

MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	DRUG-ELUTING SINUS STENTS FOR POSTOPERATIVE USE FOLLOWING ENDOSCOPIC SINUS SURGERY
Policy Number	7.01.99
Category	Technology Assessment
Effective Date	03/21/19
Revised Date	
Product Disclaimer	<ul style="list-style-type: none"> • If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. • If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit. • If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY STATEMENT

- I. Based upon our criteria and assessment of peer-reviewed literature, the use of the Propel® drug-eluting sinus stent for postoperative treatment following endoscopic sinus surgery and the treatment of recurrent chronic rhinosinusitis with or without sinonasal polyps is considered **investigational**.
- II. Based upon our criteria and assessment of peer-reviewed literature, the use of the Sinuva® drug-eluting sinus stent for the treatment of recurrent chronic rhinosinusitis with sinonasal polyps following ethmoid sinus surgery is considered **investigational**.
- III. Based upon our criteria and assessment of peer-reviewed literature, repeat use of drug-eluting sinus stents is considered **investigational**.

POLICY GUIDELINES

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

Rhinosinusitis is defined as inflammation of the sinuses and nasal cavity. Rhinosinusitis may be classified based on duration. Acute sinusitis is defined as symptoms lasting less than 12 weeks, recurrent acute rhinosinusitis consists of 3 or more episodes of acute bacterial rhinosinusitis in a year while chronic rhinosinusitis is defined as symptoms lasting longer than 12 weeks. Chronic rhinosinusitis (CRS) is characterized by purulent nasal discharge, usually without fever, that persists for weeks to months. Symptoms of congestion often accompany the nasal discharge. There also may be mild pain and/or headache. In some cases of chronic sinusitis, surgical drainage may be necessary. Chronic rhinosinusitis may occur with or without nasal polyps.

Rhinosinusitis is one of the most commonly diagnosed diseases in the world and is believed to affect more than 12% of the US population. Rhinosinusitis is associated with significant negative impact on quality of life and is associated with high healthcare costs due to medical visits, prescriptions and over the counter medications, sinus surgeries and missed days from work and school. Treatment for chronic sinusitis may include topical intranasal corticosteroids to decrease inflammation, short-term oral corticosteroids to help shrink nasal polyps and reduce inflammation, saline nasal irrigation, and for those patients who fail aggressive medical therapy, endoscopic sinus surgery may be performed.

Functional endoscopic sinus surgery (FESS), has become an important aspect for surgical management of chronic sinusitis. For this procedure, a fiberoptic nasal endoscope is used to visualize the sinus ostia, and any obstruction found is corrected. This procedure restores patency and allows air and mucous transport through the natural ostium. Endoscopic sinus surgery for chronic rhinosinusitis maybe compromised by postoperative inflammation, polyposis, and adhesions,

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often requiring subsequent medical and surgical intervention. Postoperative interventions are employed to reduce these complications and often are time-consuming and uncomfortable for the patient. Current medical therapies such as oral corticosteroids, topical steroid spray, and nasal packing all have limitations.

Sinus stents are devices used postoperatively following endoscopic sinus surgery (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 sinus may be important in achieving optimal sinus drainage and may impact recovery from surgery.

The Propel sinus implant separates mucosal tissues, provides stabilization of the middle turbinate, prevents obstruction by adhesions, and reduces edema.” The implant is manufactured from a synthetic bioabsorbable copolymer, poly (L-lactide-co-glycolide) and contains 370 µg mometasone furoate a synthetic corticosteroid. The implant is designed to accommodate the size and variability of the post-surgical ethmoid sinus anatomy. The device is dissolvable over a period of several weeks, and thereby does not require removal. The Sinuva sinus implant contains 1350 mcg of mometasone furoate and is proposed for implantation in the physician’s office and is left in place for 90 days.

RATIONALE

Han et al (2012) performed a meta-analysis of the 2 published RCTs assessing the PROPEL implant, both of which compared a steroid-eluting stent with a non-steroid-eluting stent.13 Trial results were combined at the patient level, with reanalysis of the endoscopy videos by a panel of 3 independent ear, nose, and throat experts. The combined results were that the steroid-eluting device reduced postoperative interventions by 35% (p<0.001).

