

# MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	Ablation, Implants, and Sinus Stents for Nasal Conditions
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Category	Technology Assessment
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Archive Review Date	N/A
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 or Child Health Plus product), medical policy criteria apply to the benefit.</li> <li>• 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.</li> <li>• 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.</li> <li>• If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.</li> </ul>

## 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, posterior nasal nerve ablation/neurolysis has not been medically proven to be effective and, therefore, is considered **investigational** for **ALL** indications, including the treatment of chronic rhinitis (allergic or nonallergic).
  - A. Cryoablation (e.g., ClariFix device);
  - B. Radiofrequency ablation (e.g., RhinAer stylus);
  - C. Laser ablation.
- V. 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.
- VI. Based upon our criteria and assessment of peer-reviewed literature, radiofrequency ablation/neurolysis of the nasal valve (e.g., VivAer stylus) has not been medically proven to be effective and, therefore, is considered **investigational** for all indications, including the treatment for nasal airway obstruction.

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*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 four cardinal symptoms: nasal obstruction (congestion), mucopurulent drainage (anterior and/or posterior), facial pain/pressure/fullness, or decreased/loss of sense of smell. Non-specific symptoms can include fatigue, cough, ear pain/pressure, dental pain, or sleep disturbance) CRS may occur with or without nasal polyps. Symptoms persist for weeks to months. In some cases of CRS, surgical drainage may be necessary.

Rhinitis is defined as symptomatic inflammation of the paranasal sinuses and nasal cavity. Chronic rhinitis is defined as rhinorrhea with or without nasal congestion symptoms despite medical therapy lasting longer than 3 months. Allergic rhinitis is defined as an immunoglobulin E (IgE)-mediated inflammatory response of the nasal mucous membranes after exposure to inhaled allergens. Symptoms include rhinorrhea (anterior or postnasal drip), nasal congestion, nasal itching, and sneezing. Allergic rhinitis can be seasonal or perennial, with symptoms being intermittent or persistent.

Nasal obstruction is a symptom of difficulty moving air through the nose and can be caused by a variety of factors including anatomic narrowing (e.g., deviated nasal septum, neoplasm, scarring, nasal fracture), dynamic collapse (e.g., internal nasal valve collapse), inflammation (e.g., swelling, polyposis), turbulent airflow (e.g., septal perforation), and excessive secretions or crusting in the nasal cavity. Commonly, patients will feel that they have nasal congestion or stuffiness. Unilateral symptoms are more suggestive of structural causes of nasal obstruction. A history of trauma or previous nasal surgery, especially septoplasty or rhinoplasty, is also important.

Nasal valve collapse (NVC) is a readily identifiable cause of nasal obstruction. Specifically, the internal nasal valve represents the narrowest portion of the nasal airway with the upper lateral nasal cartilages present as supporting structures. The external nasal valve is an area of potential dynamic collapse that is supported by the lower lateral cartilages. Damaged or weakened cartilage will further decrease airway capacity and increase airflow resistance and may be associated with symptoms of obstruction (e.g., congestion, difficulty breathing with exertion or lying down, and mouth breathing). Patients with NVC may be treated with nonsurgical interventions to increase the airway capacity, but surgery may be necessary for severe symptoms and anatomic distortion.

Nasal and sinus conditions are a commonly diagnosed disease in the U.S. Symptoms are associated with significant negative impacts on quality of life, missed days from work and school, and high healthcare costs due to medical visits, prescriptions and over-the-counter medications, sinus surgeries. Treatments are based on the underlying etiology and experienced symptoms. Medical management (e.g., over-the-counter nasal strips, intranasal corticosteroids, short-term oral corticosteroid, saline nasal irrigation, nasal valve dilator) is the standard first-line treatment option; however, minimally invasive surgical interventions (e.g., post-operative stents, implants, ablation) may be necessary for patient who fail medical therapy.

#### **Drug-Eluting Sinus Stents**

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 (e.g., oral corticosteroids, topical steroid spray, and nasal packing) all have limitations; therefore, sinus stents have been investigated as an option to 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-lactide-co-glycolide), and contains 370µg mometasone furoate, a synthetic

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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.

