7.01.156	Radiofrequency Volumetric Tissue Reduction for Nasal Obstruction		
Original Policy Date:	May 1, 2025	**Effective Date:**	May 1, 2025
Section:	7.0 Surgery	**Page:**	Page 1 of 13

Policy Statement

I. Radiofrequency volumetric tissue reduction for nasal obstruction due to internal nasal valve collapse is considered **investigational**.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding

See the Codes table for details.

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.

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 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.

Additional Information
Not applicable.

Related Policies

- Absorbable Nasal Implant for Treatment of Nasal Valve Collapse
- Balloon Ostial Dilation for Treatment of Chronic and Recurrent Acute Rhinosinusitis
- Cryoablation, Radiofrequency Ablation, and Laser Ablation for Treatment of Chronic Rhinitis
- Functional Endoscopic Sinus Surgery for Chronic Rhinosinusitis
- Steroid-Eluting Sinus Stents and Implants

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

In April 2020, the VivAer® Stylus (Aerin Medical) was cleared for use in otorhinolaryngology (ENT) 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 (ENT) 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) currently reviewed in evidence review 7.01.168 (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

Evidence reviews 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 review.

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.

Review of Evidence

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 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 12-month and 24-month outcomes have been published.[13,14,]

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) and Slivers 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.[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.

Table 2. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Silvers et al (2021); VATRAC[12,]	US	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. 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.	VivAer; n=77	Sham; n=40

RCT: randomized controlled trial; SD: standard deviation.
[a] 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)[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	

NOSE: Nasal Obstruction Symptom Evaluation; CI: confidence interval; 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]	Intervention[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	1, 2: Follow-up limited to 3 months

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
				could still have severe symptoms	

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 to the nature of the sham procedure	1. Physicians were not blinded to treatment-arm assignment		6. Not intent-to-treat. 7. Lack of control for confounding medication or 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.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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,]

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 6.

Table 6. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05573919	VivAer: A Correlation Between Symptom Scores and Objective Findings	25	Oct 2024
NCT04277507[a]	A Prospective, Multicenter Study of the AERin Medical Vivaer® ARC Stylus for Nasal AirWAY Obstruction (AERWAY)	122	Dec 2024
NCT05099263[a]	The Vivaer Procedure for Treatment of the Septal Swell Bodies for Airway Obstruction - A Prospective Open-Label Multicenter Study (SWELL)	70	Oct 2025
NCT04549545[a]	The Vivaer® Procedure for Treatment of Nasal Airway Obstruction - A ProspecTive, Multicenter Randomized Controlled TriAl Comparing Vivaer to Sham Control (VATRAC)	119	Oct 2024
Unpublished			
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.

References

1. Lee DY, Won TB. Management of Nasal Valve Dysfunction. Clin Exp Otorhinolaryngol. Aug 2024; 17(3): 189-197. PMID 39111772
2. Wang Y, Bonaparte JP. Diagnosis and management of septal deviation and nasal valve collapse - a survey of Canadian otolaryngologists. J Otolaryngol Head Neck Surg. Dec 16 2019; 48(1): 71. PMID 31842991
3. American Academy of Otolaryngology-Head and Neck Surgery. Position Statement: Nasal Valve Repair, 2023; https://www.entnet.org/resource/position-statement-nasal-valve-repair/. Accessed December 19, 2024.

