MEDICAL POLICY

Medical Policy Title	**Sinus Excision/Destruction, Implants, and Repair**
Policy Number	**7.01.99**
Current Effective Date	**December 18, 2025**
Next Review Date	**December 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Drug- Eluting Implants (Mometasone Furoate)

A. The SINUVA implant is considered **medically necessary** when **ALL** of the following criteria are met:

1. 18 years of age or older;
2. Diagnosis of recurrent nasal polyps secondary to chronic rhinosinusitis;
3. History of ethmoid sinus surgery and would be candidates for revision sinus surgery;
4. Have nasal obstruction/congestion syndromes despite use of intranasal steroid irrigations or sprays;
5. Previous treatment, contraindication, intolerance to conventional nasal polyp therapy such as leukotriene receptor antagonist, steroid taper, or intranasal steroids.

B. The use of the PROPEL drug-eluting sinus stent is considered **investigational**.

C. Repeat use of drug-eluting sinus stents has not been medically proven to be effective and, therefore, is considered **investigational**.

II. Repair of Nasal Valve Collapse (NVC)/Nasal Obstruction

A. The use of an absorbable nasal implant (e.g., Latera) is **investigational** for the treatment of NVC in patients with nasal obstruction.

B. Radiofrequency ablation/neurolysis of the nasal valve (e.g., VivAer stylus) is considered **investigational** for **ALL** indications, including treatment of nasal airway obstruction.

III. Excision/Destruction of the Posterior Nasal Nerve (PNN)

A. Excision/Destruction of the PNN utilizing ANY of the following approaches is **investigational** for **ALL** indications, including the treatment of chronic rhinitis (allergic or nonallergic):

1. Cryoablation (e.g., ClariFix device);
2. RF ablation (e.g., RhinAer stylus, NEUROMARK);
3. Laser ablation.

RELATED POLICIES

Corporate Medical Policy

7.01.41 Surgical Management of Sleep Disorders

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

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 three 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 cause 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-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 implantation can be performed in the physician's office. It is left in place for up to 90 days, or earlier, at the physician's discretion, to gradually release the corticosteroid, and then requires removal.

Treatment of Nasal Valve Collapse (NVC) 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 RF 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 RF 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)

Excision/ destruction (cryoablation, RF, and laser) is a proposed alternative to medical management for patients with chronic rhinitis symptoms (allergic or nonallergic). Excision/destruction 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 PNN to correct the imbalance of autonomic input to the nasal mucosa to reduce nasal antigen responses and vascular hyperreactivity.

RF 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 RF energy to target and calm overactive nerves in the PNN region to reduce symptoms of moderate to severe chronic rhinitis.

Laser surgery is a common minimally invasive treatment for a wide range of otolaryngological conditions including but not limited to hereditary hemorrhagic telangiectasia, turbinate hypertrophy, septoplasty, and choanal atresia. Its use has also been proposed for the treatment of rhinitis via destruction of the PNN. Lasers utilized for rhinology include argon, potassium titanyl phosphate, diode, neodymium-doped yttrium aluminum garnet, and carbon dioxide. Each laser type has different properties for whether it cuts, coagulates, or evaporates tissues, and many have differing delivery systems.

SUPPORTIVE LITERATURE

Drug-Eluting Stents

A 2025 systematic review and meta-analysis (Zamaili et al) aimed to assess the impact of steroid-eluting middle meatal implant after ESS for patients with CRS. The primary outcome was the rate of adhesion following surgery, and secondary outcomes were mucosal inflammation, polyp reformation, the need for oral steroids and additional surgery, post-operative bleeding, sinus pain and discomfort, postoperative sinus infection and change in intraocular pressure. Randomized controlled trials were included and eligible if they involved adult patients receiving ESS for CRS with or without nasal polyps utilizing a steroid-eluting middle meatal implant within the four weeks postoperative period. A total of seven studies were included in the review, representative of 1122 participants (568 in implant and 554 in control groups). The implants utilized in the studies included PROPEL, PROPEL Mini or Contour, BISORB, and SinuBand FP. Results indicated that although beneficial effects were noted including fewer postoperative treatments, decreased rates of adhesions, inflammation and recurrent polyp development, these effects are based on measurements conducted 30 days post-surgery. Authors noted that only a few studies examined outcomes after this time frame. Additionally, the

study design is open to potential bias impacting the overall conclusion of the analysis, therefore, trials looking into longer-term effects of the implants on the outcome of ESS are warranted.