### Treatment of Nasal Valve Collapse with Obstruction

The placement of an absorbable implant to support the lateral nasal cartilage has been proposed as an alternative to more invasive grafting procedures in patients with severe nasal obstruction and can be implanted in the office-setting under local anesthesia. The concept is that the implant may provide support to the lateral nasal wall prior to its resorption, and then stiffens the wall with scarring as it is resorbed. The Latera absorbable nasal implant 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 and is intended to support cartilage in the nasal lateral wall. Latera is designed to be absorbed by the body over the period of 18-24 months post-implant.

Temperature-controlled radiofrequency ablation has been proposed as a minimally invasive option to reduce nasal-valve obstruction by submucosal remodeling to improve nasal airflow (Jacobowitz et al., 2022). The VivAer Stylus delivers bipolar temperature-controlled radiofrequency energy to targeted nasal tissue. Researchers theorize that as the tissue heals, the scarring and remodeling may increase the nasal valve opening, shrink submucosal tissue, and increases resistance to valve collapse.

### Treatment of Chronic Rhinitis (allergic or nonallergic)

Ablation therapy (cryoablation, radiofrequency, and laser) is a proposed alternative to medical management for patients with chronic rhinitis symptoms (allergic or nonallergic). Ablation of the distal branches of the nasal parasympathetic system, the posterior nasal nerve (PNN), is a proposed treatment to improve symptoms of chronic rhinitis by reducing parasympathetic innervation to the nasal cavity. The procedure is thought to correct the imbalance of autonomic input to the nasal mucosa, reducing nasal antigen responses and vascular hyperreactivity.

Cryoablation freezes nerve fibers of the PNN to reduce the overactivity that causes excess mucus. The ClariFix device is a cryosurgical tool that uses nitrous oxide to freeze the posterior nasal nerve (PNN) to correct the imbalance of autonomic input to the nasal mucosa to reduce nasal antigen responses and vascular hyperreactivity.

Radiofrequency ablation uses low-temperature energy to disrupt the PNN to correct the imbalance of autonomic input to the nasal mucosa to reduce symptoms of chronic rhinitis. The RhinAer Stylus delivers temperature-controlled radiofrequency energy to target and calm overactive nerves in the PNN region to reduce symptoms of moderate to severe chronic rhinitis.

## **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

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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.

### 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.

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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 sequelae. 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.

Stolovitzky et al. (2019) conducted a prospective, multicenter, randomized sham-controlled single blinded trial evaluating the safety and efficacy of a bioabsorbable 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 ( $-42.4 \pm 23.4$  vs  $-22.7 \pm 27.9$ ,  $p < 0.0001$  and  $-39.0 \pm 29.7$  vs  $-13.3 \pm 30.0$ ,  $p < 0.0001$ , 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 Stolovitzky 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 24-months 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 24 months. 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.

### Cryoablation of the Posterior Nasal Nerve (PNN) (e.g., ClariFix device)

Chang et al. (2020) conducted an industry-sponsored, prospective, multi-center, single-arm study of 98 adults diagnosed with chronic, medically intractable rhinitis (moderate to severe allergic or non-allergic) and treated with PNN cryoablation. Participants were over the age of 21 and had a minimum total score of 4 out of 12 on the Reflective Total Nasal Symptom Score (rTNSS). Excluded were participants with anatomy limiting visualization and access to the posterior nasal cavity, ocular symptoms, sinus infection, recent history of epistaxis, bleeding disorder, anticoagulation medication, Raynaud's disease, and/or pregnancy. All 98 participants underwent PNN cryoablation in-office under local anesthesia. Patients discontinued use of intranasal ipratropium 3 days prior to treatment and throughout the study period.

