Anthem

Medical Policy

Subject: Nasal Valve Repair
Document #: SURG.00079
Status: Reviewed

Publish Date: 09/27/2023
Last Review Date: 08/10/2023

Description/Scope

This document addresses the following procedures or products used to treat nasal obstruction.

1. Nasal valve suspension for the treatment of nasal valve collapse;
2. Implantation of an absorbable nasal implant for the treatment of nasal airway obstruction caused by nasal wall collapse; and
3. Low-dose radiofrequency intranasal tissue remodeling (for example, the VivAer® procedure [Aerin Medical Inc., Sunnyvale, CA]) for the treatment of nasal airway obstruction.

Note: Please see the following related documents for additional information:

- CG-SURG-18 Septoplasty
- CG-SURG-87 Nasal Surgery for the Treatment of Obstructive Sleep Apnea and Snoring
- SURG.00129 Oral, Pharyngeal and Maxillofacial Surgical Treatment for Obstructive Sleep Apnea or Snoring
- SURG.00157 Minimally Invasive Treatment of the Posterior Nasal Nerve to Treat Rhinitis

Position Statement

Investigational and Not Medically Necessary:

Nasal valve suspension as a surgical technique for the repair of nasal valve collapse is considered**investigational and not medically necessary.**

Low-dose radiofrequency intranasal tissue remodeling as a treatment of nasal airway obstruction is considered**investigational and not medically necessary**.

Use of an absorbable nasal implant to repair collapsed nasal wall tissue is considered**investigational and not medically necessary**.

Rationale

Nasal obstruction has been defined as a sensation of insufficient airflow through the nose. Symptoms associated with chronic nasal obstruction may include nasal congestion, stuffiness, headache, fatigue, sleep disturbance, daytime sleepiness, snoring, and a decline in health-related quality of life (QoL). The internal nasal valve is the narrowest cross-sectional area within the nasal airway and is most impacted by changes in dimension due to anatomic variation or surgical intervention (Schuman 2019).

Nasal Valve Suspension

Nasal valve suspension is a surgical nasal valve repair that attaches nasal valve tissues to the orbital rim or lateral suture(s) suspension to perinasal structures.

The first report on nasal valve suspension as a simplified technique for nasal valve repair was published by Paniello (1996). This report, based on the experience with 12 individuals, concluded that nasal valve suspension was effective at providing symptomatic relief of airway obstruction. A more in-depth report (Friedman, 2003) discusses the experience of the procedure (with slight modifications) in over 100 individuals. The results indicate that the vast majority of individuals undergoing nasal valve suspension surgery had a self-reported improvement in airway symptoms. The study did, however, have several limitations. First, the follow-up for most individuals in the study was less than 1 year; long-term results are not available. Second, the basis for the improvement as reported by individuals is purely subjective and no objective measures were used to demonstrate effectiveness. Lastly, the authors indicated that the precise indicators for this procedure are unclear and require further study.

Friedman (2004) reported on 52 individuals thought to have nasal valve obstruction that were treated with a modified nasal valve suspension technique and had a mean follow-up of 12.6 months. Eighty-four percent showed improvement in a QoL outcome measure (Sino-Nasal Outcome Test) and 94.2% had postoperative increases in cross sectional area as measured by acoustic rhinometry. However, the QoL tool used did not include either nasal stuffiness or nasal obstruction as one of the questions but instead asked about such sensations as alertness, energy levels and general well-being. The authors acknowledge that many alternative surgical techniques are available to correct nasal valve obstruction, and that the long-term effectiveness of this suspension procedure remains to be evaluated. They conclude: “Long term studies are needed to assess the performance of this corrective technique” and “Follow up periods beyond 30 months will help determine the natural course of the suspended valve and the possibility of its release.” To date, no well-designed additional studies comparing nasal valve suspension with other surgical alternatives have been published. There are inadequate data to make determinations about whether nasal valve suspension results in improved outcomes in individuals with airway obstruction.

