

Minimally Invasive Treatment of Nasal Valve Collapse

Policy # 00657

Original Effective Date: 01/23/2019

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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Ablation and Surgical Treatment of Chronic Rhinitis is addressed separately in medical policy 00723.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers insertion of an absorbable lateral nasal implant for the treatment of symptomatic nasal valve collapse to be **investigational**.*

Based on review of available data, the Company considers ablative techniques (e.g. radiofrequency ablation) that create submucosal lesions in the nostril and/or lateral nasal wall for the treatment of symptomatic nasal valve collapse to be **investigational**.*

Based on review of available data, the Company considers all other minimally invasive techniques, including those that do not involve cartilage grafting and/or complex suture techniques (e.g. lateral crural turn in flap), for the treatment of symptomatic nasal valve collapse to be **investigational**.*

Background/Overview

Nasal Obstruction

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

Nasal valve collapse (NVC) is a readily identifiable cause of nasal obstruction. 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

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in patients with NVC, severe symptoms and significant anatomical distortion typically require surgical cartilage graft procedures.

Etiology

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

Pathophysiology

The internal nasal valve, bordered by the collapsible soft tissue between the upper and lower lateral cartilages, the anterior end of the inferior turbinate, and the nasal septum, forms the narrowest part of the nasal airway. During inspiration, the lateral wall cartilage is dynamic and draws inward toward the septum and the internal nasal valve narrows providing protection to the upper airways. The angle at the junction between the septum and upper lateral cartilage is normally 10° to 15° in white populations. Given that the internal nasal valve accounts for at least half of the nasal airway resistance; even minor further narrowing of this area can lead to symptomatic obstruction for a patient. Damaged or weakened lateral nasal cartilage will further decrease airway capacity of the internal nasal valve area, increasing airflow resistance and symptoms of congestion.

Physical Examination

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

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

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

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

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Treatment

Treatment of symptomatic nasal valve collapse includes the use of non-surgical interventions such as the adhesive strips applied externally across the nose (applying the principle of the Cottle maneuver) or use of nasal dilators, cones, or other devices that support the lateral nasal wall internally (applying the principle of the modified Cottle maneuver).

Severe cases of obstruction resulting from nasal valve deformities are treated with surgical grafting to widen and/or strengthen the valve. Common materials include cartilaginous autografts and allografts, as well as permanent synthetic grafts. Cartilage grafts are most commonly harvested from the patient's nasal septum or ear.

Nasal Implants

The placement of an absorbable implant to support the lateral nasal cartilages has been proposed as an alternative to more invasive grafting procedures in patients with severe nasal obstruction.

Ablative Techniques

The use of ablative technologies, such as radiofrequency ablation, has been proposed as a treatment alternative to grafting procedures in patients with severe nasal obstruction. Typically, several submucosal lesions are created in the nasal ala and/or nasal side wall. It is believed that as these lesions heal over time, there is resultant remodeling of the lateral nasal wall and the generation of scar tissue that adds rigidity and prevents collapse.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In May 2016, LATERA^{®‡} (Entellus Medical/Stryker ENT, previously Spirox) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. LATERA^{®‡} is the only commercially available absorbable nasal implant for the treatment of nasal valve collapse. It is a class II device and regulatory details are summarized in Table 1.

Table 1. Absorbable Nasal Implant Cleared by the U.S. Food and Drug Administration

Product	Manufacturer	Date Cleared	510(k) No.	Product Code	Indication
LATERA ^{®‡} absorbable nasal implant	Spirox (part of Stryker)	2016	K161191	NHB	Supporting nasal upper and lower lateral cartilage

At this time, several different devices are used to create submucosal lesions in the nasal ala and/or nasal sidewall using ablative techniques. Examples include the Aquamantys by Medtronic and

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Vivaer by Aerin Medical. The Aquamantys system has been used for many years and creates bipolar cautery lesions.

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). 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 medical policy 00723 (Ablation and Surgical 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/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Description

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 placement of an absorbable implant to support the lateral nasal cartilages has been proposed as an alternative to more invasive grafting procedures in patients with severe nasal obstruction. The concept is that the implant may provide support to the lateral nasal wall prior to resorption and then stiffen the wall with scarring as it is resorbed.

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.

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Summary of Evidence

For individuals with symptomatic nasal obstruction due to internal nasal valve collapse (NVC) who receive an absorbable lateral nasal valve implant, the evidence includes 1 randomized controlled trial (RCT) with a 24-month uncontrolled follow-up phase and 3 nonrandomized prospective, single-cohort studies. Relevant outcomes are symptoms, change in disease status, treatment-related morbidity, functional outcomes, and quality of life (QOL). Overall, improvements in nasal obstruction score have been demonstrated in study reports. Follow-up at 3 months in the RCT showed a statistically significant improvement in response with the implant compared to the sham group, although over half of the control group were also considered responders. Twenty-four month follow-up has been reported in the 3 multicenter cohort studies and the uncontrolled crossover phase of the RCT. Loss to follow-up was high, although sensitivity analysis with a worst-case scenario supported an improvement in symptoms at 24 months. As reported, adverse events appeared to be mild in severity and self-limiting, but still common. In the larger cohorts, device retrievals or extrusions occurred in 4% of patients. The need for device retrievals appears to occur early in the course of follow-up (1 month); suggesting technical experience limitations on the part of the operator or inappropriate patient selection. No studies have been identified that compared insertion of an implant with inferior turbinate reduction and/or septoplasty. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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. Due to the limitations in the published studies, the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

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

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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."

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 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
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	70	Oct 2025

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	Prospective Open-Label Multicenter Study (SWELL)		
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
<i>Unpublished</i>			
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.

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Policy History

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01/10/2019	Medical Policy Committee review
01/23/2019	Medical Policy Implementation Committee approval. New policy.
01/03/2020	Medical Policy Committee review
01/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/07/2021	Medical Policy Committee review
01/13/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/24/2021	Coding update
01/06/2022	Medical Policy Committee review
01/12/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/05/2022	Medical Policy Committee review
05/11/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/07/2022	Coding update
01/05/2023	Medical Policy Committee review

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01/11/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

01/04/2024 Medical Policy Committee review

01/10/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

01/02/2025 Medical Policy Committee review

01/08/2025 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

04/03/2025 Medical Policy Committee review

04/09/2025 Medical Policy Implementation Committee approval. Added a reference Note for medical policy 00723 at the beginning of the policy. Additional content added to the body of the policy, including the References section. Coverage eligibility unchanged.

Next Scheduled Review Date: 04/2026

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	30117, 30465, 30468, 30469, 30999
HCPCS	C1889
ICD-10 Diagnosis	J34.2, J34.89, J34.9

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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: 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.