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There were no comparators. Following treatment, the total rTNSS scores were significantly improved over baseline at all post-procedure evaluations: baseline ( $6.1 \pm 1.9$ ), at 1 month ( $2.9 \pm 1.9$ ,  $p < 0.001$ ), 3 months ( $3.0 \pm 2.3$ ,  $p < 0.001$ ), 6 months ( $3.0 \pm 2.1$ ,  $p < 0.001$ ), and 9 months ( $3.0 \pm 2.4$ ,  $p < 0.001$ ). The authors defined the minimal clinically important difference (MCID) as a 30% reduction in baseline score. Following the procedure, 29 adverse events (AEs) related to the procedure or device were reported. Adverse events included two instances of epistaxis requiring office cautery or suction cautery in the operating room; two cases of new ostia (one uncinata process perforation and one maxillary sinus accessory os); and one case of nasal synechia. Other reported AEs were headache, eye dryness and sinus infections. The study was limited by a lack of control group, unblinded provider and patient, short term follow-up period, participant loss to follow up and exclusion only for use of intranasal corticosteroids (but not other medications that would affect rhinorrhea). The authors concluded cryoablation of the PNN for chronic rhinitis was safe, could decrease nasal symptoms of rhinitis, and could improve disease-specific quality of life. They acknowledged future randomized controlled studies, perhaps incorporating a sham treatment arm, would be helpful to further validate the efficacy of PNN cryoablation.

Ow et al. (2021) published additional post-procedure results (12-24 months) of the prospective single arm study above (Chang, 2020). Individuals were evaluated by office visit or phone for changes rTNSS scores from baseline at 12 and 24 months. Ninety-one participants completed the study through the initial 12-month study period. Fifty-seven participants completed the 24-month follow-up. Significant improvements in the total rTNSS were reflected in a median change from baseline of  $-3.0$  or  $-4.0$  at all time points ( $P < .001$ ). Greater than 80.0% of participants achieved the minimum clinically important difference (MCID) of improvement by  $\geq 1$  point on the rTNSS at all follow-ups. Total RQLQ scores indicated significant improvement ( $P < .0001$ ) in quality of life. Over 77% of participants achieved the MCID ( $\geq 0.5$  points) for the total RQLQ score. One participant experienced two treatment-related serious adverse events (epistaxis and retained pledget). A total of 29 nonserious treatment related AEs were reported in 23 participants; most events were transient and resolved with little to no intervention. This follow-up study is limited by single arm design without a concurrent control arm and loss of 30% of the participants after the 12-months. The authors concluded cryotherapy significantly and clinically improves rhinitis symptoms and quality of life with outcomes that are durable through 24 months after treatment. Randomized trials with a control or sham treatment arm evaluating outcomes are needed to evaluate the relative net health benefit of this treatment compared to standard treatment.

Yen et al. (2020) evaluated cryoablation of the PNN at the inferior and middle meatus in 30 individuals with moderate to severe rhinorrhea and mild to severe nasal congestion for at least 3 months. Most previous studies were limited to applying cryoablation to the PNN at the middle meatus. While the participants reported significant symptom improvement at 3 months, the study was limited by the limited number of participants and follow-up and no control arm. This is representative of the body of evidence for this technology; larger studies with long-term follow-up are needed to better assess the safety and efficacy of this therapy.

Hwang et al. (2017) reported on a series of 27 adults who were treated with the ClariFix cryoablation device for allergic and non-allergic rhinitis with or without nasal congestion symptoms despite medical therapy  $\geq 3$  months. Individuals were evaluated using the TNSS and those with a minimum rhinorrhea and/or congestion subscore of two (moderate symptoms) were included. Treatment was completed in office under topical or injected local anesthesia. TNSS mean scores decreased significantly at 7 days post procedure compared to baseline ( $6.2 \pm 0.5$  versus  $4.3 \pm 0.4$ ;  $p < 0.005$ ). At 90 days, the 27 individuals continued to report a decline in the TNSS mean score at  $2.7 \pm 0.4$ ;  $p < 0.001$ . While the TNSS scores continued to decline at 180 days ( $2.3 \pm 0.5$ ) and 365 days ( $1.9 \pm 0.3$ ), six individuals (22%) were lost to follow-up at 180 days and 12 individuals (44%) were lost to follow-up at 365 days. Subjects reported mild pain/discomfort, severe ear blockage and severe nasal dryness, all of which had improved or resolved at the 30-day follow-up. A moderate nosebleed reported approximately one-month post-procedure, was managed by electrocautery. The findings of this study were limited by its small size and the high rate of subject attrition during follow-up. In addition, as medication use was not tracked during the study, other factors for improvement in symptoms may have confounded the results. The authors concluded cryotherapy of the PNN region is safe and well tolerated.

