

BLUE CROSS OF NORTHEASTERN PA "BCNEPA" MEDICAL POLICY BULLETIN	MANUAL: MEDICAL POLICY REFERENCE NO.: MPO-139-0001
EFFECTIVE DATE February 1, 2014	SUBJECT: Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery

### **Blue Cross of Northeastern Pennsylvania ("BCNEPA") Medical Policy**

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical policy and claims payment policy are applied. Policies are provided for informational purposes only and are developed to assist in administering plan benefits and do not constitute medical advice.

Treating providers are solely responsible for medical advice and treatment. Policies are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease.

Medical practices and information are constantly changing and BCNEPA may review and revise its medical policies periodically. Also, due to the rapid pace of changing technology and the advent of new medical procedures, BCNEPA may not have a policy to address every procedure.

In those cases, BCNEPA may review other sources of information including, but not limited to, current medical literature and other medical resources, such as Technology Evaluation Center Assessments (TEC) published by the Blue Cross Blue Shield Association. BCNEPA may also consult with health care providers possessing particular expertise in the services at issue.

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#### **DESCRIPTION:**

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.

#### **BENEFIT POLICY STATEMENT:**

BCNEPA makes decisions on coverage based on Policy Bulletins, benefit plan documents, and the member's medical history and condition. Benefits may vary based on product line, group or contract, therefore, Member benefits must be verified. In the event of a conflict between the Member's benefit plan document and topics addressed in Medical Policy Bulletins (i.e., specific contract exclusions), the Member's benefit plan document always supersedes the information in the Medical Policy Bulletins. BCNEPA determines medical necessity only if the benefit exists and no contract exclusions are applicable.

Benefits are determined by the terms of the Member's specific benefit plan document [i.e., the Fully Insured policy, the Administrative Services Only (ASO) agreement applicable to the Self-Funded Plan Participant, or the Individual Policy] that is in effect at the time services are rendered.

**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/spacers are another option for postoperative management following ESS. These implants are inserted under endoscopic guidance. They 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.

**MEDICAL POLICY STATEMENT:**

BCNEPA will not provide coverage for the use of implantable sinus stents/spacers for postoperative treatment following endoscopic sinus surgery as this is considered investigational.

## **GUIDELINES:**

Sinus stents/spacers are defined as implantable devices that are specifically designed to improve patency and/or deliver local medication. These are distinguished from sinus packing and variations on packing devices that are routinely employed post sinus surgery.

Foam dressings, such as SinuFoam™, are used as nasal packs for a variety of conditions, including nosebleeds, and have also been used post-ESS. These are considered different types of nasal packing.

Middle meatal spacers are related but separate devices that are intended to maintain sinus patency post-ESS. They are splint-like devices that are inserted directly rather than under endoscopic guidance, and they do not have the capability of delivering local medication.

The PROPEL™ system was granted U.S. Food and Drug Administration (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.

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. 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 U.S.

## **RATIONALE:**

Implantable sinus stents/spacers have been used post-ESS (endoscopic sinus surgery) with the intent of maintaining patency of the sinuses and delivering local steroids. Two RCTs have compared the Propel™ device with steroids to the same device without steroids and reported that the steroid-eluting device reduced postoperative inflammation, reduced the need for oral steroids, and reduced 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, since 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 to usual care.

This evidence is insufficient 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, the use of postoperative sinus stents is considered investigational.

## **Medicare National Coverage**

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**DEFINITIONS:**

N/A

**CODING:**

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The five character codes included in the **Blue Cross of Northeastern Pennsylvania's Medical Policy** are obtained from Current Procedural Terminology (CPT\*), copyright 2013 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures.

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- **The identification of a code in this section does not denote coverage or separate reimbursement.**
- Covered procedure codes are dependent upon meeting criteria of the policy and appropriate diagnosis code.
- The following list of codes may not be all-inclusive, and are subject to change at any time.
- Benefits are determined by the terms of the Member's specific benefit plan document [i.e., the Fully Insured policy, the Administrative Services Only (ASO) agreement applicable to the Self-Funded Plan Participant, or the Individual Policy] that is in effect at the time services are rendered.

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**PROCEDURE CODES**

S1090

**SOURCES:**

1. Rudmik L, Mace J, Mechor B. Effect of a dexamethasone SinuFoam™ middle meatal spacer on endoscopic sinus surgery outcomes: A randomized, double-blind, placebo-controlled trial. *Int Forum Allergy Rhinol* 2012; 2(3):248-51.
2. 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* 2009; 266(6):839-45.
3. Cote DW, Wright ED. Triamcinolone-impregnated nasal dressing following endoscopic sinus surgery: a randomized, double-blind, placebo-controlled study. *Laryngoscope* 2010; 120(6):1269-73.
4. 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* 2008; 33(5):462-5.
5. 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* 2011; 121(12):2702-5.
6. 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* 2012; 2(6):477-86.
7. 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.* 2012; 146(6):1004-11.
8. Murr AH, Smith TL, Hwang PH et al. Safety and efficacy of a novel bioabsorbable, steroid-eluting sinus stent. *Int Forum Allergy Rhinol* 2011; 1(1):23-32.
9. Forwith KD, Chandra RK, Yun PT et al. ADVANCE: a multisite trial of bioabsorbable steroid-eluting sinus implants. *Laryngoscope* 2011; 121(11):2473-80.
10. Catalona PJ TM, Weiss R, Rimash T. The MicroFlow Spacer: a drug-eluting stent for the ethmoid sinus. *Indian J Otolaryngol Head Neck Surg* 2011; 63(3):258.
11. 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* 2011; 1(6):417-30.
12. Han JK, Marple BF, Smith TL. Effect of steroid-releasing sinus implants on postoperative medical and surgical interventions: an efficacy meta-analysis. *Int Forum Allergy Rhinol* 2012; 2(4):271-9.

**APPROVALS:**

Approved by Vice President, Clinical Operations & Chief Medical Officer:



Signature: \_\_\_\_\_  
(Nina M. Taggart, MA, MD, MBA)

Date of Approval: January 14, 2014

**HISTORY:**

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Policy developed by: Medical Policy Department