Nasal Implant for the Treatment of Nasal Airway Obstruction

In June 2016, the Latera™ Absorbable Nasal Implant (Spirox™ Inc., Menlo Park, CA) was cleared by the FDA for “Supporting nasal upper and lower lateral cartilage.” This implantable device is proposed to assist in the surgical correction of collapsed nasal wall tissue, possibly improving nasal obstruction. The implant consists of copolymer materials and is designed to be absorbed by the body within approximately 18 months following implantation. The Latera system also includes a disposable delivery device that enables minimally invasive placement of the implant. The Latera implant and accessory delivery device have the same fundamental scientific technology and intended indications for use as the predicate device, the INEX Absorbable Nasal Implant and accessory delivery tool that received FDA 510(k) clearance on December 4, 2015 (K152958). Studies have been limited by small numbers of participants, lack of randomization, short term outcomes data and study design not robust enough to demonstrate the safety and efficacy of this implant for any indication (San Nicoló, 2017, 2018; Stolovitzky, 2018).

Low-dose Radiofrequency Intranasal Tissue Remodeling as a Treatment of Nasal Airway Obstruction

Researchers have also been exploring the use of low-dose radiofrequency (RF) energy as a means to reshape nasal tissue to treat nasal valve collapse.

The VivAer procedure is a non-invasive, office-based procedure that uses low-dose RF energy to alter the soft tissue of the nose.

In 2017, the VivAer ARC Stylus received 510(k) clearance to be used:

> In otorhinolaryngology (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. (FDA, 2017).

Brehmer et al. (2019) conducted a nonrandomized prospective study evaluating the safety and efficacy of low-dose RF remodeling treatment of narrowed nasal valves and to measure changes in the symptoms of snoring and nasal obstruction. The study included 31 participants presenting with symptoms of nasal obstruction and snoring. Researchers used the VivAer low energy RF system to remodel the nasal sidewall in order to improve airflow. Thirty days after treatment, participants completed two questionnaires measuring perceived nasal obstruction and snoring (NOSE, Snore Outcomes Survey [SOS]). The participants' satisfaction with the RF 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 RF 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.

Jacobowitz and colleagues (2019) reported 6-month results of an industry-sponsored study of minimally invasive office treatment for nasal airway obstruction using a bipolar, temperature-controlled RF device to reshape the nasal valve. The 50 participants in the study all had severe or extreme obstruction at baseline. None of the participants had previous surgery to the nasal valve in the preceding 12 months. Participants continued to use oral and topical treatments for nasal obstruction during the study. A positive response to the Cottle or modified Cottle maneuver showed that, for each participant, the nasal valve was the primary contributor to nasal obstruction. Symptoms self-reported using the average NOSE Scale score (Nasal congestion, nasal blockage, trouble breathing, trouble sleeping, and inability to get enough air during exercise) decreased by 69% at the 6-month assessment. No procedure- or device-related serious adverse events occurred. Edema, soreness, and crusting resolved by 1 month and participants reported high satisfaction with the procedure. The authors assert that objective measures of airflow resistance do not correspond to self-reported airway obstruction. Lack of a randomized control group makes it impossible to evaluate how much of the subjectively reported outcomes could have been due to a placebo effect. The findings of this study are further limited by the small study size, lack of standardization and analysis of oral and topical medication use, and the short follow-up period.