### Radiofrequency Ablation of the Posterior Nasal Nerve (PNN) (e.g., RhinAer Stylus)

Stolovitzky et al. (2021) evaluated of the safety and efficacy of radiofrequency (RF) ablation (also known as neurolysis) of the PNN in the treatment of moderate to severe chronic rhinitis. Individuals were randomized to receive active treatment of the PNN area with a RF device ( $n=77$ ) or with a sham device ( $n=39$ ). The primary endpoint was the responder rate (at least a 30 improvement in rTNSS score from baseline) at 3 months. A significantly higher responder

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rate was reported in the active treatment arm compared to the sham arm: 67.5% (95% CI, 55.9%-77.8%) versus 41.0% (95% CI, 25.6%-57.9%) at 3 months. No serious AEs were reported. The study did not limit the use of prescribed medications but did track medication use. At 3-month follow-up 7 individuals (9.1%) in the active treatment arm and 5 individuals (12.8%) in the sham treatment group increased their use of medications during the follow-up. Individuals who increased their medication use were assigned to non-responder status, regardless of rTNSS scores.

Takashima et al. (2023) reported the 12-month safety and efficacy the Stolovitzky et al. (2021) study. At 12 months, the responder rate was 80.6% (n = 67) and the mean change in rTNSS was -4.8 (p < 0.001), a 57.8% improvement. The improvement in rTNSS of the index active treatment arm, significantly greater than of the index sham-control arm at 3 months was also sustained through 12 months. The mean baseline rTNSS for the index active treatment arm was 8.3, with an adjusted mean change in rTNSS of -3.6, -4.4, and -4.8 at 3-, 6-, and 12-months (p < 0.001), when comparing each follow up timepoint vs baseline. This represents improvement of 43.3%, 53.0%, and 57.8% over baseline at 3-, 6-, and 12-months, respectively. Although nasal itching and sneezing did not exhibit a difference between the index active treatment and index sham-control arms at 3 months, the researchers reported a sustained reduction in the severity of these symptoms over baseline through 12 months. Postnasal drip and cough, which are common and troublesome symptoms of chronic rhinitis, showed a similar improvement compared with baseline over time, although there was no significant difference between the index active treatment and index sham-control arms at 3 months.

Ehmer et al. (2022) reported on the results of a prospective, single-arm multicenter study of 50 individuals with chronic rhinitis who underwent RF treatment to the PNN area. Participants were evaluated at 2, 4-, 12-, 26- and 52-weeks post-procedure, with 47 participants completing the study. The primary efficacy point was the change in rTNSS score from baseline through 12 weeks. The mean rTNSS score improved from 8.5 at baseline to 3.4 at 12 weeks. At 12 months, the mean rTNSS score was reported to be 3.6. There were no serious AEs reported. This early study was limited by the lack of blinding and lack of a control group.

### Laser Ablation of the Posterior Nasal Nerve (PNN)

Krespi et al. (2020) conducted a small (n=32) prospective study to evaluate the effectiveness of an endoscopic diode laser as a tool for PNN ablation for individuals with chronic medically intractable rhinitis. Endoscopic laser ablation was completed in an office or ambulatory surgical center, with follow up 90 days following treatment. Symptom severity and treatment outcomes were measured using the TNSS. The procedure was successfully performed in 31 of the participants. TNSS scores were significantly reduced after 90 days (mean ± Standard Deviation (SD): 6.0 ± 0.7 prior to ablation, 2.3 ± 0.4 at 90 days, p<0.001). The authors reported no laser safety events or other post procedure complications. The study is limited by small size, limited follow up period, no control arm, and non-standardized concomitant use of medications. There are no FDA approved laser devices for ablation treatment of rhinitis.