4. Food & Drug Administration. VivAer Stylus 510(k) Premarket Notification. 2020 (K200300). https://www.accessdata.fda.gov/cdrh_docs/pdf20/K200300.pdf. Accessed December 10, 2024.
5. Stolovitzky P, Sidle DM, Ow RA, et al. A prospective study for treatment of nasal valve collapse due to lateral wall insufficiency: Outcomes using a bioabsorbable implant. Laryngoscope. Nov 2018; 128(11): 2483-2489. PMID 29756407
6. Fraser L, Kelly G. An evidence-based approach to the management of the adult with nasal obstruction. Clin Otolaryngol. Apr 2009; 34(2): 151-5. PMID 19413614
7. Stewart MG, Witsell DL, Smith TL, et al. Development and validation of the Nasal Obstruction Symptom Evaluation (NOSE) scale. Otolaryngol Head Neck Surg. Feb 2004; 130(2): 157-63. PMID 14990910
8. Lipan MJ, Most SP. Development of a severity classification system for subjective nasal obstruction. JAMA Facial Plast Surg. 2013; 15(5): 358-61. PMID 23846399
9. Casale M, Moffa A, Giorgi L, et al. Could the use of a new novel bipolar radiofrequency device (Aerin) improve nasal valve collapse? A systematic review and meta-analysis. J Otolaryngol Head Neck Surg. Jun 22 2023; 52(1): 42. PMID 37349806
10. Han JK, Perkins J, Lerner D, et al. Comparison of nasal valve dysfunction treatment outcomes for temperature-controlled radiofrequency and functional rhinoplasty surgery: a systematic review and meta-analyses. Rhinology. Jun 01 2024; 62(3): 258-270. PMID 38217624
11. Kang YJ, Kim DH, Stybayeva G, et al. Effectiveness of Radiofrequency Device Treatment for Nasal Valve Collapse in Patients With Nasal Obstruction. Otolaryngol Head Neck Surg. Jan 2024; 170(1): 34-44. PMID 37702187
12. Silvers SL, Rosenthal JN, McDuffie CM, et al. Temperature-controlled radiofrequency device treatment of the nasal valve for nasal airway obstruction: A randomized controlled trial. Int Forum Allergy Rhinol. Dec 2021; 11(12): 1676-1684. PMID 34240571
13. Han JK, Silvers SL, Rosenthal JN, et al. Outcomes 12 Months After Temperature-Controlled Radiofrequency Device Treatment of the Nasal Valve for Patients With Nasal Airway Obstruction. JAMA Otolaryngol Head Neck Surg. Oct 01 2022; 148(10): 940-946. PMID 36048465
14. Silvers SL, McDuffie CM, Yen DM, et al. Two-year outcomes of radiofrequency device treatment of the nasal valve for nasal airway obstruction. Rhinology. Jun 01 2024; 62(3): 310-319. PMID 38217847
15. Brehmer D, Bodlaj R, Gerhards F. A prospective, non-randomized evaluation of a novel low energy radiofrequency treatment for nasal obstruction and snoring. Eur Arch Otorhinolaryngol. Apr 2019; 276(4): 1039-1047. PMID 30607559
16. Jacobowitz O, Driver M, Ephrat M. In-office treatment of nasal valve obstruction using a novel, bipolar radiofrequency device. Laryngoscope Investig Otolaryngol. Apr 2019; 4(2): 211-217. PMID 31024989
17. Wu Z, Krebs JP, Spector BM, et al. Regional Peak Mucosal Cooling Predicts Radiofrequency Treatment Outcomes of Nasal Valve Obstruction. Laryngoscope. Jun 2021; 131(6): E1760-E1769. PMID 33140876
18. Yao WC, Ow RA, and Barham HP (2021). Temperature-Controlled Radiofrequency Treatment of the Nasal Valve and Nasal Airway Obstruction: Early Results of a Prospective, Multi-Center Study. Journal of Otolaryngology and Rhinology ISSN: 2572-4193 J Otolaryngol Rhinol Abbrevation: jor DOI: 10.23937/2572-4193.1510105 Pub Date: July 10, 2021.
19. Ephrat M, Jacobowitz O, Driver M. Quality-of-life impact after in-office treatment of nasal valve obstruction with a radiofrequency device: 2-year results from a multicenter, prospective clinical trial. Int Forum Allergy Rhinol. Apr 2021; 11(4): 755-765. PMID 32810380
20. Weissman JD, Most SP. Radiofrequency thermotherapy vs bone-anchored suspension for treatment of lateral nasal wall insufficiency: a randomized clinical trial. JAMA Facial Plast Surg. 2015; 17(2): 84-9. PMID 25633257

Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	30469	Repair of nasal valve collapse with low energy, temperature-controlled (i.e., radiofrequency) subcutaneous/submucosal remodeling
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
05/01/2025	New policy.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	**AFTER** **Blue font: Verbiage Changes/Additions**
New Policy **Policy Statement:** N/A	**Radiofrequency Volumetric Tissue Reduction for Nasal Obstruction 7.01.156** **Policy Statement** Radiofrequency volumetric tissue reduction for nasal obstruction due to internal nasal valve collapse is considered **investigational**.