Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 9/1/24**
(See policy history boxes for previous effective dates)

Title: Low-Dose Radiofrequency for Nasal Valve Remodeling

Description/Background

The nasal passage or inside of the nose does not function as a true valve but is nevertheless sometimes referred to as the "nasal valve" in conjunction with explaining a variety of nasal symptoms presumably caused by weakening of the nasal cartilages ("nasal valve collapse") or obstruction by tissues in the nasal passages. A variety of appliances and surgical treatments designed to open the "nasal valve" and relieve these symptoms have been promoted.

Low-Dose Radiofrequency Ablation
Low-dose radiofrequency ablation (e.g. VivAer®, Aerin Medical Inc) is being promoted as a technique that can be used to alter the soft tissues in the nasal passage. The operator inserts the stylus into the nasal cavity, targeting the tissue (including lateral wall, inferior turbinate, and septal wall body) to be ablated and delivers a temperature controlled (60-75^0) low-dose radiofrequency energy. The intent is to improve airflow.

The VivAer System is comprised of the Aerin console and single-use VivAer Stylus Temperature-controlled bipolar radiofrequency energy is delivered to the stylus via the console. The device monitors the tissue temperature via 8 electrodes and automatically adjusts and delivers the radiofrequency current to maintain a therapeutic treatment temperature of approximately 60 °C.

Regulatory Status

In 2017, VivAer ARC Stylus (Aerin Medical, Inc) was cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process. The VivAer ARC Stylus is indicated for use in otorhinolaryngology surgery for the coagulation of soft tissue in the nasal airway, to treat

nasal obstruction by shrinking submucosal tissue, including cartilage in the internal nasal valve area. Product Code: GEI

Medical Policy Statement

Low-dose, temperature-controlled radiofrequency intranasal tissue remodeling as a treatment of nasal airway obstruction is considered experimental/investigational. The positive impact on clinical outcomes has not been definitively demonstrated.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

30469

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Repair of Nasal Valve Collapse with Low Energy, Temperature-Controlled Nasal Remodeling

VivAer is a novel treatment for nasal airway obstruction associated with nasal valve dysfunction. Although there are similar radiofrequency treatments, VivAer allows delivery of energy to multiple intranasal surfaces (as opposed to only the turbinate) during a treatment session. VivAer can also be used after nasal surgeries, which are a common cause of nasal valve collapse.

Jacobowitz et al (2019) assessed the safety and efficacy of in-office bipolar radiofrequency treatment for nasal valve obstruction via an industry sponsored report. The study design consisted of prospective, nonrandomized, multicenter case series. Individuals were clinically diagnosed with dynamic or static internal nasal valve obstruction as primary or significant contributor to obstruction and were required to have a positive response to nasal mechanical dilators or lateralization maneuvers. Patients with prior nasal valve surgery or other surgical nasal procedures within the past 12 months were excluded. Fifty individuals with severe or extreme obstruction (Nasal Obstruction Symptom Evaluation [NOSE] score of ≥ 60; [score of

80-100 – extreme; 55-75 - severe) were treated with bilateral radiofrequency (RF) in a single visit using Aerin Medical's Vivaer Stylus with a Model ORA-50S generator. At 26 weeks efficacy was determined using the NOSE score and participant satisfaction results.

Ephrat (2021) and other industry consultants reviewed the long term effects of VivAer RF for nasal valve dysfunction associated with airway obstruction. Thirty-nine adult individuals from an original cohort (n=49/50 were eligible) were evaluated at 6, 12, 18, and 24 months. Authors reported improvement from baseline in NOSE Scale score change demonstrated at 6 months (mean, 55.9; standard deviation [SD], 23.6; p< 0.0001) was maintained through 24 months (mean, 53.5; SD, 24.6; p< 0.0001). Responders consisted of 92.3% of participants at 6 months and 97.2 at 24 months and showed a ≥ 15 point improvement in their NOSE Scale score. Participant QOL indicated an improvement however, the questions were not in the form of a validated survey instrument and were not asked before the procedure; therefore, scores were not assigned to responses nor was there an analysis of change. Authors concluded that additional randomized, controlled trials are necessary to determine the relative true treatment effect versus potential placebo effects.

