsorbable steroid-releasing sinus implants. Otolaryngol Head Neck Surg. 2012 Jun;146(6):1004-11.

Murr AH, Smith TL, Hwang PH, Bhattacharyya N, Lanier BJ, Stambaugh JW, Mugglin AS. Safety and efficacy of a novel bioabsorbable, steroid-eluting sinus stent. International Forum of Allergy & Rhinology;1(1);January/February;2011:23-32.

Rotenberg BW, Zhang I, Arra I, Payton KB. Postoperative Care for Samter's Triad Patients Undergoing Endoscopic Sinus Surgery: A Double-Blinded, Randomized Controlled Trial. Laryngoscope 121: December 2011:2702-5.

Rudmik L MJ, Mechor B. Effect of a dexamethasone SinuFoam middle meatal spacer on endoscopic sinus surgery outcomes: A randomized, double-blind, placebo-controlled trial. International Forum Allergy Rhinology;2011;May-Jun;2(3):248-51.

Rudmik L, Soler ZM, Orlandi RR, Stewart MG,Bhattacharyya N, Kennedy DW,Smith TL.*Early postoperative care following endoscopic sinus surgery:an evidence-based review with recommendations.* International Forum of Allergy & Rhinology;1(6);November/December 2011:417-430.