Ephrat 2021 and another industry consultant conducted a prospective, nonrandomized, multicenter, extended follow-up study of the same subjects who had participated in and completed the Jacobowitz et al (2019) trial (discussed above). In this study, the authors sought to determine whether the results achieved at 6 months would be sustained for 24 months and to assess the impact of the treatment on measures of individuals' quality of life. Participants in this follow-up study provided self-administered evaluations of the NOSE and QoL measures at 12, 18, and 24 months post procedure. Participants were given the option to complete the follow-up assessments via in-person clinic visits, by telephone, or by mailed response. Forty-nine of the 50 subjects in the original 6-month trial were eligible for this follow-up study. Thirty-nine individuals from 8 sites in the 6-month trial chose to enroll in the follow-up study. Three participants enrolled after the window for the 12-month visit was closed and were only evaluated for 18 months. All 39 subjects had evaluations at 18 months and 36 of the 39 completed the 24-month follow-up. The researchers reported the clinically significant 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 the 24-month follow-up period (mean, 53.5; SD, 24.6; $p<0.0001$). Respondents (≥ 15-point improvement) consisted of 92.3% of participants at 6 months and 97.2% at 24 months. Responses to the QoL questions also showed improvement in participant QoL. Other than the short duration, this trial shares the limitations of the Jacobowitz study cited above. In addition, it is limited by loss of 22% of the original cohort, raising the possibility of retention bias. Ephrat and colleagues acknowledged that in order to distinguish the relative true treatment effect from placebo effects, "it will be necessary to confirm the results of this study in additional patients as part of a planned randomized, controlled trial".

Silvers and colleagues (2021) reported the results of an industry-sponsored prospective, multicenter, single-blinded, randomized controlled trial that assessed the safety and efficacy of a temperature-controlled RF device for the treatment of nasal valve collapse in subjects with nasal airway obstruction. Participants were assigned to one of two arms: (A) bilateral temperature-controlled RF treatment of the nasal valve (n=77) or (B) a sham procedure (n=41). For the sham treatment, the participant was prepared as for surgery, anesthetized, and the RF device was inserted into the nostrils, but no RF energy was transferred to the target tissue. The device was applied to the mucosa over the lower lateral cartilage of the lateral nasal wall. The main endpoint was responder rate at 3 months, defined as a 20% or greater reduction in NOSE scale score or ≥ 1 reduction in clinical severity category. At baseline, participants demonstrated 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 appreciably 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 demonstrated a significantly greater improvement 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 were considered at least possibly related to the device and/or procedure. In the active treatment arm, 1 participant experienced a vasovagal reaction, and another had intermittent nasal bleeding with mucus, both of which resolved. In the sham-control arm, 1 individual had intermittent headache, which also resolved. Results for this study of 118 individuals 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 blinded, perception of the presence or absence of local effects of RF treatment could have given participants an indication of their study group. The authors did not investigate whether participants were aware of their study group. 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.

Han and colleagues (2022) published results of a prospective, multicenter, single-blinded, randomized clinical trial which reported safety and efficacy of temperature-controlled RF device on nasal airway obstruction through 12 months of follow-up. Enrolment criteria included a baseline NOSE Scale score of 55 or greater with nasal valve collapse as the primary or substantial contributor to the score. The primary endpoint was a 20% or greater reduction in NOSE Scale score or 1 or greater reduction in NOSE Scale clinical severity category. Eligible study participants were randomly assigned in a 2:1 fashion to temperature-controlled RF device treatment of the nasal valve or a sham control procedure (with no RF energy). A total of 117 participants were randomized and included in the final analysis; 77 received active treatment and 40 were in the sham control arm. Following evaluation of the primary endpoint at 3 months, eligible participants in the sham control arm crossed over to active treatment (n=31; 76% 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, 73.6-79.1). 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%-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. Further investigation is warranted.

Jacobowitz and colleagues (2022) published outcomes of an extended 48-month follow-up study. The initial study (described in more detail above; Jacobowitz, 2019) was a prospective, single-arm multicenter study enrolling individuals with chronic severe nasal obstruction with nasal valve collapse identified as the primary cause of obstruction. Bilateral treatment with temperature-controlled RF was administered to all study participants. Of the 49 individuals in the initial study (Jacobowitz, 2019), 29 agreed to the current study with extended follow-up through 48 months. NOSE scores decreased from 81.0 (± 9.9) at baseline to 25.7 (± 19.1) after 48 months follow-up (68.3% change; $p<0.001$). A total of 96.4% (27 of 28) of participants were considered responders (defined as a ≥ 15-point improvement on the NOSE score scale). This study's results are to be interpreted with caution due to the limitations described in the primary study: lack of randomized comparison group, use of subjective measures, no control of medication usage and the limited sample size which was further hampered by significant loss to follow-up at 48 months. Further investigation is warranted.

At the time of this review, no clinical practice guidelines and professional medical society position statements were identified that support the use of low energy RF intranasal remodeling treatment for the management of nasal valve collapse. The peer-reviewed studies have been limited by lack of randomization, lack of control groups, small numbers of participants, short duration, and lack of control for confounding medication use. Additionally, no studies were identified that compared low energy RF 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 2 years) of this procedure.

Background/Overview

Nasal airway obstruction can impact an individual's life by affecting routine daily activities such as breathing and sleeping. Treatment options for nasal airway obstruction are contingent upon the underlying cause of the symptoms.

Nasal valve collapse is a common cause of nasal airway obstruction. Nasal valve suspension refers to a surgical approach for nasal valve repair that involves suspension of the valve to the orbital rim. During the procedure, an anchored suture is first attached to the orbital rim and then a suture is passed through the collapsed valve. The suspension suture is then returned to the anchor site at the orbital rim and tied, resulting in a repaired nasal valve that presumably allows for less obstructed airflow. Modifications to this procedure or other types of suspensions, such as those using sutures tunneled within the facial soft tissue to an infraorbital incision on each side of the nose, have also been reported.

The Latera implant has been proposed as a method to support the lateral nasal cartilage in individuals with severe nasal obstruction. The device can be implanted unilaterally or bilaterally, using local anesthesia. After implantation, a fibrous capsule forms around the device and tissue continues to encapsulate the implant. Gradually, the implant degrades and is absorbed so that by 24 months following implantation, collagen replaces the implant.

Researchers are exploring the use of low-dose RF energy as a means to reshape nasal tissue to treat nasal valve collapse. VivAer is intended to improve airflow for individuals with nasal valve collapse. During this procedure, the clinician inserts the tip of the VivAer ARC Stylus into an individual's nostril to deliver low RF energy to the target tissue of the nasal airway. The low-dose RF energy creates a coagulation lesion. As the lesion heals, the tissue shrinks and stiffens to diminish widen the airway, reduce airflow resistance, and improve the inhaled flow of air through the nose. The Aerin™ System automatically modifies the power output to maintain target temperature for therapeutic benefit while sparing the mucosa and surrounding tissue. The device consists of a console and two styluses, one for nasal airway obstruction and one for chronic rhinitis (FDA, 2017).

Definitions

Acoustic rhinometry: A technique that measures nasal patency; for example, the degree of openness of the nose.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. 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.

When services are Investigational and Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT	
30468	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)
30469	Repair of nasal valve collapse with low energy, temperature-controlled (ie, radiofrequency) subcutaneous/submucosal remodeling
30999	Unlisted procedure, nose [when specified as nasal valve suspension by any method]

ICD-10 Diagnosis	
	All diagnoses

References

Peer Reviewed Publications:

1. 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; 276(4):1039-1047.
2. Capone RB, Sykes JM. The effect of rhytidectomy on the nasal valve. Arch Facial Plast Surg. 2005; 7(1):45-50.
3. 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(4):755-765.
4. Fischer J, Gubisch W. Nasal valves-importance and surgical procedures. Facial Plast Surg. 2006; 22(4):266-280.
5. Friedman M, Ibrahim H, Lee G, Joseph NJ. A simplified technique for airway correction of the nasal valve area. Otolaryngol Head Neck Surg. 2004; 131(4):519-524.
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7. 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 1; 148(10):940-946.
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12. Paniello RC. Nasal valve suspension. An effective treatment for nasal valve collapse. Arch Otolaryngol Head Neck Surg. 1996; 122(12):1342-1346.
13. Rhee JS, Poetker DM, Smith TL, et al. Nasal valve surgery improves disease-specific quality of life. Laryngoscope. 2005; 115(3):437-440.
14. San Nicoló M, Stelter K, Sadick H, et al. Absorbable implant to treat nasal valve collapse. Facial Plast Surg. 2017; 33(2):233-240.
15. San Nicoló M, Stelter K, Sadick H, et al. A 2-year follow-up study of an absorbable implant to treat nasal valve collapse. Facial Plast Surg. 2018; 34(5):545-550.
16. 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. 2021; 11(12):1676-1684.
17. 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. 2018; 128(11):2483-2489.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS). Position statement: Nasal valve repair. March 22, 2023. Available at: https://www.entnet.org/resource/position-statement-nasal-valve-repair/. Accessed on July 13, 2023.
2. U. S. States Food and Drug Administration (FDA). 510(k) 510(k) Premarket Approval (PMA) Letter. Latera Absorbable Nasal Implant. No. K161191. June 23, 2016. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf16/K161191.pdf. Accessed on July 20, 2023.
3. U. S. States Food and Drug Administration (FDA). 510(k) Premarket Approval (PMA) Letter. VivAer ARC Stylus. No. K172529. December 05, 2017. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf17/K172529.pdf. Accessed on July 20, 2023.

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Document History

Status	Date	Action
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale and References sections.
	12/28/2022	Updated Coding section with 01/01/2023 CPT changes; added 30469 (30999 no longer applicable for radiofrequency tissue remodeling).
Revised	08/11/2022	MPTAC review. Title changed to “Nasal Valve Repair” Expanded scope of document to address an absorbable nasal implant and low-dose radiofrequency intranasal tissue remodeling for the treatment of nasal airway obstruction. Revised the Position Statement and updated the Description, Rationale, Background/Overview, References, Index and History sections. Content related to the absorbable nasal implant (Latera) moved from CG-SURG-87 to this document. Updated Coding section; added CPT code 30468 previously addressed in CG-SURG-87.
Reviewed	11/11/2021	MPTAC review. Updated review date and history sections.
Reviewed	11/05/2020	MPTAC review. Updated review date and history sections.
Reviewed	11/07/2019	MPTAC review. Updated review date and history sections.
Reviewed	01/24/2019	MPTAC review. Updated review date and History sections, Added note to the Description/Scope and History section referring the user to CG-SURG-87 Nasal Surgery for the Treatment of Obstructive Sleep Apnea and Snoring for information on the Latera nasal implant.
Reviewed	03/22/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated review date, Definitions and History sections.
Reviewed	05/04/2017	MPTAC review. Updated review date and History section.
Reviewed	05/05/2016	MPTAC review. Updated review date, Definitions and History sections. Removed ICD-9 codes from Coding section.
Reviewed	05/07/2015	MPTAC review. Updated review date and History sections.
Reviewed	05/15/2014	MPTAC review. Updated review date, References and History sections.
Reviewed	05/09/2013	MPTAC review. Updated review date, References and History sections.
Reviewed	05/10/2012	MPTAC review. Updated review date, References and History sections.
Reviewed	05/19/2011	MPTAC review. Updated review date, References and History sections.
Reviewed	05/13/2010	MPTAC review. Updated review date, References and History sections.
Reviewed	05/21/2009	MPTAC review. No change to position statement.
Reviewed	05/15/2008	MPTAC review. No change to position statement. References were updated
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Reviewed	05/17/2007	MPTAC review. References updated.
Reviewed	06/08/2006	MPTAC review. Updated Description, Background and References.

Revised	09/22/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.			No document
WellPoint Health Networks, Inc.	09/23/2004	3.03.25	Nasal Valve Suspension

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Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

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 eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.