There are four randomized controlled trials evaluating PROPEL implants. Murr et al (2011) and Marple et al (2012) compared unilateral PROPEL stent use in the ethmoid sinus with a non-drug eluting stent on the contralateral side. These studies, although they demonstrated some success in the reduction of inflammation rated by the treating physician, were also limited by a lack of knowledge on whether the comparator received optimal treatment (e.g., packing, intranasal steroids, and irrigation). Smith et al (2016) and Luong et al (2017) aimed to compare the use of PROPEL mini or PROPEL Contour sinus implant in the frontal sinus versus surgery alone on the contralateral side. These trials demonstrated a 22% reduction in the need for additional surgical intervention but also consisted of a high percentage of patients that were not included in the evaluation due to poor video quality. Further studies are needed with appropriately treated comparison subjects to provide high-quality evidence that steroid-eluting stents reduce adhesion, mucosal inflammation, polyp recurrence, the need for oral steroids post-surgery or additional surgical procedures.

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 with recurrent or persistent nasal polyposis after ESS, the use of steroid-eluting nasal implants was investigated to determine improvements in polyp grade and ethmoid obstruction in two randomized controlled trials (RCTs) (RESOLVE I and RESOLVE II, Forwith et al (2016) and Kern et al (2018)). A total of 400 patients were represented between these two studies, and did demonstrate improvements utilizing a sham-controlled design, however both studies were at high risk for bias as the outcome assessment was unblinded to the treatment group.

In 2019, Ernst and colleagues aimed to evaluate the economic impact of insertion of a steroid-eluting sinus implant (SINUVA) after a previous endoscopic surgery compared to a repeat sinus surgery in adults with chronic sinusitis and nasal polyps. A budget impact analysis over a one-year period was

conducted to determine annual total and per-member per-month (PMPM) direct health care costs for a commercial health plan with one-million members. Multiple data sources were utilized to inform the input model values, including a database of 86,052 patients with an ESS performed between 2012-2015. Results from the RESOLVE trial were used to calculate the rate of recurrent sinusitis and the proportion of patients still indicated for revision surgery at study completion. Several other assumptions were made including no preprocedural work up required for the drug implant procedure as well as likelihood of two implants obtained per encounter (bilateral nature of sinonasal polyps). Results of the analysis estimated that 1000 hypothetical members of a commercial health plan would be candidates to receive an implant or revision surgery. Estimated treatment costs for patients with chronic sinusitis with nasal polyps using only revision surgery was $11.03 million, or $0.92 PMPM. Authors used the assumption that the implant would replace surgery in 50% of cases, and if 63% of those individuals received a second treatment with implant during the year, the cost savings would be $2.56 million or $0.21 PMPM. An additional scenario analysis revealed that the cost savings would decrease to $1,278,336 ($0.11 PMPM) if uptake of the implant were 25% versus 50% or would conversely increase to $3,835,007 ($0.32 PMPM) if uptake of the implant was 75%. Authors concluded that use of the implant over revision surgery could result in considerable savings given much lower procedure-related costs and that more research is warranted to include real-world market adoption data for the implants.

Per the drug labeling, the repeat implantation of SINUVA has not been studied.

Absorbable Nasal Implant for Nasal Obstruction

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, which 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 RCTs 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 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 greater than 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.

<u>Cryoablation of the Posterior Nasal Nerve (PNN) (e.g., ClariFix device)</u>

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 four out of 12 on the Reflective Total Nasal Symptom Score (rTNSS). Excluded from the study, 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 three days prior to treatment and throughout the study period. There were no comparators. Following treatment, the

total rTNSS scores were significantly improved over baseline at all post-procedure evaluations: baseline (6.1 ± 1.9), at one month (2.9 ± 1.9, p<0.001), three months (3.0 ± 2.3, p<0.001), six months (3.0 ± 2.1, p<0.001), and nine months (3.0 ± 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. AEs included two instances of epistaxis requiring office cautery or suction cautery in the operating room; two cases of new ostia (one uncinate 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 RCTs, 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 greater than or equal to one (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 (≥0.5 points) for the total RQLQ score. One participant experienced two treatment-related serious AEs (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 three months. Most previous studies were limited to applying cryoablation to the PNN at the middle meatus. While the participants reported significant symptom improvement at three 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 greater than or equal to three 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 seven days post procedure compared to baseline (6.2 ± 0.5 versus 4.3 ± 0.4; p<0.005). At 90 days, the 27 individuals continued to report a decline in the TNSS mean score at 2.7 ± 0.4; p<0.001. While the TNSS scores continued to decline at 180 days (2.3 ± 0.5) and 365 days (1.9 ± 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 (RF) Ablation of the Posterior Nasal Nerve (PNN) (e.g., RhinAer Stylus)

Stolovitzky et al (2021) evaluated the safety and efficacy of 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 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 three-month follow-up seven 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 of 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 three 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 three, six 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 three 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 three 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 two, four, 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.