### Radiofrequency Ablation of Nasal Valves to Treat Nasal Airway Obstruction (VivAer ARC Stylus)

Han et al. (2022) and Yao et al. (2023) reported the long-term (12-month and 2-year respectively) follow-up outcomes from the industry-sponsored trial conducted by Silvers et al. in 2019, summarized below. Following the 3-month primary end point, the trial was unblinded and all patient eligible to cross-over to the treatment arm (n=31) elected to undergo treatment. After two patients were excluded, 108 patients underwent treatment in the trial (77 as index active treatment, 31 after crossover). The crossover arm had a mean baseline NOSE Scale score comparable to the index arm.

The researchers acknowledge the study's limitations of lacking a control arm and the predominantly white study population. They indicated that although further studies that incorporate more liberal application of TCRF to address multiple NAO contributors are needed; the researchers concluded that this multi-institutional cohort study contributes substantial real-world evidence that minimally invasive TCRF device treatment of the internal nasal valve for NAO is well tolerated and effective in significantly and sustainably reducing NAO symptom severity through 2 years. Furthermore, TCRF treatment is effective in patients with either static or dynamic NVC, septal deviation, turbinate enlargement, and prior nasal surgery, all of which are common characteristics of patients who present at clinics seeking relief from their symptomatic NAO.

Silvers et al. (2021) conducted an industry-sponsored prospective, multicenter, single-blinded, randomized controlled trial comparing a temperature-controlled RF device for treatment of the nasal valve collapse in subjects with obstruction. Participants were randomized to either active treatment arm (n=77; RF device/VivAer Stylus) or a sham procedure arm

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(n=40; control group/where a stylus was applied in the same manner but without RF energy delivery). Patients were assessed with a physical and endoscopic exam, NOSE scale score, a 100-mm ease-of-breathing visual analog scale (VAS), and a 100-mm VAS for nasal pain. At baseline, patients had a mean NOSE-scale score of 76.7 (95% confidence interval [CI], 73.8 to 79.5) and 78.8 (95% CI, 74.2 to 83.3) ( $p = 0.424$ ) in the active treatment and sham-control arms, respectively. At three months, the responder rate was significantly higher in the active treatment arm (88.3% [95% CI, 79.2%-93.7%] vs 42.5% [95% CI, 28.5%-57.8%];  $p < 0.001$ ). The active treatment arm had a significantly greater decrease in NOSE scale score (mean, -42.3 [95% CI, -47.6 to -37.1] vs -16.8 [95% CI, -26.3 to -7.2];  $p < 0.001$ ). Three adverse events likely related to the device and/or procedure were reported, and all resolved. This study is limited by non-blinded physicians, medication use was not dictated by the protocol, and short-term follow-up. Results are reported through three months, but the trial will continue follow-up through two years – as summarized above.

Jacobowitz et al. (2019) 6-month results of an industry-sponsored study of minimally invasive office treatment for nasal airway obstruction. This nonrandomized, prospective, multicenter case series assessed the safety and effectiveness of in-office bipolar temperature-controlled radiofrequency treatment of nasal valve obstruction. The study included 50 patients with severe or extreme obstruction (NOSE score at baseline  $\geq 60$  who had a positive response to nasal mechanical dilators or lateralization maneuvers. Bilateral radiofrequency treatment was applied intranasally, using the Vivaer Stylus, under local anesthesia in one session. Efficacy was determined by using the NOSE score and patient-reported satisfaction survey at 26 weeks. The mean baseline NOSE score was 79.9 (SD 10.8, range 60-100), and all had severe or extreme obstruction. At 26 weeks, mean NOSE score was 69% lower at 24.7 ( $P < .0001$ ) with 95% two-sided confidence intervals 48.5 to 61.1 for decrease. The decrease in NOSE score did not differ significantly between patients who did or did not have prior nasal surgery. Patient satisfaction mean by survey was 8.2 of 10. No device or procedure-related serious adverse events occurred. The study is limited by the small sample size, lack of randomization, single-arm study with short-term follow-up.

