



# 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	03/19/20
Product Disclaimer	<ul style="list-style-type: none"> <li>• If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</li> <li>• If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</li> <li>• 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.</li> </ul>

## 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 or for 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**.

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services.

## 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 having symptoms fewer than 12 weeks. Recurrent acute rhinosinusitis consists of three or more episodes of acute bacterial rhinosinusitis in a year while chronic rhinosinusitis is characterized by 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 may also 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 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.

## **Medical Policy: DRUG-ELUTING SINUS STENTS FOR POSTOPERATIVE USE FOLLOWING ENDOSCOPIC SINUS SURGERY**

**Policy Number: 7.01.99**

**Page: 2 of 5**

Functional endoscopic sinus surgery (FESS), has become an important aspect of 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. The procedure restores patency and allows air and mucous transport through the natural ostium. Endoscopic sinus surgery for chronic rhinosinusitis may be compromised by postoperative inflammation, polyposis, and adhesions, 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 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<sup>®</sup> 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, therefore, does not require removal. The Sinuva<sup>®</sup> sinus implant contains 1350 mcg of mometasone furoate and is proposed for implantation in the physician’s office. It is left in place for 90 days.

### **RATIONALE**

Han et al (2012) performed a meta-analysis of the two published RCTs assessing the PROPEL<sup>®</sup> implant, both of which compared a steroid-eluting stent with a non-steroid-eluting stent. Trial results were combined at the patient level, with reanalysis of the endoscopy videos by a panel of three 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<sup>®</sup> 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 one 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 post procedure. A panel of three 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 nine (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 in 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 post procedure.

ADVANCE was a prospective, multicenter, single-arm trial involving placement of a mometasone-eluting absorbable stent in 50 patients scheduled to undergo ESS. 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 seven post procedure, the inflammation scores were in the “minimal” range and remained there for the rest of the time points. At one 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 post procedure.

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. Eligible

## **Medical Policy: DRUG-ELUTING SINUS STENTS FOR POSTOPERATIVE USE FOLLOWING ENDOSCOPIC SINUS SURGERY**

**Policy Number: 7.01.99**

**Page: 3 of 5**

patients had CRS, had undergone prior bilateral total ethmoidectomy more than three 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 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 three months based on established criteria (47% vs 77%), although statistical comparisons were not reported.

For individuals who have chronic rhinosinusitis who have undergone ESS, and who receive implantable steroid-eluting sinus stents, the evidence includes two 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 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, and 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<sup>®</sup> system (Intersect ENT, Palo Alto, CA) was approved by 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<sup>®</sup> device, the PROPEL<sup>®</sup> Mini Sinus Implant, was approved for use in patients older than age 18 years following ethmoid sinus surgery.

In 2017, the SINUVA<sup>®</sup> Sinus Implant (Intersect ENT, Palo Alto, CA) was approved by the FDA through the premarket approval process. SINUVA<sup>®</sup> Sinus Implant targeted the treatment of recurrent nasal polyp disease in patients 18 years or older 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.*

**Medical Policy: DRUG-ELUTING SINUS STENTS FOR POSTOPERATIVE USE FOLLOWING ENDOSCOPIC SINUS SURGERY**

**Policy Number: 7.01.99**

**Page: 4 of 5**

**CPT Codes**

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

*Copyright © 2020 American Medical Association, Chicago, IL*

**HCPCS Codes**

<b>Code</b>	<b>Description</b>
C1874 (E/I)	Stent, coated/covered, with delivery system
J3490	Unclassified drugs- E/I for diagnoses listed in this policy
J7401 (E/I)	Mometasone furoate sinus implant, 10 micrograms

**ICD10 Codes**

<b>Code</b>	<b>Description</b>
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

**REFERENCES**

Blue Cross Blue Shield Association. Implantable sinus stents for postoperative use following endoscopic sinus surgery and for recurrent sinus disease. Medical Policy Reference Manual. Policy #7.01.134. 2019 Feb 14.

Forwith KD, et al. ADVANCE: a multisite trial of bioabsorbable steroid-eluting sinus implants. Laryngoscope 2011;121:2473-2480.

Forwith KD, 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 2016;6(6):573-581.

Han JK, et al. Effect of steroid-releasing implants on postoperative medical and surgical interventions: an efficacy meta-analysis. Int Forum Allergy Rhinol 2012;2(4):271-279.

Han JK, 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 2014;4(11): 861-870.

Han JK and Kern RC. Topical therapies for management of chronic rhinosinusitis: steroid implants. Int Forum Allergy Rhinol. 2019 Mar; 9: S22–S26.

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.

Kern RC, et al. A phase 3 trial of mometasone furoate sinus implants for chronic sinusitis with recurrent nasal polyps. Int Forum Allergy Rhinol 2018;8:471-481.

Marple BF, et al. 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.

**Medical Policy: DRUG-ELUTING SINUS STENTS FOR POSTOPERATIVE USE FOLLOWING ENDOSCOPIC SINUS SURGERY**

**Policy Number: 7.01.99**

**Page: 5 of 5**

World Allergy Organization. Rhinosinusitis: synopsis. Initial posting: 2005 Jun. Last update: 2015 May. [<http://www.worldallergy.org/education-and-programs/education/allergic-disease-resource-center/professionals/rhinosinusitis-synopsis>] accessed 1/27/2020.

\*Key Article

**KEY WORDS**

Sinus stent, sinus implant, Propel<sup>®</sup>, Sinuva<sup>®</sup>

**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for Drug-Eluting Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery.