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Radiofrequency Volumetric Tissue Reduction for Nasal Obstruction

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Legislative Mandates

EXCEPTION: For Illinois only: Illinois Public Act 103-0123 (IL HB 1384) Coverage for Reconstructive Services requires the following policies amended, delivered, issued, or renewed on or after January 1, 2025 (Individual and family PPO/HMO/POS; Student; Group [Small Group; Mid-Market; Large Group Fully Insured PPO/HMO/POS] or Medicaid), to provide coverage for medically necessary services that are intended to restore physical appearance on structures of the body damaged by trauma.

Coverage

Radiofrequency volumetric tissue reduction for nasal obstruction due to internal nasal valve collapse **is considered experimental, investigational and/or unproven**.

Policy Guidelines

None.

Description

Nasal obstruction is defined clinically as a patient symptom that presents as a sensation of reduced or insufficient airflow through the nose. 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. Patients with NVC may be treated with nonsurgical interventions in an attempt to increase the airway capacity but severe symptoms and anatomic distortion are treated with surgical cartilage graft procedures. The application of radiofrequency volumetric tissue reduction for nasal obstruction has been proposed as a less invasive means to treat nasal obstruction due to internal NVC. By utilizing RF energy, the treatment aims to provide relief with reduced recovery times and fewer complications compared to traditional surgical methods.

Nasal Obstruction

Nasal obstruction is defined clinically as a patient symptom that presents as a sensation of reduced or insufficient airflow through the nose. Commonly, patients will feel that they have nasal congestion or stuffiness. In adults, clinicians focus on the evaluation of important features of the history provided by the patient such as whether symptoms are unilateral or bilateral. 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. Diurnal or seasonal variation in symptoms is associated with allergic conditions.

Nasal valve collapse (NVC) is a is a readily identifiable cause of nasal obstruction. (1, 2) The internal nasal valve is the narrowest part of the nasal passage and is supported by the upper lateral nasal cartilages (see pathophysiology below). On the other hand, the external nasal valve, also known as the nasal entrance, is prone to dynamic collapse and is supported by the lower lateral cartilages. When cartilage is damaged or weakened, it can reduce airway capacity, increase airflow resistance, and lead to symptoms of obstruction. While nonsurgical treatments aim to enhance airway capacity in patients with NVC, severe symptoms and significant anatomical distortion typically require surgical cartilage graft procedures.

<u>Etiology</u>

Nasal obstruction associated with the external nasal valve is commonly associated with post-rhinoplasty or traumatic sequelae and may require functional rhinoplasty procedures. A common cause of internal nasal valve collapse is a septal deviation. Prior nasal surgery, nasal trauma, and congenital anomaly are additional causes.

Pathophysiology

The internal nasal valve, bordered by the collapsible soft tissue between the upper and lower lateral cartilages, the anterior end of the inferior turbinate, and the nasal septum, forms the narrowest part of the nasal airway. During inspiration, the lateral wall cartilage is dynamic and draws inward toward the septum and the internal nasal valve narrows providing protection to the upper airways. Given that the internal nasal valve accounts for at least half of the nasal airway resistance; even minor further narrowing of this area can lead to symptomatic obstruction for a patient. Damaged or weakened lateral nasal cartilage will further decrease airway capacity of the internal nasal valve area, increasing airflow resistance and symptoms of congestion. (1)

Physical Examination

A thorough physical examination of the nose, nasal cavity, and nasopharynx is generally sufficient to identify the most likely etiology for the nasal obstruction. Both the external and internal nasal valve areas should be examined. The external nasal valve is at the level of the internal nostril. It is formed by the caudal portion of the lower lateral cartilage, surrounding soft tissue, and the membranous septum.

The Cottle maneuver is an examination in which the cheek on the symptomatic side is gently pulled laterally with 1 to 2 fingers. If the patient is less symptomatic with inspiration during the maneuver, the assumption is that the nasal valve has been widened from a collapsed state or dynamic nasal valve collapse. An individual can perform the maneuver on oneself and it is subjective. A clinician performs the modified Cottle maneuver. A cotton swab or curette is inserted into the nasal cavity to support the nasal cartilage and the patient reports whether there is an improvement in the symptoms with inspiration. In both instances, a change in the external contour of the lateral nose may be apparent to both the patient and the examiner.

According to American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS, 2023):

- "The diagnosis of symptomatic nasal valve dysfunction is a clinical diagnosis, made by patient history and physical exam. These diagnoses are made by a qualified Otolaryngologist as a part of a thorough physical examination of the nose...Subjective improvement in nasal breathing with the Cottle or modified Cottle maneuver confirms the diagnosis of nasal valve collapse." (3)

Treatment

Treatment of symptomatic nasal valve collapse includes the use of non-surgical interventions such as the adhesive strips applied externally across the nose or use of nasal dilators, cones, or other devices that support the lateral nasal wall internally applying the principle of the modified Cottle maneuver. Severe cases of obstruction resulting from nasal valve deformities are treated with surgical grafting to widen and/or strengthen the valve. Common materials include cartilaginous autografts and allografts, as well as permanent synthetic grafts. Cartilage grafts are most commonly harvested from the patient's nasal septum or ear.

Radiofrequency Volumetric Tissue Reduction

The application of low-dose radiofrequency (RF) energy has been proposed as an alternative technique for reshaping nasal tissue to address NVC. This method has been suggested as a viable alternative to more invasive grafting procedures, particularly for patients experiencing severe nasal obstruction. By utilizing RF energy, the treatment aims to provide relief with reduced recovery times and fewer complications compared to traditional surgical methods.

Regulatory Status
NOTE: This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

In April 2020, the VivAer® Stylus (Aerin Medical) was cleared for use in otorhinolaryngology (ENT) surgery by the Food and Drug Administration (FDA) through the 510(k) process as a tool to treat nasal obstruction (K200300). (4) Clearance was based on equivalence in design and intended use of a predicate device, the Vivaer® ARC Stylus (K172529). The VivAer® Stylus is functionally unchanged from the predicate in design and intended use to generate and deliver bipolar RF energy to treat tissue in otorhinolaryngology (ENT) procedures. As per the FDA 510(k) summary, the VivAer® Stylus is indicated for use in ENT surgery for the 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.

The VivAer® Stylus is distinct from the RhinAer® device (Aerin Medical) currently reviewed in medical policy SUR706.020 (Cryoablation, Radiofrequency Ablation, and Laser Ablation for Treatment of Chronic Rhinitis) as it targets nasal tissue for remodeling to improve airflow as opposed to disrupting the posterior nasal nerve in rhinitis.

Rationale

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be

adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Radiofrequency Volumetric Tissue Reduction

Clinical Context and Therapy Purpose

The purpose of radiofrequency volumetric tissue reduction in individuals who have symptomatic nasal valve obstruction due to nasal valve collapse (NVC) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is adults who have severe symptomatic nasal obstruction symptoms due to the internal NVC. (5) NVC is one of the recognized structural causes of obstructed breathing and congestion, and the diagnosis is primarily clinical. NVC may be unilateral or bilateral and is typically constant with each inspiration. The condition may occur in association with prior trauma or rhinonasal surgery. The evaluation consists of a clinical history to elicit alternative causes or co-occurring conditions such as obstructive sleep apnea or medication use. In addition to examination of the head and neck, the Cottle maneuver or modified Cottle maneuver is used to rule-in NVC. Anterior rhinoscopy and nasal endoscopy are used to rule out structural abnormalities such as septal deviation or mucosal conditions such as enlarged turbinates. Radiographic studies are not generally indicated. (6)

Interventions

The therapy being considered is the VivAer® Stylus (VivAer) which is a disposable, handheld device capable of delivering bipolar radiofrequency energy to tissue. The stylus consists of an array of bipolar electrodes positioned on a non-conductive tip which is attached to a handle via a non-conductive shaft. A temperature sensor is located on the tip to monitor tissue temperature during treatment. VivAer improves nasal breathing by modifying the soft tissues of the nasal airway through the use of low doses of radiofrequency energy. The low-power radiofrequency generates heat within the submucosal tissue, creating a coagulation lesion. As the lesion heals, the tissue retracts and stiffens. This decreases the nasal airflow resistance thereby improving inflow of air through the nose.

Comparators

The following therapies and practices are currently being used to treat NVC: nonsurgical treatments include the use of externally applied adhesive strips or intranasal insertion of nasal cones. The basic mechanism of action of these treatments is to widen the nasal valve and permit increased airflow. Surgical grafting using either autologous cartilage (typically from the nasal septum, ear, or homologous irradiated rib cartilage) or a permanent synthetic implant may be performed to provide structural support to the lateral wall support defect.

Outcomes
The general outcomes of interest are a change in symptoms and disease status, treatment-related morbidity, functional status, and change in the quality of life (QOL). The Nasal Obstruction Symptom Evaluation (NOSE) score is an accepted symptom questionnaire for research purposes. The score can also be stratified to indicate the degree of severity of the nasal obstruction symptoms. The insertion of the absorbable implant is performed under local anesthesia and the adverse event profile includes mild pain, irritation, bruising and inflammation, awareness of the presence of the implant, infection, and the need for device retrieval prior to complete absorption.

Stewart et al. (2004) proposed the NOSE as a validated sinonasal-specific health status instrument that is used to assess the impact of nasal obstruction on the QOL of affected persons. (7) It is a 5-item questionnaire on breathing problems: nasal congestion or stuffiness, nasal blockage or obstruction, trouble breathing through the nose, trouble sleeping, and inability to get enough air through the nose during exercise or exertion. The responses are made on a Likert-type scale ranging from 0 (not a problem) to 4 (severe problem). The range of raw scores is 0 to 20. The score is then scaled to a potential total score of 0 to 100 by multiplying the raw score by 5. A score of 100 means the worst possible problem with nasal obstruction.

The NOSE scale-based nasal obstruction severity classification system is proposed as a means to classify patients for clinical management as well as to better define study populations and describe treatment or intervention responses (Table 1). (8)

Table 1. NOSE Severity Classification

Severity Class	NOSE Score Range
Mild	5 to 25
Moderate	30 to 50
Severe	55 to 75
Extreme	80 to 100

NOSE: Nasal Obstruction Symptom Evaluation.

The duration of follow-up to assess early procedural outcomes is 1 month and at least 24 months would be required to evaluate the durability of symptom improvement as well as to confirm the association with the purported device mechanism of action.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for randomized controlled trial (RCTs).
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

The efficacy of radiofrequency volumetric tissue reduction (RFVTR) to treat nasal obstruction has been assessed through several systematic reviews. (9, 10, 11) Trials included in these systematic reviews can be compared in Appendix Table A1.

Casale et al. (2023) performed a systematic review and meta-analysis to evaluate the effectiveness of VivAer for treating nasal obstruction. (9) The review included prospective and retrospective studies involving participants with nasal obstruction due to NVC and high NOSE scores (>55). Five studies (N=297 participants), published through December 2021, met the criteria and involved bilateral treatment of the nasal valve regions. Participants were excluded if they had undergone additional procedures such as septoplasty, turbinoplasty, rhinoplasty, or orthognathic surgery. Studies that did not report quantifiable outcomes or lacked extractable data were also excluded. The primary outcome measured was the NOSE questionnaire scores, which reflect the disease-specific quality of life. Comparisons were made between pre-treatment and post-treatment values, and between post-treatment and control (sham) outcomes over a 3-month follow-up period. Minor adverse events were reported, but none of the studies mentioned changes in the external appearance of the nose. Three months post-treatment, NOSE scores significantly decreased (pre-treatment: 76.16 ± 6.39; post-treatment: 31.20 ± 2.73; mean difference [MD]: 46.13; 95% confidence interval [CI] 43.28 to 48.99), with moderate heterogeneity (I^2 =70%, $p < 0.01$). In the only RCT by Silvers et al. (2021), the active group showed significantly better results than the sham-control group 3 months after treatment (see below). The review authors cautioned that due to moderate heterogeneity and the limited number of small population studies with short follow-up periods, these results should be interpreted with caution. They also noted a risk of bias ranging from moderate to serious. The authors concluded that VivAer could be effective for treating NVC and substantially improved subjective breathing symptom scores. However, they emphasized that additional large-scale studies are necessary to confirm these findings.

Han et al. (2024) conducted a systematic review and meta-analysis to compare the treatment effect sizes of RFVTR using VivAer on the internal nasal valve alone, against functional rhinoplasty surgery. (10) Given that functional rhinoplasty for nasal valve dysfunction is often accompanied by septoplasty, turbinate treatment, and cosmetic techniques, they performed analyses to compare RFVTR with (i) rhinoplasty focused solely on the nasal valve, (ii) rhinoplasty excluding turbinate procedures, and (iii) all types of rhinoplasty surgery. The treatment effect was measured using NOSE scale scores at pre-procedural baseline and at 3, 6, and 12 months post-procedure. A pre-procedural NOSE score cutoff of 45 or higher was used to include participants with moderate to severe nasal airway obstruction and to exclude those focused solely on cosmetic outcomes. Five studies on RFVTR and 63 studies on functional rhinoplasty,

published through December 2022, were included in the analysis. Pooled effect sizes for RFVTR and all forms of rhinoplasty were comparable. At 12 months, weighted mean difference (WMD) was -48.8 (95% CI, -56.9 to -40.7), I^2 =68% for RFVTR treatment and WMD, -47.7 (95% CI, -51.1 to -44.4), I^2 =90.0% for functional rhinoplasty. The study concluded that RFVTR of the internal nasal valve has lasting effects comparable to functional rhinoplasty, whether focused on the nasal valve alone or not including turbinate treatment, as well as all rhinoplasty procedures. The study had some limitations, including a follow-up period limited to 12 months to increase the quantity of evaluable data, as studies with longer follow-ups were fewer. It was noted that some datasets might include participants with less than moderate nasal airway obstruction (NAO), but the cutoff of 45 ensured most participants had at least moderate nasal airway obstruction. The quality of the included studies varied, with many traditional procedure studies being of moderate to poor quality and showing high heterogeneity.

In a systematic review and meta-analysis, Kang et al. (2024) examined the efficacy of RFVTR in mitigating nasal obstruction by addressing NVC. (11) The analysis included studies that assessed QOL and NOSE scores before and after RFVTR with VivAer and also evaluated sham-controlled studies. Eight studies (N=451 participants) met the inclusion criteria. Participants who underwent RFVTR reported a significantly improved QOL 24 months post-treatment compared to pre-treatment scores. The rates of clinically improved states and positive responses regarding QOL post-treatment were 82% and 91%, respectively. Furthermore, the disease-specific QOL, as measured by the NOSE score, showed significant improvement: At 24 months, MD, 56.35 (95% CI, 50.29 to 62.41, I^2=0.0%). The authors concluded that RFVTR may be beneficial in alleviating nasal obstruction symptoms; however, further RCTs with larger sample sizes are necessary to confirm the effectiveness of RFVTR in enhancing nasal valve function.

Randomized Controlled Trials

A sham-controlled randomized trial with a 3-month follow-up was identified, (12) and its long-term outcomes have been published. (13, 14, 15)

Silvers et al. (2021) presented findings from a prospective, multicenter, single-blinded, industry-funded RCT, which evaluated the safety and efficacy of RFVTR with VivAer for NVC in patients with nasal obstruction (The Vivaer® Procedure for Treatment of Nasal Airway Obstruction: A ProspecTive, Multicenter Randomized Controlled TriAl Comparing Vivaer to Sham Control [VATRAC]). (12) Participants were divided into two groups: (A) received bilateral RFVTR of the nasal valve (n=77), and (B) underwent a sham procedure (n=40). During the sham treatment, participants were prepped for surgery, anesthetized, and VivAer was inserted into their nostrils without transferring RF energy to the target tissue. The device was applied to the mucosa over the lower lateral cartilage of the lateral nasal wall. The primary endpoint was the responder rate at 3 months, defined as a 20% or greater reduction in the NOSE scale score or at least a 1-point reduction in clinical severity category. At baseline, participants exhibited a mean NOSE-scale score of 76.7 (95% CI, 73.8 to 79.5) in the active treatment group and 78.8 (95% CI, 74.2 to 83.3) (p=.424) in the sham-control group. After 3 months, the responder rate was significantly higher in the active treatment group (see Table 3). Moreover, the active treatment group showed a significantly greater improvement in the NOSE-scale score. Three adverse events

were considered at least possibly related to the device and/or procedure. In the active treatment group, one participant experienced a vasovagal reaction, and another had intermittent nasal bleeding with mucus, both of which resolved. In the sham-control group, one individual experienced intermittent headache, which also resolved. It is important to note that the results of this study may not be generalizable to broader populations. This trial did not control for or analyze possible differences in oral or topical medication use during the trial. Although the study was blinded, the perception of the presence or absence of local effects of RFVTR could have provided participants with an indication of their study group. The authors did not investigate whether participants were aware of their study group.

Studies by Han et al. (2022), Slivers et al. (2024), and Han et al. (2025) have reported on the 12-month, 24-month, and 36-month results of the VATRAC trial, respectively. After the 3-month visit, which served as the primary endpoint, participants in the VATRAC trial were unblinded. Patients in the index sham-control group who remained eligible and consented to continue in the trial were given crossover treatment. For the follow-up period extending from 3 to 24 months, all participants who received active treatment, including both initial active treatment patients and those who crossed over from the sham-control arm, were combined into a single analysis cohort.

Han et al. (2022) published results of the VATRAC trial through 12 months of follow-up. (13) Following evaluation of the primary endpoint at 3 months, eligible participants in the sham control arm crossed over to active treatment (n=31; 77% of the sham control cohort). The mean baseline NOSE Scale score of the combined group of participants who received treatment (N=108) was 76.3 (95% CI, 73.6 to 79.1). At 12 months (81% of those treated were available for analysis; n=88), the rate of participants who were defined as 'responders' by meeting the primary endpoint was 89.8% (95% CI, 81.7% to 94.5%) and the median NOSE Scale score improved from baseline (mean change, -44.9, 95% CI, -52.1 to -37.7). No device nor procedure-related serious adverse events were reported. The high attrition rate and cross-over at 3 months render conclusions regarding this study's outcomes subject to serious bias.

Silvers et al. (2024) presented the two-year results of the VATRAC trial, which aimed to evaluate the long-term effects of RFVTR and changes in the usage of medication and nasal dilators over the study period. (14) At the 24-month mark, the responder rate was 90% (N=108 participants), with a NOSE score treatment effect of -41.7, indicating a 55% improvement. Among participants who used medications or nasal dilators at the beginning of the study, 79% had reduced or stopped use in at least one class. No new adverse events related to the RFVTR procedure were reported during the study period. The authors concluded that RFVTR treatment for nasal valve dysfunction led to significant and sustained improvements in nasal airway obstruction symptoms and a notable reduction in the use of medications or nasal dilators. They also noted that conditions such as turbinate enlargement, septal deviation, or septal swell body did not significantly affect the likelihood of achieving a NOSE score of ≤25 at two years. However, there were several study limitations: the long-term follow-up consisted of a single group, despite the trial originally being an RCT with a primary endpoint at three months. Additionally, because the NOSE score is a subjective, patient-reported measure, future studies

could benefit from including objective measures such as acoustic rhinometry or rhinomanometry. Furthermore, the study population was predominantly Caucasian, limiting the analysis of outcomes in non-Caucasian populations who might have meaningful differences in nasal anatomy.

Han et al. (2025) reported 3-year outcomes of the VATRAC trial. Following initial randomization and crossover, 108 patients received active treatment; 54 patients completed the 3-year follow-up. (15) The mean baseline NOSE Scale score was 76.9 (95% CI, 74.4 to 79.6). At 36 months, the adjusted mean NOSE score was 27.1 (95% CI, 20.4 to 33.8), representing a mean change of -49.5 (95% CI, -56.6 to -42.4; p<.001) and a 64.6% improvement from baseline; significant improvements were observed across all NOSE subdomains (nasal blockage, trouble breathing, trouble sleeping, nasal congestion, and getting enough air during exercise). Medication use decreased or remained stable for 91.8% of participants, and no device- or procedure-related serious adverse events occurred. To note, there was a high attrition rate, patients were allowed to continue or adjust nasal medications throughout the study (which could confound symptom improvement results), and the study relied on patient-reported outcomes.

Table 2. Summary of Key RCT Characteristics

Study; Trial	**Countries**	**Sites**	**Dates**	**Participants**	**Interventions**	
					Active	*Comparator*
Silvers et al. (2021); VATRAC (12)	United States	16	August 2020 - December 2020	N=119[a] Baseline patient characteristics: Age 18 to 85 years • The mean (SD) age of patients was 48.5 years (12.3) years • 66 (61%) were women • All seeking treatment for nasal obstruction Baseline NOSE scale score ≥55 • Mean score of 77 (95% CI, 74 to 79) and 79 (95% CI, 74 to 83) (p=.42) in the active treatment and sham-control arms, respectively	VivAer; n=77	Sham; n=40

				Nasal valve collapse as the primary or a significant contributor to the nasal obstruction Positive response to a temporary nasal dilation measure, such as the modified Cottle maneuver Patient dissatisfaction with medical management		

CI: confidence interval; NOSE: Nasal Obstruction Symptom Evaluation; RCT: randomized controlled trial; SD: standard deviation.
[a] Of 119 participants, 1 patient in VivAer arm withdrew consent before treatment, and 1 patient in the sham-control arm was lost to follow-up before the 3-month visit (primary endpoint).

Table 3. Summary of Key RCT Results at 3 months

Study	**NOSE Responder Rate at 3 mo % (95% CI)[1]**	**Change in NOSE Score at 3 mo (95% CI)**	**Mean change in VAS at 3 mo (95% CI)**	**Adverse events n (%)**
Silvers et al. (2021); VATRAC (12)	N=117	N=117	N=117	N=117
VivAer	88.3 (79.2 to 93.7)	-42.3 (-47.6 to -37.1)	-31.4 (-38.5 to -24.2)	3 (4)
Sham	42.5 (28.5 to 57.8)	-16.8 (-26.3 to -7.2)	-16.1 (-26.3 to -6.0)	1 (2.5)
p value	<.001	<.001	.015	

CI: confidence interval; mo: month(s); NOSE: Nasal Obstruction Symptom Evaluation; RCT: randomized controlled trial; VAS: visual analog scale.
[1] Defined as a ≥20% reduction in NOSE-scale score or ≥1 reduction in clinical severity category.

Tables 4 and 5 summarize the limitations of the RCT.

Table 4. Study Relevance Limitations

Study	**Population[a]**	**Inter-vention[b]**	**Comparator[c]**	**Outcomes[d]**	**Duration of Follow-up[e]**

Silvers et al. (2021); VATRAC (12)	4. Only 10% participants in each group were from diverse racial/ethnic backgrounds		2. Lack of comparison to other treatments for nasal obstruction (medications, nasal dilators and rhinoplasty)	1. NOSE score is a subjective, patient-reported measure, future studies could benefit from including objective measures such as acoustic rhinometry or rhinomanometry 6. Clinically significant difference not supported. A positive responder could still have severe symptoms	1, 2. Follow-up limited to 3 months

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 5. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Silvers et al. (2021); VATRAC (12)	5. Potential for participants to discern their treatment group due	1. Physicians were not blinded to treatment-		6. Not intent-to-treat. 7. Lack of control for confounding medication or		

	to the nature of the sham procedure	arm assignment		nasal dilator use		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Summary of Evidence

For individuals with symptomatic nasal obstruction due to internal nasal valve collapse who receive radiofrequency volumetric tissue reduction (RFVTR), the evidence includes systematic reviews and a randomized controlled trial (RCT) with 12-month and 24-month uncontrolled follow-up phases. Relevant outcomes are symptoms, change in disease status, treatment-related morbidity, functional outcomes, and quality of life. Systematic reviews have generally shown improvements in nasal obstruction scores. In the RCT, follow-up at 3 months revealed a statistically significant improvement in response with the RFVTR procedure compared to the sham group. However, these results are limited by the small study size, lack of diversity, short duration, and failure to control for confounding factors such as medication or nasal dilator use. Moreover, the trial's results may not fully represent the potential effect of RFVTR since treatment was limited to lateral nasal wall repair, not addressing soft tissues like septal swell bodies and inferior turbinates. A significant and durable effect on nasal obstruction post-RFVTR treatment was reported up to 36 months during the uncontrolled crossover phase of the trial. Additional RCTs with extended follow-up periods, larger and more diverse populations, and comparisons of RFVTR to other treatments (medications, nasal dilators, and rhinoplasty) are necessary to confirm the procedure's efficacy for nasal obstruction. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American Academy of Otolaryngology-Head Neck Surgery

In 2023, the American Academy of Otolaryngology-Head Neck Surgery (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 radiofrequency treatment aimed at stabilizing the nasal valve…The nasal valve may be stabilized using office-based treatments, such as implants or radiofrequency treatment. For patients who require anatomic widening and definitive stabilization of the nasal valve, surgical treatment of nasal valve collapse, 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." (3)

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 6.

Table 6. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
NCT06922955	A Prospective, Open-label, Multi-center, Non-inferiority Study Comparing VivAer® to Alternative Surgical Procedures to Treat Nasal Airway Obstruction in Patients With Nasal Valve Dysfunction (The CompAer Study)	400	Dec 2027
NCT05573919	VivAer: A Correlation Between Symptom Scores and Objective Findings	25	Oct 2024
NCT04717791[a]	Low Temperature Controlled Radiofrequency Intranasal Remodeling Treatment of the Nasal Valve Area. A Multicentric Long-term Evaluation	118	Oct 2022 (last update on Jan 2023)

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	30469
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2025 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
09/01/2026	Document updated. Coverage unchanged. Reference 15 added.
01/01/2026	Document updated. The following changes were made to Coverage: 1) Narrowed scope of policy to address only Radiofrequency Volumetric Tissue Reduction for Nasal Obstruction; 2) Modified statement on use of radiofrequency volumetric tissue reduction for nasal obstruction due to internal nasal valve collapse is considered experimental, investigational

	and/or unproven; 3) Moved information on drug-eluting sinus implants to medical policy SUR706.021; 4) See medical policy ADM1001.036 for a listing of services previously addressed on this policy. Title changed from: Nasal and Sinus Surgery.
09/15/2024	Document updated with literature review. The following changes were made to Coverage: 1) Added criteria for septoplasty and turbinate resection; 2) Added criteria to the Drug-Eluting Sinus Implants section; 3) Added: Repeat Administration coverage statements for mometasone furoate products; and 4) Replaced information on NOTE 3 with indications for the PROPEL family of devices; 5) Added: "Balloon septoplasty for treatment of septal deviation is considered experimental, investigational and/or unproven." References added: 10, 41, 43-44, 52-59.
11/01/2022	Document updated with literature review. The following changes were made to Coverage: 1) Clarified the section addressing Drug-Eluting Sinus Implants; 2) Removed the section on Cryotherapy for Treatment of Rhinitis from this policy, it has been relocated to SUR706.020 Cryoablation, Radiofrequency Ablation, and Laser Ablation for Treatment of Chronic Rhinitis. References added: 16, 39-40, and 47.
07/01/2021	Document updated with literature review. The following change was made to Coverage: Added "Cryosurgical ablation of the posterior nasal nerve region (e.g., ClariFix®) to decrease symptoms associated with chronic rhinitis is considered experimental, investigational and/or unproven". References added: 2, 39-43.
03/15/2021	Document updated with literature review. The following changes were made to Coverage: 1) Added the following statement: "The use of radiofrequency to the nasal valve region (e.g. Vivaer [Aerin Medical]) for the treatment of nasal airway obstruction is considered experimental, investigational and/or unproven."; 2) Added NOTES 2 and 3 and NOTES were renumbered, and 3) Removed Coverage statements pertaining to Balloon Ostial Dilation. Information on the topic of balloon ostial dilation for the treatment of chronic rhinosinusitis is now located on medical policy SUR706.019. References added: 1, 9, 11-15, 17-30, 35-37.
04/15/2020	Document updated with literature review. The following changes were made to Coverage: For Rhinoplasty: 1) Added septoplasty and septal deformity to the rhinoplasty statements; 2) Added the following: OR significant deformity in individuals with documented obstructive sleep apnea. For Balloon Ostial Dilation: 3) Coverage separated into Coverage for adults and children; 4) NOTE 2 added defining adult chronic rhinosinusitis; 5) Added NOTE 3: Balloon sinus ostial dilation may be performed either as a stand-alone procedure or as part of FESS when criteria are met; 6) Added Balloon sinus ostial dilation is considered experimental, investigational and/or unproven for patients with chronic rhinosinusitis that have nasal polyps. 7) NOTE 4 added defining pediatric chronic rhinosinusitis. Added references: 9-10, 26,

	39-40, 42, and 45. Information on Balloon Dilation of the Eustachian Tube has been removed from this document and is now housed on Medical Policy SUR706.018 Balloon Dilation of the Eustachian Tube.
01/15/2019	Document updated with literature review. The following changes were made to Coverage: 1) added coverage under Drug-eluting Sinus Implants to address FDA drug approved sinus implant 2) clarification of coverage per the FDA device or FDA drug approved indications for drug-eluting sinus implants and 3) added the following: NOTE 2: See the Regulatory Status section of this medical policy for additional information concerning drug and devices containing mometasone furoate and their indications. Added references: 54-55.
05/01/2018	Document updated with literature review. The following coverage criteria for Rhinoplasty was changed: within the previous 12 months, was removed from the following statement: Significant external nasal pyramid collapse following documented trauma or injury within the previous 12 months. PROPEL Contour was added to the coverage statements for Drug-eluting Sinus Implants.
07/01/2017	Document updated with literature review. The following coverage statement was added: Balloon dilation of the Eustachian tube for persistent Eustachian tube dysfunction is considered experimental, investigational and/or unproven.
11/15/2016	Document updated with literature review. The following changes to coverage were made: 1) Rhinoplasty coverage criteria changed from 5 criteria to the following 3 criteria: Rhinoplasty may be considered medically necessary when performed to correct any one of the following: Nasal deformity secondary to congenital craniofacial deformity (e.g. cleft lip, cleft palate, or maxillonasal dysplasia); OR Significant external nasal pyramid collapse following documented trauma or injury within the previous 12 months; OR Significant deformity following removal of a nasal malignancy, an abscess or osteomyelitis. 2) Balloon Ostial Dilations coverage changed to the following: Balloon ostial dilation using a U. S. Food and Drug Administration (FDA) approved catheter-based inflatable device performed in accordance with the device's FDA-approved labeling for the treatment of medically refractory chronic sinusitis in adults may be considered medically necessary as a minimally invasive alternative to functional endoscopic sinus surgery. The use of a balloon ostial dilation device, with a FDA approved device specified for children, (children age 17 and under) may be considered medically necessary when treating the maxillary sinus space as a minimally invasive alternative to functional endoscopic sinus surgery for the treatment of medically refractory chronic sinusitis. The use of a balloon ostial dilation device, with a FDA approved device specified for children, (children age 17 and under) is considered experimental, investigational and/or unproven in all other sinus spaces but the maxillary sinus space as a minimally invasive alternative to functional endoscopic sinus surgery for the treatment of

	medically refractory chronic sinusitis. 3) the following coverage statement was changed under the Drug-eluting Sinus Implants section: Placement of a mometasone furoate sinus implant (Propel®/Propel® mini) may be considered medically necessary in conjunction with ethmoid sinus and/or frontal sinus surgery when criteria are met.
05/01/2015	Document updated with literature review. Coverage language clarified for balloon ostial dilation. Coverage for implantable sinus stent has changed to may be considered medically necessary when listed criteria are met.
07/01/2012	Document updated with literature review. CPT/HCPCS code(s) updated. The following was added to Sinus Spacers and Other implantable Devices: Bioabsorbable sinus implants (e.g. Propel™) are considered experimental, investigational and unproven for all indications, including delivery of steroids to the sinus cavities.
06/01/2012	Document updated with literature review. CPT/HCPCS code(S) updated. The following was added to coverage: Use of a catheter-based inflatable device (balloon sinuplasty) for the treatment of medically refractory chronic sinusitis may be considered medically necessary as a minimally invasive alternative to functional endoscopic sinus surgery. Information regarding catheter –based inflatable balloon device found in the pricing section was removed.
12/01/2010	Document updated with literature review. Explained when FESS is medically necessary (not a new indication); Use of a spacer (e.g. Relieva Stratus™ MicroFlow Spacers and Deployment Guides) for all indications, including delivery of steroids to the sinus cavities, is considered experimental, investigational and unproven.
04/15/2009	Policy revised with literature search, no coverage change.
01/01/2009	Revised/Updated Entire Document
04/15/2008	Coverage revised
05/01/2007	Coverage revised
03/01/2007	Revised/Updated Entire Document
01/01/2007	Codes revised/added/deleted
11/01/2006	Codes revised/added/deleted
01/01/2005	Revised/Updated Entire Document
06/01/2001	Codes revised/added/deleted
11/01/1999	Revised/Updated Entire Document
05/01/1996	Revised/Updated Entire Document
03/01/1996	Revised/Updated Entire Document
01/01/1993	Revised/Updated Entire Document
05/01/1990	New Medical Document

Appendix

Table A1. Comparison of Studies Included in Systematic Reviews & Meta-analyses

Study	Casale et al. (2023) (9)	Han et al. (2024) (10)	Kang et al. (2024) (11)
Brehmer et al. (2019) (16)	●	●	●
Jacobowitz et al. (2019) (17)	●		●
Wu et al. (2021) (18)	●	●	●
Silvers et al. (2021) (12)	●		●
Yao et al. (2021) (19)	●	●	●
Han et al. (2022) (13)		●	●
Ephrat et al. (2021) (20)		●	●
Weissman et al. (2015) (21)			●