Ephrat et al. (2021) conducted an extended 24-month follow-up of subjects who participated in the above study conducted by Jacobowitz et al. (2019). This study aimed to determine whether the results achieved at 6 months would be sustained through 24-months and included 39 patients from the original cohort of 49 patients. Study participants completed self-administered evaluations of the NOSE and QoL measures at 12-, 18-, and 24-months post procedure. The researchers reported clinically significant improvement from baseline in NOSE Scale score change demonstrated at six months (mean, 55.9; standard deviation [SD], 23.6;  $p < 0.0001$ ) was maintained through 24 months (mean, 53.5; SD, 24.6;  $p < 0.0001$ ). Responders ( $\geq 15$ -point improvement) consisted of 92.3% of participants at six months and 97.2% at 24 months. Responses to the QOL questions also showed improvement in patients' QOL. Other than the short duration, this trial shares the limitations of the Jacobowitz study cited above. In addition, it is limited by loss of 22% of the original cohort, raising the possibility of retention bias. Ephrat and colleagues acknowledged that in order to distinguish the relative true treatment effect from placebo effects, "it will be necessary to confirm the results of this study in additional patients as part of a planned randomized, controlled trial".

Jacobowitz et al. (2022) reported extended 48-month follow-up outcomes following the initial 26-week study by Jacobowitz et al. (2019). Of the 49 patients in the initial study, 39 completed follow-ups through 24 months and 29 completed follow-ups through 48 months. Compared with baseline, mean total NOSE scores improved after treatment and were maintained throughout the 48 months. Mean NOSE scores decreased from 81.0 at baseline to 21.6 after 6 months (73.3% change), 25.6 after 12 months (68.3% change), 29.3 after 18 months (63.8% change), 22.5 ( $\pm 20.9$ ) after 24 months (72.2% change), 32.3 after 36 months (60.1% change), and 25.7 after 48 months (68.3% change) ( $p < 0.001$  for all comparisons). Mean NOSE domain scores showed sustained improvement through 48 months, including patients with NOSE scores in the "extreme" (score of 80-100) or "severe" (score of 55-75) categories at baseline.

Brehmer et al. (2019) conducted a nonrandomized prospective study to evaluate the safety and efficacy of low-dose RF energy, using the Vivaer system, for the treatment of narrowed nasal valves. The study included 31 participants presenting with symptoms of nasal obstruction and snoring. Researchers used the VivAer low energy RF system to remodel the nasal sidewall to improve airflow. Thirty days after the treatment patients completed two questionnaires measuring nasal obstruction and snoring (NOSE, Snore Outcomes Survey [SOS]). Patient satisfaction was then assessed 90-days after the intervention by means of a 10-point Likert scale (1 = completely dissatisfied; 10 = very satisfied). An improvement in nasal breathing was observed in all patients by NOSE score, sleep quality by SOS questionnaire and quality of life as



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measured by EQ-5D and SNOT-22. The study is limited by the small number of participants, the lack of randomization, control group and comparator, and by the short follow-up period.

### Regulatory Status

In 2011, the PROPEL system (Intersect ENT, Menlo Park, CA) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process (P100044). 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 to maintain patency. In 2017, the PROPEL Contour was approved through a premarket approval supplement. The PROPEL Contour sinus implant is an adaptable implant that is designed to maximize drug delivery to the frontal and maxillary sinus.

In 1987, the SINUVA Sinus Implant (Intersect ENT, Inc., Menlo Park, CA) received its initial FDA approval. In 2017, the SINUVA Sinus Implant was approved with a new dose (1350 µg mometasone furoate) under a New Drug Application (NDA 209310). The SINUVA Sinus Implant is indicated for the treatment of nasal polyps in adult patients who have had ethmoid sinus surgery.