Jacobowitz et al (2022) discussed an industry funded study which evaluated long term outcomes of using temperature-controlled radiofrequency treatment (VivAer) to repair nasal valve collapse through 48 months. Of the 49 participants in the initial study, 39 agreed to follow-up through 24 months. Of these, 29 participants agreed to extended follow-up through 48 months. Patients underwent bilateral treatment with a Vivaer device, which maintains treatment temperature at 60 degrees C. The stylus tip was placed against mucosa underlying the lower edge of the upper lateral cartilage; 3 to 4 non-overlapping sites on the lateral nasal wall received treatment for 12 seconds. Compared with baseline, mean total NOSE scores significantly improved after treatment and were maintained throughout the 48 months. NOSE scores decreased from 81.0 (±9.9) at baseline to 21.6 (±18.6) after 6 months (73.3% change), 25.6 (±21.1) after 12 months (68.3% change), 29.3 (±26.6) after 18 months (63.8% change), 22.5 (±20.9) after 24 months (72.2% change), 32.3 (±21.4) after 36 months (60.1% change), and 25.7 (±19.1) after 48 months (68.3% change) (p < 0.001 for all comparisons). At 48 months, 67.9% of participants had severity scores in the "no problems" or "mild" categories, 21.4% were in the "moderate" and 10.7% were in the "severe" categories, and none in the "extreme" category, representing significant changes in the proportion of participants in each category (p < 0.001). This study was limited by its use of a single-arm design without randomized control, no control of medication usage, and significant participant attrition relative to the primary study.

Han (2022) and other industry funded consultants evaluated a prospective, multicenter, single-blinded, randomized clinical trial, with 108 patients in 16 centers in the US. Individuals were assigned to either a sham treatment group or treatment via a temperature-controlled radiofrequency device. Patients had a baseline NOSE Scale score of 55 or greater with nasal valve collapse as the primary or substantial contributor to nasal airway obstruction. After primary end point evaluation at 3 months, eligible individuals in the sham control arm crossed over to active treatment. Treatments were provided bilaterally at ≤ 4 nonoverlapping areas on the nasal mucosa at the junction of the upper and lower lateral cartilage on the lateral nasal wall. Treatment settings were temperature, 60 °C; power, 4 W; treatment time, 18 seconds; cooling time, 12 seconds. No repeat touch-up procedures were allowed. A total of 108 patients received active treatment (77 as index active treatment, 31 after crossover). The mean (SD) age of patients was 48.5 (12.3) years; 66 (61.1%) were women. The combined group of

individuals receiving active treatment had a mean baseline NOSE Scale score of 76.3 (95%CI, 73.6-79.1). At 12 months (n = 88), the responder rate was 89.8%(95%CI, 81.7%-94.5%). The NOSE Scale score improved from baseline (mean change, −44.9 [95%CI, −52.1 to −37.7]). No device/procedure-related serious adverse events were reported. Limitations of the study included a lack of medication dictation by the protocol which could have had some confounding effect on symptoms relief. Longer-term durability of effect will be needed to confirm the findings within larger cohorts that compare this technology to the current standard of care.

Yao et al (2021) complied the results of an industry sponsored, prospective, single-arm, multi-institutional study (NCT04277507) which included 12 otolaryngology centers across the United States. One-hundred twenty-two adults > 18 years suffering from nasal airway obstruction and with a baseline NOSE scale score ≥ 60 were treated in the nasal valve region with temperature-controlled radiofrequency energy and followed up at 3 months. Prior medications were continued throughout the study. All patients were treated bilaterally, with the exception of 1 unilateral case. Treatment was applied at 1-10 sites per side using the following default treatment settings: Temperature, 60 °C; power, 4 watts; treatment time, 18 seconds treatment time (could be varied from 10-20 seconds based on case-specific needs); cooling time, 12 seconds. Treatment sites were evaluated post-procedure via endoscopy. At the 3 month mark, NOSE scores were significantly improved relative to baseline, from 80.3 (± 12.6; range: 60-100) to 32.9 (± 24.2; range: 0-100) ($P < 0.001$). Subjective data regarding satisfaction was obtained and 91.6% of individuals reported a positive response to temperature-controlled radiofrequency treatment of nasal valve collapse. Limitation of this study included a small subject population, lack of a control arm, short follow-up times, and a lack of medication regimen. Larger, longer, random controlled trials which compare the technology to the standard of care are need to determine if the technology is better than current standards.

