MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Drug-Eluting Sinus Stents and Nasal Implants**
Policy Number	**7.01.99**
Category	**Technology Assessment**
Original Effective Date	**03/21/19**
Committee Approval Date	**03/21/19, 03/19/20, 03/18/21, 05/19/22, 05/18/23**
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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.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

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.

II. 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.

III. 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.**

IV. Based upon our criteria and assessment of the peer-reviewed literature, the use of an absorbable nasal implant (e.g., Latera) has not been medically proven to be effective and, therefore, is considered **investigational** for the treatment of nasal valve collapse in patients with nasal obstruction.

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

DESCRIPTION

Drug-Eluting Stents:

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.

Absorbable Nasal Implant:

Nasal airway obstruction (NAO), also known as nasal congestion, is caused by an underlying narrowing of the nasal valve as the result of tissue enlargement decreasing the nasal airway area. The nasal valve is composed of three primary structures: the nasal septum which is a narrow ridge of bone and tissue between two nostrils; the turbinates which are nasal tissue projections that direct and warm air as it enters the nasal cavity; and the lateral wall which is the side tissue that forms the outer structure of the nose. A condition known as nasal valve collapse (NVC), also known as nasal valve stenosis, is the most common cause of NAO. NVC triggers include trauma, deviated septum, previous nasal surgery, scar tissue, inflammation, and age-related atrophy of the nasal tissue. Typical symptoms of NVC include congestion, difficulty breathing with exertion or lying down, and mouth breathing. The diagnosis is made through patient history and an examination using the Cottle Maneuver, a test of nasal valve integrity. While septoplasty and turbinate redirection are used to address NVC secondary to those structures, they do not address NVC secondary to lateral wall insufficiency (LWI). Proposed treatments of LWI, including over-the-counter nasal strips, various surgical interventions, nasal valve dilators, stents, and radiofrequency ablation, all have their limitations.

The Latera absorbable nasal implant received 510(k) FDA clearance in 2016 for the indication of supporting nasal upper and lower lateral cartilage. The system consists of a PLLA-PDLA copolymer that is predominantly cylindrical in shape with an approximate diameter of one mm and length of 24mm as well as a disposable delivery device. Latera is intended to support cartilage in the nasal lateral wall. It is proposed as an alternative to more commonly used invasive surgical techniques and can be implanted in the office-setting under local anesthesia. Latera is designed to be absorbed by the body over the period of 18-24 months post-implant.

RATIONALE

Drug-Eluting Stents:

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.

Absorbable Nasal Implant:

Research evaluating the use of absorbable nasal implants (i.e., Latera) in individuals with symptomatic nasal obstruction due to internal NVC has included one small, short-term RCT and four non-randomized prospective cohort studies with follow-up of up to 24 months. Overall, improvements in nasal obstruction symptom scores have been demonstrated. Additionally, adverse effects have been mild and self-limiting. There have been no prospective studies evaluating device efficacy against a comparable procedure (e.g., inferior turbinate reduction and/or septoplasty), and the evidence is insufficient to determine patient selection criteria as well as net health outcomes.

A 2020 meta-analysis by Kim et al. evaluated the effectiveness of Latera in the treatment of nasal obstruction caused by lateral wall insufficiency (LWI). Five studies, including 396 patients, that scored endoscopic lateral wall movement and nasal obstruction related to quality of life (QOL) before and after bioabsorbable nasal implants were included in the analysis. One study included a comparison of the treatment to a sham group. Researchers found that bioabsorbable nasal implants significantly reduced endoscopic lateral wall motion as well as improved QOL up to 12 months postoperatively. Adverse effects were reported in five percent of implant patients, were mild and resolved without sequalae. Researchers acknowledged that, while bioabsorbable nasal implants may reduce nasal wall movement and subjective symptoms compared to preoperative status, more randomized clinical trials must be conducted to verify their effectiveness.

Stolovitzy et al. (2019) conducted a prospective, multicenter, randomized sham-controlled single blinded trial evaluating the safety and efficacy of a bioabsorable implant treatment for NVC. A total of 137 patients with NAO due to dynamic bilateral wall insufficiency confirmed by a positive modified Cottle maneuver with Nasal Obstruction Symptom Evaluation (NOSE) scores of at least 55 (classified as severe) and failed medical management were randomized into the treatment (n=71) and sham control (n=66) groups. Following initial evaluation, patients underwent cannula-introduced bioabsorbable nasal implant (treatment group) or sham procedure involving the cannula without implant insertion. Patients were followed for three months. The primary endpoint was the responder rate at three months after the index procedure. Responders were defined as patients who had at least one NOSE class improvement or a NOSE score reduction of at least 20% from baseline. Secondary endpoints included the frequency of procedure-related adverse events at index procedure and all follow-up visits, and the change in NOSE and VAS scores from baseline to all follow-up visits. At three months after treatment, the treatment arm had a significantly greater reduction in NOSE and VAS scores compared to the sham group (-42.4 ± 23.4 vs -22.7 ± 27.9, $p < 0.0001$ and -39.0 ± 29.7 vs -13.3 ± 30.0, $p < 0.0001$, respectively). A total of 19 procedure-related or implant-related adverse events were reported in 17 patients, including six implant retrievals. This study's conclusions are limited by the short-term follow-up and the single blind design introduced risk of bias.

Bikhazi et al. (2021) performed a follow-up to the Stolovityzy et al. (2019) three-month trial in which sham participants still meeting inclusion criteria (i.e., NOSE score of 55 or greater) were invited to crossover to the treatment arm and were followed up to 24 months post-placement. A total of 111 participants (71 treatment as well as 40 out of 66 sham participants) enrolled in this follow-up, however 70 participants completed the 24-month follow-up visit. Participants underwent follow-up visits at three, six, 12, 18, and 24months post implant. Visits included collection of patient-reported outcome measures of the NOSE, a nasal obstruction visual analog scale (VAS), and the Epworth Sleepiness Scale (ESS). Adverse event reporting was also evaluated at each visit. A NOSE responder was defined as a participant with at least one NOSE class improvement or a NOSE score reduction of at least 20% compared with baseline. Researchers found NOSE responder rates are greater than 80% at all follow-ups through 24months. Mean reduction from baseline in NOSE scores is equal to or greater than 30 points and statistically significant ($p<0.001$) at all timepoints through 24 months. The mean VAS score reduction was at least 29.7 points and statistically significant ($p <0.001$) at all time points. A subgroup of participants with baseline ESS values >10 experienced statistically significant ($p <0.001$) and clinically meaningful reductions at all postimplant periods, suggesting that the reduction in nasal symptoms may reduce daytime sleepiness for patients who have problems with sleep quality. No serious device-/procedure-related adverse events were reported. Implant migration/retrieval rate was 4.5%. This study is limited by design as well as small and homogenous population, demonstrating the need for more robust, comparable, long-term clinical trials.

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.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
30468 **(E/I)**	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)
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
S1091 **(E/I)**	Stent, non-coronary, temporary, with delivery system, (propel)

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, nasal implant, nasal valve collapse, Propel, Sinuva, Latera

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.