LOUISIANA BLUE

Minimally Invasive Treatment of Nasal Valve Collapse

Policy # 00657
Original Effective Date: 01/23/2019
Current Effective Date: 02/10/2025

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.

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 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.

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.

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 result 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 Vivaer by Aerin Medical. The Aquamantys system has been used for many years and creates bipolar cautery lesions. Vivaer was designed specifically for the treatment of nasal valve collapse and received Premarket approval from the FDA via the 501(k) pathway in December 2017.

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.

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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.

These devices work by inserting a probe into the subcutaneous tissues of the nasa ala and/or lateral nasal wall and ablating the surrounding tissue. As the tissue heals, there is theoretically scarring and remodeling that may lead to stiffening of the lateral wall and resistance to collapse. To date, no studies have been published on this technology. FDA approval of Vivaer was obtained through submission of results on 50 patients by Aerin Medical, and data has been presented in abstract form at one national otolaryngology meeting. The company (Aerin Medical) also states on their website that over 1,000 patients have been treated with their device. However, there is no published data on the use of submucosal ablative technologies in the treatment of nasal valve collapse. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUMMARY OF EVIDENCE
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. Lastly, the use of minimally invasive ablative technologies to treat nasal valve collapse is a new technique that does not yet have sufficient published data to support its use.

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 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 2010, the American Academy of Otolaryngology-Head Neck Surgery released a clinical consensus statement on the diagnosis and management of nasal valve compromise. No more recent guidelines were identified. Table 2 summarizes the key consensus statements relevant to this review. The statement also indicated that nasal endoscopy and nasal photography were both deemed useful but not routinely required.

Table 2. Consensus Agreement: Diagnosis and Treatment of Nasal Valve Compromise

Item	Statement	Level of Consensus
Definition	Nasal valve compromise is a distinct clinical entity separate from other anatomic reasons for nasal obstruction	Agreement/strong agreement
History and physical	Main symptom of nasal valve compromise is decreased airflow as reported by the patient	Strong agreement
	Anterior rhinoscopy can be adequate for an intranasal evaluation of the nasal valve, weak or malformed nasal cartilages	Agreement/strong agreement
	Inspiratory collapse of the lateral nasal wall or alar rim is consistent with nasal valve compromise	Agreement/strong agreement
	Increased nasal obstruction associated with deep inspiration is consistent with nasal valve compromise	Agreement/strong agreement
Adjunctive tests	Criterion standard test to diagnose nasal valve compromise exists	Strong disagreement
Outcome measures	Various patient-reported outcomes (eg, visual analog scales, satisfaction measures, quality of life scales) are valid indicators of successful intervention	General agreement

Management	Nasal strips, stents, or cones can be used to treat some patients	Strong agreement
	A surgical procedure that is intended to support the lateral nasal wall/alar rim is a distinct entity from procedures that correct a deviated nasal septum or hypertrophied turbinate	Strong agreement

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
Unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
Unpublished			
NCT03793218	A Comparison of Alar Batten Graft to the Latera Nasal Implant for the Treatment of Nasal Valve Collapse	30	Nov 2021 (status unknown, last update Jan 2019)

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

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15. https://www.ncbi.nlm.nih.gov/pubmed/?term=jacobowitz+radiofrequency+nasal+valve
16. https://www.ncbi.nlm.nih.gov/pubmed/30607559

Policy History

Original Effective Date: 01/23/2019
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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
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.

Next Scheduled Review Date: 01/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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CPT is a registered trademark of the American Medical Association.

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

*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.

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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.