Yao (2023) reported that 91 participants reached 2 years for follow up. The mean baseline NOSE Scale score was 80.3 (95% CI, 78.1–82.6). The adjusted mean change in score at 2 years was -45.8 (95% CI, -53.5 to -38.1), $p < 0.001$; a 57.0% improvement. The 2-year responder rate was 90.1% (95% CI, 82.3%–94.7%). No serious adverse events with a relationship to the study device and/or procedure were reported. Level of evidence for the study was reported to be 2b, however a guide was not provided to explain the rating. The study was limited as it lacked a control arm, had a small population, and only contained treatment of the internal nasal valve. Reports indicated it was well tolerated and led to improvement in nasal airway obstruction (NAO) symptom severity through 2 years. However, authors concluded that further studies that incorporate more liberal application of temperature controlled radiofrequency (TCRF) to address multiple NAO contributors are needed to evaluate the full potential of TCRF-based treatment of NAO.

Silvers et al (2021) reviewed an industry sponsored prospective, multicenter, single-blinded, randomized controlled trial on the treatment of the nasal valve using a temperature-controlled radiofrequency device. Subjects were assigned to bilateral temperature-controlled RF treatment of the nasal valve (n = 77) or a sham procedure (n = 41), in which no RF energy was transferred to the device/treatment area. The device was applied to the mucosa over the lower lateral cartilage on the lateral nasal wall. The primary endpoint was responder rate at 3 months, defined as a ≥20% reduction in Nasal Obstruction Symptom Evaluation (NOSE)-scale score or ≥1 reduction in clinical severity category. At baseline, patients had a mean NOSE-scale score of 76.7 (95% confidence interval [CI], 73.8 to 79.5) and 78.8 (95% CI, 74.2 to 83.3)

(p = 0.424) in the active treatment and sham-control arms, respectively. At 3 months, the responder rate was significantly higher in the active treatment arm (88.3% [95% CI, 79.2%-93.7%] vs 42.5% [95% CI, 28.5%-57.8%]; p < 0.001). The active treatment arm had a significantly greater decrease in NOSE-scale score (mean, -42.3 [95% CI, -47.6 to -37.1] vs -16.8 [95% CI, -26.3 to -7.2]; p < 0.001). Three adverse events at least possibly related to the device and/or procedure were reported, and all resolved. This study does not show whether the proposed treatment effects last for longer than 3 months. The authors acknowledge that longer-term follow-up is needed to reveal the durability of the effect reported in this trial.

Brehmer et al (2019) reported no conflicts of interest and conducted a prospective, uncontrolled open-label bicenter trial to investigate the effect of using isolated intranasal remodeling of the internal nasal valve on measures of nasal breathing and snoring. Thirty-one individuals (17 females, 14 males) reporting snoring during sleep due to nasal obstruction or problems breathing through the nose were recruited for low energy radiofrequency remodeling treatment of the nasal valve. Thirty days after treatment, participants completed 2 questionnaires measuring perceived nasal obstruction and snoring (NOSE, Snore Outcomes Survey [SOS]). The participants' satisfaction with the radiofrequency ablative treatment was evaluated 90 days after the intervention using a 10-point Likert scale (1 = completely dissatisfied; 10 = very satisfied). All participants reported improvement in nasal breathing measured by NOSE score, sleep quality by SOS questionnaire, and quality of life as measured by EQ-5D and SNOT-22. The authors concluded that the radiofrequency remodeling treatment provides a durable and well-tolerated non-invasive treatment for those individuals suffering with congestion due to narrowness or collapse of the internal nasal valve. This study's findings are limited by the small size, lack of randomization, control group and comparator, and by the short follow-up period.

Casale et al (2023) conducted a meta-analysis of which only 4 studies (n=218) met the inclusion criteria and treated the nasal valve regions bilaterally with the Aerin Medical Vivaer System. Bias risk was assessed in areas including - confounding, selection of participants, classification of interventions, deviations from intended interventions, missing data, measurement of outcomes and selection of the reported results. The overall bias risk was found to be moderate in 3 of the 4 studies and serious in 1 of the 4 studies. However, authors found the device to be useful for treating nasal valve collapse, significantly improving subjective breathing symptom scores (NOSE) compared to preoperative status and control procedures. Authors also determined that the device was easy to use, effective and safe, and can be combined with other surgical procedures such as septoplasty and/or turbinate surgery. Recommendations were made that further large scale studies are needed to assess the role of this technology in reducing nasal valve collapse and to confirm the promising results.