In May 2016, the Latera (Entellus Medical/Stryker ENT) was cleared for marketing by the FDA through the 510(k) process for the indication of supporting nasal upper and lower lateral cartilage.

In December 2017, the VivAer device (Aerin Medical) received its first 510(k) premarket notification FDA clearance (K172529). In April 2020, a second clearance (K200300) was issued for the VivAer Stylus, as substantially equivalent in function, design, and intended use as the predicate device for the intended use of coagulation of soft tissue in the nasal airway, to treat nasal airway obstruction by shrinking submucosal tissue, including cartilage in the internal nasal valve area.

In February 2019, the ClariFix device (Stryker) was cleared for use in adults with chronic rhinitis by the FDA through the 510(k) process (K190356). Clearance was based on substantial equivalence to the predicate device, ClariFix (K162608). The only modification to the subject device was an update to the indications for use to include adults with chronic rhinitis.

In December 2019, the RhinAer stylus (Aerin Medical) was cleared for use by the FDA through the 510(k) process as a tool to treat chronic rhinitis (K192471). Clearance was based on equivalence in design and intended use of a predicate device, the InSeca ARC Stylus (K162810). The RhinAer stylus includes modification of the InSeca ARC stylus shaft components and flexibility.

There are currently no laser ablation devices with FDA clearance for treatment of chronic rhinitis.

### 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**

<b>Code</b>	<b>Description</b>
30117 (*E/I)	Excision or destruction (e.g., laser), intranasal lesion; internal approach (*E/I when requested/billed as ablation of posterior nasal nerve [e.g., RhinAer or ClariFix procedures])
30468 (E/I)	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s) (e.g., Latera)
30469 (*E/I)	Repair of nasal valve collapse with low energy, temperature-controlled (ie, radiofrequency) subcutaneous/submucosal remodeling (*E/I when requested/billed as radiofrequency ablation of the nasal valve [e.g., VivAer procedure])

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<b>Code</b>	<b>Description</b>
30801 (*E/I)	Ablation, soft tissue of inferior turbinates, unilateral or bilateral, any method (e.g., electrocautery, radiofrequency ablation, or tissue volume reduction); superficial (*E/I when requested/billed in combination with 30117, 30469, 30999 [ClariFix, RhinAer or VivAer procedure])
30802 (*E/I)	Ablation, soft tissue of inferior turbinates, unilateral or bilateral, any method (e.g., electrocautery, radiofrequency ablation, or tissue volume reduction); intramural (ie, submucosal) (*E/I when requested/billed in combination with 30117, 30469, 30999 [ClariFix, RhinAer or VivAer procedure])
30999 (*E/I)	Unlisted procedure, nose (*E/I when requested/billed in combination with C1874, C9771, J7402, S1091, 30117, 30801, 30802, 30468, 30469)
31242 (E/I)	Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve (effective 1/01/24)
31243 (E/I)	Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve (effective 1/01/24)
31237	Nasal/sinus endoscopy, surgical; with biopsy, polypectomy or debridement (separate procedure)
31299 (*E/I)	Unlisted procedure, accessory sinuses (*E/I when requested/billed with C1874, C9771, J7402, S1091, 30117, 30801, 30802, 30468, 30469)

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**HCPCS Codes**

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

<b>Code</b>	<b>Description</b>
J30.0 - J30.9	Vasomotor and allergic rhinitis (code range)
J31.0 - J31.2	Chronic rhinitis, nasopharyngitis and pharyngitis (code range)
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 (code range)
R09.81	Nasal congestion
R09.82	Postnasal drip

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\*Key Article

### **KEY WORDS**

Sinus stent, sinus implant, nasal implant, nasal valve collapse, Propel, Sinuva, Latera, posterior nasal nerve, radiofrequency ablation, cryoablation, rhinitis, rhinorrhea, nasal airway obstruction, ClariFix, RhinAer, VivAer.

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**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for sinus stents for postoperative use following endoscopic sinus surgery.

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for posterior nasal nerve ablation for any indication.

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for intranasal radiofrequency ablation to treatment nasal airway obstruction.