# MEDICAL POLICY

| MEDICAL POLICY DETAILS | |
|---|---|
| **Medical Policy Title** | **Drug-Eluting Sinus Stents for Post-operative Use Following Endoscopic Sinus Surgery** |
| **Policy Number** | **7.01.99** |
| **Category** | **Technology Assessment** |
| **Original Effective Date** | **03/21/19** |
| **Committee Approval Date** | **03/18/21** |
| **Revised Effective Date** | **03/19/20, 03/18/21** |
| **Archived Date** | **N/A** |
| **Archive Review Date** | **N/A** |
| **Product Disclaimer** | • *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.*<br>• *If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.*<br>• *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 the peer-reviewed literature, the use of the PROPEL drug-eluting sinus stent has not been medically proven to be effective and, therefore, is considered **investigational** for post-operative treatment following endoscopic sinus surgery, or for the treatment of recurrent chronic rhinosinusitis with or without sinonasal polyps.

Based upon our criteria and assessment of the peer-reviewed literature, the use of the SINUVA drug-eluting sinus stent has not been medically proven to be effective and, therefore, is considered **investigational** for the treatment of recurrent chronic rhinosinusitis with sinonasal polyps following ethmoid sinus surgery.

II. Based upon our criteria and assessment of the peer-reviewed literature, repeat use of drug-eluting sinus stents has not been medically proven to be effective and, therefore, is considered **investigational.**

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

## 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 lasting for 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 12 weeks or more. 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 CRS, surgical drainage may be necessary. CRS 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 U.S. 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 CRS 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.

Endoscopic sinus surgery (ESS), 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. ESS for CRS may be compromised by post-operative inflammation, polyposis, and adhesions, often requiring subsequent medical and surgical intervention. Post-operative interventions employed to reduce these complications are often 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 ESS. These devices maintain patency of the sinus openings in the post-operative period, and/or serve as a local drug delivery vehicle. Reducing post-operative 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 manufacturer claims that the PROPEL stent "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-lactideco-glycolide), and contains 370µg 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 sinus implant contains 1350 mcg of mometasone furoate and is proposed for implantation in the physician's office. It is left in place for up to 90 days, to gradually release the corticosteroid, and then requires removal.

## RATIONALE

Han et al. (2012) performed a meta-analysis of the two published, randomized, controlled trials (RCTs) assessing the PROPEL 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 post-operative 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 intra-patient 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 post-operative 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, the experts identified a need for post-operative intervention 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.

The ADVANCE trial was a prospective, multi-center, 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 Visual Analogue Scale (VAS) and semi-quantitative 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 Sino-Nasal Outcome Test (SNOT-22) and the Rhinosinusitis Disability Index improved significantly in the first month post-procedure.

Han et al. (2014) reported on results from the RESOLVE trial, which was a sham-controlled, randomized trial evaluating the use of office-based placement of the RESOLVE mometasone-eluting nasal stent for patients with recurrent nasal polyposis after ESS. Eligible 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 CRS, have undergone ESS, and 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, have undergone ESS, and 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 to 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 pre-specified or be made by a clinician blinded to the 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 United States 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 FDA through the premarket approval process. The SINUVA 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.*

**CPT Codes**

| Code | Description |
|---|---|
| 30468 (E/I) | Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant (s) (*effective 01/01/21)* |
| 31237 | Nasal/sinus endoscopy, surgical; with biopsy, polypectomy or debridement (separate procedure) |
| 31299 | Unlisted procedure, accessory sinuses |



**HCPCS Codes**

| Code | Description |
|---|---|
| C1874 (E/I) | Stent, coated/covered, with delivery system |
| J7402 (E/I) | Mometasone furoate sinus implant, (sinuva), 10mcg *(effective 04/01/2021)* |
| S1091 (E/I) | Stent, non-coronary, temporary, with delivery system, (propel) *(effective 04/01/2021)* |

**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 |

## REFERENCES

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*Key Article

## KEY WORDS

Sinus stent, sinus implant, Propel, Sinuva

## 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.