Kim et al (2024) conducted a systematic review and meta-analysis to compare posterior nerve ablation with cryoablation versus RF neurolysis. The review included 10 studies representing 738 patients with 12 months of follow up, by assessing the clinical response rates after both treatments using the TNSS score as well as quality of life scoring. Of the studies included, there were none that directly compared the two treatments, therefore, the results must be carefully interpreted. Score differences at the 12-month mark were less than those at 6 months, with quality-of-life scores not differing between the two treatments. Additionally, there were several limitations to the review, including a majority of the studies being of a single-arm design and small number of participants. The authors also state that medications, both pre- and post-surgery, were not carefully controlled and therefore, conclude that long term double blinded RCTs are needed.

Hwang and colleagues (2025) aimed to determine if the combination of RF ablation of the inferior turbinates and intraturbinate segments of the PNN with laser PNN would improve short-term response rates and enhance symptom control in chronic rhinitis patients. The retrospective study enrolled 54 patients aged 18-65 years with chronic rhinitis refractory to medical treatment for greater than six months with sinonasal symptoms. All patients were treated with both RF ablation and laser ablation. A total of 50 patients completed a 6-month follow-up. Outcomes measured were Reflective Total Nasal Symptom Score (rtNSSS) and Nasal Obstruction Symptom Evaluation (NOSE). Results demonstrated a significant post-surgical reduction in both rTNSS and NOSE (From baseline scores of 8.7 [95% CI, 8.2–9.2] and 61.6 [95% CI, 56.8–66.3], respectively, rTNSS decreased to 1.46 [95%CI, 1.9–1.1] and NOSE to 2.9 [95% CI, 4.4–1.4] at 6 months [both $p < 0.001$]). The study's retrospective design, lack of a comparator group, and short six-month follow-up period limit the interpretation of the findings. Authors conclude that future prospective studies with longer follow up and comparative analyses are needed.

<u>Radiofrequency (RF) Ablation of Nasal Valves to Treat Nasal Airway Obstruction (NAO) (VivAer ARC Stylus)</u>

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 three-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 while study population. They indicated that although further studies that incorporate more liberal application of temperature-controlled radiofrequency (TCRF) to address multiple nasal airway obstruction (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 two 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 NVC in subjects with obstruction. Participants were randomized to either active treatment arm (n=77; RF device/VivAer Stylus) or a sham procedure arm (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 AEs 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.

Jacobowitz et al (2019) six-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 RF treatment of nasal valve obstruction. The study included 50 patients with severe or extreme obstruction (NOSE score at baseline ≥60 who had a positive response to nasal mechanical dilators or lateralization maneuvers. Bilateral RF 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 AEs 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 six (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 (≥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 (±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 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.

PROFESSIONAL GUIDELINE(S)

The following information is included for reference purposes only. Its inclusion does not imply endorsement or alignment with the outcomes of the review of the evidence.

Drug-Eluting Sinus Stents

In 2023, the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) issued a position statement on the use of drug-eluting sinus implants for the management of mucosal inflammation of the paranasal sinuses. This statement was not based on a systematic review of the evidence.

"The AAO-HNS considers drug-eluting implants in the paranasal sinuses as a proven and effective therapeutic option for mucosal inflammation." The recommendation additionally states, "Multiple studies have demonstrated the efficacy and safety of drug-eluting implants in controlling sinonasal inflammation. Clinical evidence regarding the use of drug-eluting implants after sinus surgery has particularly shown enhanced wound healing through the reduction of both scar formation and anatomic obstruction."

In 2025, AAO-HNS updated a 2015 position statement on the use of biomaterials in sinonasal procedures, supporting the use of FDA-approved implants, stents, and packing material in sinonasal procedures to improve patient outcomes and reduce complications, stating that, "Updated studies continue to support the statistically significant efficacy of drug eluting implants in maintaining sinus outlet patency following surgery compared to other standard nasal dressings in nearly all clinical situations. It remains clear that the decision to place stents, either at surgery or in the office environment needs to be made expeditiously, based upon endoscopic findings and surgical judgement, before scarring or polyposis obstructs the region. This is not an intervention that should be delayed by requirements to try stepwise less invasive or less expensive therapies, as findings can be evident at 2 to 4 weeks in patients."