Marple et al (2012) published results of the ADVANCE II trial, an RCT of the PROPEL sinus implant for 105 patients with CRS refractory to medical management. This trial also used an inpatient control design, with each patient receiving a drug-eluting stent on 1 side and a non-drug-eluting stent on the other via random assignment. Patients were not permitted to use topical or oral steroids for 30 days following the procedure. A 14-day course of antibiotics was given to all patients. The primary efficacy outcome was reduction in the need for postoperative interventions at day 30 postprocedure. A panel of 3 independent experts, blinded to treatment assignment and clinical information, viewed the endoscopic results and determined whether an intervention was indicated. The primary safety end point was the absence of clinically significant increased ocular pressure through day 90. Three (2.9%) patients were lost to follow-up, and 9 (8.6%) patients could not be evaluated because the video of the endoscopy could not be graded. Two patients had the device removed within 30 days of placement. Of the remaining patients, need for postoperative intervention by expert judgment was found in 33.3% of patients in the steroid-eluting arm and in 46.9% in the non-steroid-eluting arm (p=0.028). According to the judgments of the clinical investigators treating the patients, intervention was required in 21.9% of the steroid-eluting group and 31.4% of the non-steroid-eluting group (p=0.068). The reduction in interventions was primarily driven by a 52% reduction in lysis of adhesions (p=0.005). The primary safety hypothesis was met, because there were no cases of clinically significant increases in ocular pressure recorded over the 90-day period postprocedure.

ADVANCE was a prospective, multicenter, single-arm trial of placement of a mometasone-eluting absorbable stent in 50 patients scheduled to undergo ESS.16 As reported by Forwith et al (2011), the end points evaluated on follow-up endoscopies were the degree of inflammation scored on a 100-mm VAS and semiquantitative grading for polypoid changes, middle turbinate position, and adhesions. By day 7 postprocedure, the inflammation scores were in the “minimal” range and remained there for the rest of the time points. At 1 month, polypoid lesions were present in 10% of patients, adhesions in 1.1%, and middle turbinate lateralization in 4.4%. Scores on the SNOT-22 and the Rhinosinusitis Disability Index improved significantly in the first month postprocedure.

Han et al (2014) reported on results from RESOLVE, a sham-controlled randomized trial evaluating the use of office-based placement of a mometasone-eluting nasal stent for patients with recurrent nasal polyposis after ESS.18 Eligible patients had CRS, had undergone prior bilateral total ethmoidectomy more than 3 months earlier, had endoscopically confirmed recurrent bilateral ethmoid sinus obstruction due to polyposis that was refractory to medical therapy, and were considered candidates for repeat surgery based on the judgment of the surgeon and patient. Patients and those who administered symptom questionnaires at follow-up visits were blinded to treatment group. The trial was powered to detect a between-group difference of at least a 0.6-point change in polyp grade from baseline, and at least a 1.0- point change in nasal obstruction/congestion score. One hundred subjects were randomized to treatment (n=53) or control (n=47). For

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endoscopically measured outcomes, at 90 days of follow-up, the treatment group had a greater reduction in polyp grade than the control group (-1.0 vs -0.1; p=0.016) and a greater reduction in percent ethmoid obstruction on a 100-mm VAS (-21.5 mm vs 1.3 mm; p=0.001), both respectively. For patient-reported outcomes, there were no significant differences in change in nasal obstruction/congestion scores between groups. Compared with controls, fewer treatment group patients required oral steroids for ethmoid obstruction (11% vs 26%) and fewer treatment group patients were indicated for sinus surgery at 3 months based on established criteria (47% vs 77%), although statistical comparisons were not reported.

For individuals who have chronic rhinosinusitis who have undergone ESS who receive implantable steroid-eluting sinus stents, the evidence includes two (2) 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 two (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.

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 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 2017, the SINUVA™ Sinus Implant (Intersect ENT, Palo Alto, CA) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. SINUVA™ Sinus Implant targeted approach to treating recurrent nasal polyp disease in patients greater than or equal to 18 years of age who have had previous ethmoid sinus surgery.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

CPT Codes

Code	Description
31237	Nasal/sinus endoscopy, surgical; with biopsy, polypectomy or debridement (separate procedure)
31299	Unlisted procedure, accessory sinuses

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HCPCS Codes

Code	Description
C1874	Stent, coated/covered, with delivery system
J3490	Unclassified drugs
S1090 (E/I)	Mometasone furoate sinus implant, 370 micrograms

ICD10 Codes

Code	Description
J32.1-J32.9	Chronic sinusitis (code range)
J33.0-J33.9	Nasal polyp (code range)
J34.89-J34.9	Other specified/unspecified disorders of nose and nasal sinuses

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*Key Article

KEY WORDS

Sinus stent, sinus implant, Propel, Sinuva

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) for Category III CPT® Codes. Please refer to the following LCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33392&ContrId=298&ver=92&ContrVer=1&CtrctrSelected=298*1&Ctrctr=298&s=41&DocType=Active&bc=AAgAAAQAAAA&