Section Summary of Evidence: Temperature-Controlled Nasal Remodeling
Large, randomized, control group studies that are peer-reviewed are lacking. Available information is limited by lack of randomization, an absence of control groups, small numbers of participants, a lack of standardization, short follow-up periods, and trials fail to control or analyze potential differences in oral or topical mediations. Although 1 trial was blinded, perception of the presence or absence of local effects of radiofrequency treatment could have given participants an indication of their study group. The authors did not investigate whether participants were aware of the study group to which they were assigned. Small study groups may have prevented the designers from identifying placebo effects. Most information available is industry sponsored or has author conflicts of interest.

Summary of Evidence

For individuals with symptomatic nasal obstruction due to internal nasal valve collapse who are treated with low-energy, temperature-controlled nasal remodeling the evidence includes industry sponsored, non-randomized, small trials that are lacking standardization. No clinical practice guidelines or professional medical society position statements were identified that support the use of low energy radiofrequency intranasal remodeling treatment for the management of nasal valve collapse. Additionally, no studies were identified that compared low energy radiofrequency intranasal remodeling of the nasal valve to other forms of treatment for nasal obstruction due to nasal valve collapse and no studies were identified that demonstrated the long-term efficacy (greater than 4 years) of this procedure.

Ongoing and Unpublished Clinical Trials

Unpublished trials that might influence this review are listed in Table 1.

Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Estimated Completion Date
Unpublished			
NCT04549545	A Comparison of the Vivaer Procedure with Radiofrequency Energy to Sham Procedure for Treatment of Nasal Airway Obstruction	119	May 31, 2023

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

Government Regulations
National:

No National determination noted that discusses the use of low-dose RF for the treatment of nasal valve remodeling.

Medicare fee schedule noted for 30469.

Local:

No Local determination noted that discusses the use of low-dose RF for the treatment of nasal valve remodeling.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Absorbable Nasal Implants for the Treatment of Nasal Valve Collapse
Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis
Steroid-Eluting Sinus Implants

References

1. Aerin Medical. VivAer: Discover the non-invasive procedure for nasal obstruction. 2023. https://vivaer.com/hcp/. Accessed February 16, 2023.
2. 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*. 2019 Apr; 276(4):1039-1047. doi: 10.1007/s00405-018-05270-y. Epub 2019 Jan 3. PMID: 30607559.
3. 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." Journal of Otolaryngology - Head & Neck Surgery. 2023; 52:42.
4. 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*. 2021; 11: 755– 765.
5. 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*. 2022; E1-E8.
6. Jacobowitz O, Ehmer D, Lanier B, et al. Long-term outcomes following repair of nasal valve collapse with temperature-controlled radiofrequency treatment for patients with nasal obstruction. *Int Forum Allergy Rhinol*. 2022;1-5.
7. Jacobowitz, O., Driver, M. and Ephrat, M. In-office treatment of nasal valve obstruction using a novel, bipolar radiofrequency device. *Laryngoscope Investigative Otolaryngology*. 2019; 4:211-217.
8. Silvers SL, Rosenthal JN, et al. Temperature-controlled radiofrequency device treatment of the nasal valve for nasal airway obstruction: A randomized controlled trial. *Int Forum Allergy Rhinol*. 2021 Dec;11(12):1676-1684. doi: 10.1002/alr.22861. Epub 2021 Jul 9. PMID: 34240571.
9. United States Food & Drug Administration. 510(k): VivAer ARC Stylus. (K172529). 2017. https://www.accessdata.fda.gov/cdrh_docs/pdf17/K172529.pdf. Accessed April 10, 2024.
10. Yao, WC., Ow, RA., Barham, HP. 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, (2021) 7:105
11. Yao, WC., Pritikin J., Sillers, MJ., et al. "Two-year outcomes of temperature-controlled radiofrequency device treatment of the nasal valve for patients with nasal airway obstruction." Laryngoscope Investigative Otolaryngology. 2023;8:808–815.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 4/9/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
9/1/23	6/13/23		• Joint policy established (slp) • Vendor managed: N/A • Replacing IMP: RFA (VivAer) for Tx of Nasal Sinus Airway Obstruction
9/1/24	6/11/24		• Routine maintenance (slp) • Vendor Managed: N/A

Next Review Date: 2nd Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: LOW-DOSE RADIOFREQUENCY FOR NASAL VALVE REMODELING

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.