

MEDICAL POLICY – 7.01.597

Radiofrequency Volumetric Tissue Reduction for Nasal Obstruction

BCBSA Ref. Policy: 7.01.156

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Replaces: N/A

RELATED MEDICAL POLICIES:

7.01.134 Steroid-Eluting Sinus Stents and Implants


7.01.163 Absorbable Nasal Implant for Treatment of Nasal Valve Collapse

7.01.168 Cryoablation, Radiofrequency Ablation, and Laser Ablation for Treatment of Chronic Rhinitis

7.01.559 Sinus Surgery in Adults

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Introduction

Nasal obstruction, which makes it difficult to breathe through your nose, can be caused by conditions such as nasal swell bodies (NSB) or nasal valve collapse (NVC). These conditions hinder airflow when either the mucous membrane of the nasal cavity is swollen or enlarged (NSB); or when the cartilage supporting the narrow parts of the nasal airway becomes weak or damaged (NVC). Mild cases can sometimes be managed with conservative treatment options, however, more severe cases may require surgery to help manually open the airway.

Radiofrequency has been proposed as an alternative to surgery. The technique is less invasive than surgery and aims to improve airflow by using the radiofrequency energy to shrink tissue. This type of treatment is investigational (unproven). There is not enough scientific evidence to show that radiofrequency energy leads to improved health results.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Investigational
Radiofrequency volumetric tissue reduction	Radiofrequency volumetric tissue reduction for nasal obstruction due to internal nasal valve collapse is considered investigational. (e.g., VivAer Stylus)
Nasal swell body reduction	Radiofrequency ablation or cryoablation for nasal swell body reduction for the treatment of nasal obstruction is considered investigational.

Coding

Code	Description
CPT	
30117	Excision or destruction (e.g., laser), intranasal lesion; internal approach (use to report: nasal swell body reduction)
30469	Repair of nasal valve collapse with low energy, temperature-controlled (i.e., radiofrequency) subcutaneous/submucosal remodeling (use to report: VivAer Nasal Airway Remodeling)

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Related Information

Definition of Terms

Nasal swell body (aka septal swell body) is an enlarged region of the anterior nasal septum located superior to the inferior turbinate and anterior to the middle turbinate. It is composed of septal cartilage, bone, and a thick mucosal lining. The nasal swell body is thought to interfere with nasal airflow and humidification due to its proximity to the internal nasal valve. The nasal



swell body may be associated with allergic rhinitis and chronic rhinosinusitis and septal deviation.

Evidence Review

Description

Nasal obstruction is defined clinically as an individual 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.

Background

Nasal Obstruction

Nasal obstruction is defined clinically as an individual symptom that presents as a sensation of reduced or insufficient airflow through the nose. Commonly, individuals will feel that they have nasal congestion or stuffiness. In adults, clinicians focus on the evaluation of important features of the history provided by the individual such as whether symptoms are unilateral or bilateral. Unilateral symptoms are more suggestive of structural causes of nasal obstruction. A history of trauma or previous nasal surgery, especially septoplasty or rhinoplasty, is also important. Diurnal or seasonal variation in symptoms is associated with allergic conditions.

Nasal valve collapse (NVC) is a readily identifiable cause of nasal obstruction.^{1,2} The internal nasal valve is the narrowest part of the nasal passage and is supported by the upper lateral nasal

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

Etiology

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

Pathophysiology

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

Physical Examination

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

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

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

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

Treatment

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

Radiofrequency Volumetric Tissue Reduction

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

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.

For individuals with nasal swell bodies who have undergone various methods of reduction or destruction such as radiofrequency ablation, coblation, surgery, laser, and micro-debridement, the evidence includes retrospective studies, a systematic review, an open-label, single arm multicenter center, and a prospective RCT. Improvement in nasal symptoms including nasal obstruction was seen with all forms of treatment. These results are promising; however, well designed controlled studies are lacking due to small sample size and need for longer-term follow-up. Additional randomized controlled studies with long-term results are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in [Table 1](#).



Table 1. 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.

Practice Guidelines and Position Statements

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

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or the 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

Medicare National Coverage

There is no national coverage determination.

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.



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History

Date	Comments
05/01/25	New policy, approved April 8, 2025. Add to Surgery section. Radiofrequency volumetric tissue reduction for nasal obstruction due to internal nasal valve collapse is considered investigational. Also, added policy statement that radiofrequency ablation or cryoablation for nasal swell body reduction for the treatment of nasal obstruction is considered investigational. References added. Added HCPCS codes 30117, 30469.

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