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## Radiofrequency Volumetric Tissue Reduction for Nasal Obstruction

Table of Contents
<a href="#">Coverage</a>
<a href="#">Policy Guidelines</a>
<a href="#">Description</a>
<a href="#">Rationale</a>
<a href="#">Coding</a>
<a href="#">References</a>
<a href="#">Policy History</a>

Related Policies (if applicable)
SUR705.030 Orthognathic Surgery

### Disclaimer

**Carefully check state regulations and/or the member contract.**

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

### 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 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 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.

### Etiology

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 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**

In April 2020, the VivAer® Stylus (Aerin Medical) was cleared for use in otorhinolaryngology surgery by the 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 procedures. As per the FDA 510K 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) as it targets nasal tissue for remodeling to improve airflow as opposed to disrupting the posterior nasal nerve in rhinitis.

## **Rationale**

### **Radiofrequency Volumetric Tissue Reduction**

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

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. (5)

VivAer® Stylus 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.

The Nasal Obstruction Symptom Evaluation 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. (6) 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). (7)

**Table 1. NOSE Severity Classification**

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

NOSE: Nasal Obstruction Symptom Evaluation.

## Systematic Reviews

The efficacy of radiofrequency volumetric tissue reduction to treat nasal obstruction has been assessed through several systematic reviews. (8, 9, 10) 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. (8) 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, turbino-plasty, 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:  $76.16 \pm 6.39$ ; post-treatment:  $31.20 \pm 2.73$ ; 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. (9) 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 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. (10) 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 12-month and 24-month outcomes have been published. (11, 12)

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<sup>®</sup> Procedure for Treatment of Nasal Airway Obstruction: A Prospective, Multicenter Randomized Controlled Trial Comparing Vivaer to Sham Control [VATRAC]). (11) 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) and Silvers et al. (2024) have reported on the 12-month and 24-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. (12) 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. (13) 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  $\leq 25$  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.

**Table 2. Summary of Key RCT Characteristics**

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Silvers et al. (2021); VATRAC (11)	United States	16	August 2020 - December 2020	N=119 <sup>a</sup> Baseline patient characteristics: <ul style="list-style-type: none"> <li>• Age 18 to 85 years</li> <li>• The mean (SD) age of patients was 48.5 years (12.3) years</li> <li>• 66 (61%) were women.</li> <li>• All seeking treatment for nasal obstruction</li> </ul> Baseline NOSE scale score $\geq 55$ <ul style="list-style-type: none"> <li>• 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.</li> </ul> Nasal valve collapse as the primary or a significant contributor to the nasal obstruction	VivAer; n=77	Sham; n=40

				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.

<sup>a</sup> Of 119 participants, 1 patient in ViAer 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) <sup>1</sup>	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 (11)	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.

<sup>1</sup> Defined as a  $\geq 20\%$  reduction in NOSE-scale score or  $\geq 1$  reduction in clinical severity category.

Tables 4 and 5 summarize the limitations of the RCT.

**Table 4. Study Relevance Limitations**

Study	Population <sup>a</sup>	Inter-vention <sup>b</sup>	Comparator <sup>c</sup>	Outcomes <sup>d</sup>	Duration of Follow-up <sup>e</sup>
Silvers et al. (2021);	4. Only 10% participants in each		2. Lack of comparison to other	1. NOSE score is a subjective, patient-reported	1, 2: Follow-up limited

VATRAC (11)	group were from diverse racial/ethnic backgrounds		treatments for nasal obstruction (medications, nasal dilators and rhinoplasty)	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	to 3 months
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The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

<sup>a</sup> 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.

<sup>b</sup> 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.

<sup>c</sup> Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

<sup>d</sup> 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.

<sup>e</sup> Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

**Table 5. Study Design and Conduct Limitations**

<b>Study</b>	<b>Allocation<sup>a</sup></b>	<b>Blinding<sup>b</sup></b>	<b>Selective Reporting<sup>c</sup></b>	<b>Data Completeness<sup>d</sup></b>	<b>Power<sup>e</sup></b>	<b>Statistical<sup>f</sup></b>
Silvers et al. (2021);	5. Potential for participants to discern	1. Physicians were		6. Not intent-to-treat.		

VATRA C (11)	their treatment group due to the nature of the sham procedure	not blinded to treatment assignment		7. Lack of control for confounding medication or nasal dilator use		
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The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

<sup>a</sup> Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.

<sup>b</sup> Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

<sup>c</sup> Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.

<sup>d</sup> 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.

<sup>e</sup> Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.

<sup>f</sup> 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, the evidence includes systematic reviews and a randomized controlled trial 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 24 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 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
NCT05573919	VivAer: A Correlation Between Symptom Scores and Objective Findings	25	Oct. 2024
NCT04277507 <sup>a</sup>	A Prospective, Multicenter Study of the AERin Medical Vivaer® ARC Stylus for Nasal AirWAY Obstruction	122	Dec. 2024
NCT05099263 <sup>a</sup>	The Vivaer Procedure for Treatment of the Septal Swell Bodies for Airway Obstruction - A Prospective Open-Label Multicenter Study	70	Oct. 2025
NCT04549545 <sup>a</sup>	The Vivaer® Procedure for Treatment of Nasal Airway Obstruction - A Prospective, Multicenter Randomized Controlled Trial Comparing Vivaer to Sham Control	119	Oct. 2024
NCT04717791 <sup>a</sup>	Low Temperature Controlled Radiofrequency Intranasal Remodeling Treatment of the Nasal Valve Area. A Multicentric Long-term Evaluation	119	Oct. 2022 (last update on Jan. 2023)

NCT: national clinical trial.

<sup>a</sup> 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.

<b>CPT Codes</b>	30469
<b>HCPCS Codes</b>	None

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

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## Centers for Medicare & Medicaid Services

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### Policy History/Revision

Date	Description of Change
5/7/2026	New medical document. Radiofrequency volumetric tissue reduction for nasal obstruction due to internal nasal valve collapse is considered experimental, investigational and/or unproven.

## 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) (15)	●	●	●
Jacobowitz et al. (2019) (16)	●		●
Wu et al. (2021) (17)	●	●	●
Silvers et al. (2021) (12)	●		●
Yao et al. (2021) (18)	●	●	●
Han et al. (2022) (13)		●	●
Ephrat et al. (2021) (19)		●	●
Weissman et al. (2015) (20)			●