In 2021, the International Consensus Statement on Allergy and Rhinology (ICAR) (Orlandi et al) was updated and included the following recommendation regarding the management of CRS with nasal polyps, using non-surgical steroid-eluting implants: Sinuva was investigated in 2 RCTs and a pooled analysis. Outcomes reported were positive but there has been no long term follow up past 6 months, and given this, it is not known whether some patients may need the implant more or less frequently. Additionally, both RCTs had implants removed at 60 days despite their ability to release drug up to 90 days. They state, "Clinical experience with this device is still relatively limited and the evidence, though at a high level, is restricted to short-term outcomes." Regarding absorbable steroid-eluting stents (i.e., PROPEL), ICAR states, "While the authors recognize the high cost of these implants, given the level of evidence, absorbable steroid-eluting implants are recommended in carefully selected patients that are similar to those included in the underlying clinical trials."

ICAR additionally commented on the use of office-based versus operating room procedures stating, "While the data suggest that office-based sinus procedures can be performed safely, there remain significant gaps in evidence. Robust long-term outcomes data is necessary, especially for emerging in-office technologies."

The American Rhinologic Society (2023) position statement on criteria for drug eluting implants, endorses the use of drug-eluting implants into the sinus cavities to optimize sinonasal inflammation resulting in a decreased use of systemic steroid prescriptions and potentially delays the need for revision surgery. The society states that "drug-eluting implants should in no way be considered investigational and should be available to patients, when selected by the physician, in order to maximize outcomes." Further, the ARS states that they endorse the AAO-HNS position statement on drug eluting sinus Implants.

<u>Excision/Destruction of the PNN</u>

Published in 2023, ICAR's recommendations for the treatment of allergic rhinitis (Wise et al) addressed cryotherapy/ RF ablation of the PNN, stating it may be considered in allergic rhinitis patients that have failed medical management, particularly for rhinorrhea, adding that the aggregate grade of evidence is a C (observational studies). Further, "because the current evidence is primarily based on industry-sponsored studies with limited long-term data, these office-based interventions remain an option for properly selected patients".

In 2023, AAO-HNS published a position statement on PNN ablation for the treatment of chronic rhinitis, stating the following:

"Posterior nasal nerve neurolysis techniques such as RF ablation and cryotherapy thermal application methods have been used to disrupt the PNN in the posterior aspect of the middle meatus in the region of the sphenopalatine foramen. Multicenter, patient-blinded, sham-controlled RCTs have been performed for RF ablation and cryoablation and have demonstrated clinical benefit for nasal symptoms. For both methods, validated quality of life surveys have demonstrated statistically significant improvement with treatment, with therapeutic effect. Based on these safety and efficacy data, the AAO endorses the use of PNN ablation for the treatment of medically-refractory chronic rhinitis. We do not consider these treatments to be experimental."

The AAO-HNS does not reference the use of laser for destruction of the PNN.

Repair of Nasal Valve Collapse (NVC)

In 2023, AAO-HNS issued a position statement on nasal valve repair stating that treatment options of nasal valve dysfunction may include implants aimed at stabilizing the nasal valve. With regards to surgical repair of the nasal valve, the AAO-HNS states:

"The treatment of nasal valve dysfunction may involve techniques that include cartilage grafting and open surgical repair, suture suspension techniques, and implants or RF treatment aimed at stabilizing the nasal valve… Surgical repair of the nasal valve can be performed as a standalone surgical procedure or in conjunction with other procedures to improve nasal obstruction. These may include septoplasty, turbinate reduction, ESS, among others. These procedures, such as septoplasty, may be complementary to nasal valve repair, but are not effective substitutes as they do not address nasal valve dysfunction. When feasible, surgical treatment to address all contributing anatomic sites should be performed concomitantly, based on patient and physician shared decision making. Requiring septoplasty and/or turbinate surgery prior to nasal valve surgery is not recommended, as this may lead to unnecessary increases in surgical encounters. The nasal valve may be stabilized using office-based treatments, such as implants or RF treatment. For patients who require anatomic widening and definitive stabilization of the nasal valve, surgical treatment of NVC, along with treatment of other possible causes of nasal airway obstruction, is required to optimize patient outcomes. Failure to perform nasal valve repair, when indicated, is a common cause of incomplete symptom resolution for patients with nasal obstruction and nasal valve dysfunction."

The ARS published a statement in 2022 endorsing the use of bioabsorbable nasal implants for the treatment of NVC as an option compared with cartilage grafts, stating that initial studies in humans support their use with studies demonstrating safety and tolerance through 18-months post procedure, with prospective studies demonstrating improvements in the NOSE survey scores through the six-month mark.

In the International Consensus Statement on Allergy and Rhinology: Allergic Rhinitis (Wise et al 2023), authors assess inferior turbinate surgery as a level of evidence grade B, that its benefits include an improvement in rhinitis symptoms including nasal breathing, congestion, sneezing, and itching, and is recommended in patients with medically refractory nasal obstruction. Authors conclude that inferior turbinate surgery is a safe and effective treatment to reduce symptoms and improve

nasal function, however, more studies are warranted to directly compare surgery methods, including RF ablation, laser-assisted, and microdebrider assisted) for the most efficacious and long-lasting outcome.

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates implants and devices for excision/destruction of the sinuses as medical devices. All devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Oct 8]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2025 Oct 8]

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.

The NEUROMARK System (Neurent Medical) originally received 510(k) approval in October of 2021, indicated for use in otorhinolaryngology surgery for creation of RF lesions to disrupt PNNs in patients with chronic rhinitis.

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

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
30117 *E/I	Excision or destruction (e.g., laser), intranasal lesion; internal approach (*E/I when treating the posterior nasal nerve [e.g., RhinAer, NEUROMARK 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 (i.e., radiofrequency) subcutaneous/submucosal remodeling (*E/I when treatment is for radiofrequency ablation of the nasal valve [e.g., VivAer procedure])
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 treatment is to be completed in combination with 30117, 30469, 30999 [ClariFix, RhinAer, NEUROMARK 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 (i.e., submucosal) (*E/I when treatment is to be completed in combination with 30117, 30469, 30999 [ClariFix, RhinAer, NEUROMARK or VivAer procedure])

Code	Description
30999 *E/I	Unlisted procedure, nose (*E/I when treatment is to be completed in combination with C1874, S1091, 30117, 30801, 30802, 30468, 30469)
31237	Nasal/sinus endoscopy, surgical; with biopsy, polypectomy, or debridement (separate procedure)
31242 E/I	Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve (e.g., RhinAer, NEUROMARK)
31243 E/I	Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve (e.g., ClariFix)
31299 *E/I	Unlisted procedure, accessory sinuses (*E/I when requested/billed with C1874, S1091, 30117, 30801, 30802, 30468, 30469)

HCPCS Codes

Code	Description
C1874 E/I	Stent, coated/covered, with delivery system
C2625 E/I	Stent, non-coronary, temporary, with delivery system (Effective 01/01/04)
J7402	Mometasone furoate sinus implant, (Sinuva), 10mcg
S1091 E/I	Stent, non-coronary, temporary, with delivery system, (propel)

ICD10 Codes

Code	Description
D14.0	Benign neoplasm of middle ear, nasal cavity and accessory sinuses (effective 10/15/2015)
J30.0 - J30.9	Vasomotor and allergic rhinitis (code range)
J31.0 - J31.2	Chronic rhinitis, nasopharyngitis and pharyngitis (code range)
J32.0 - J32.9	Chronic sinusitis (code range)

Code	Description
J33.0 - J33.9	Nasal polyp (code range)
J34.8200	Internal nasal valve collapse, unspecified
J34.8201	Internal nasal valve collapse, static
J34.8202	Internal nasal valve collapse, dynamic
J34.8210	External nasal valve collapse, unspecified
J34.8211	External nasal valve collapse, static
J34.8212	External nasal valve collapse, dynamic
J34.829	Nasal valve collapse, unspecified
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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SEARCH TERMS

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.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for sinus stents for postoperative use following ESS, PNN ablation or intranasal RF ablation to treat NAO.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, 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 HISTORY/REVISION

Committee Approval Dates

03/21/19, 03/19/20, 03/18/21, 05/19/22, 05/18/23, 11/16/23, 11/21/24, 12/18/25

Date	Summary of Changes
12/18/25	• Annual Review. Medically necessary criteria added for SINUVA implant.
01/01/25	• Summary of changes tracking implemented.
03/21/19	• Original effective date