Minimally Invasive Treatment of Nasal Valve Collapse

Policy # 00657
Original Effective Date: 01/23/2019
Current Effective Date: 02/08/2021

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 the 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 nonsurgical 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®‡ (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. FDA product code: NHB

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

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

Rationale/Source

Nasal valve collapse 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 nasal valve collapse 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.

For individuals with symptomatic nasal obstruction due to internal nasal valve collapse who receive an absorbable lateral nasal valve implant, the evidence includes 1 RCT and 2 nonrandomized prospective, single-cohort studies. Relevant outcomes are symptoms, change in disease status, treatment-related morbidity, functional outcomes, and quality of life. Overall, improvements in the Nasal Obstruction Symptom Evaluation score have been demonstrated in the 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. The duration of outcomes reporting is less than the duration of absorption of the device (18 months) and the purported completion of the tissue remodeling phase (24 months). It is noted that a follow-up to 24-months in this trial is ongoing. Longer follow-up in the prospective cohort studies is available, with 24-month follow-up reported in the smaller (n=30) of the cohort studies. However, a clinically significant difference may not be consistently apparent in small study populations. Some patients meeting the positive responder criteria still reported severe symptoms,

and 13% of patients required an additional procedure. As reported, adverse events appeared to be mild in severity and self-limiting, but still appeared common. At the 12-month follow-up in the larger (n=160) cohort, device retrievals occurred in 5% 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. Follow-up to 24-months in this cohort is needed. Lastly, the use of minimally invasive ablative technologies to treat nasal valve collapse is a new technique that does not yet have any published data to support its use. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Practice Guidelines and Position Statements

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. 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 NVC

Item	Statement	Level of Consensus
Definition	NVC is a distinct clinical entity separate from other anatomic reasons for nasal obstruction	Agreement/strong agreement
History and physical	Main symptom of NVC 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 NVC	Agreement/strong agreement

	Increased nasal obstruction associated with deep inspiration is consistent with NVC	Agreement/strong agreement
Adjunctive tests	Criterion standard test to diagnose NVC 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

NVC: nasal valve compromise.

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			
NCT03400787[a]	Latera®‡ Absorbable Nasal Implant vs Sham Control for Lateral Nasal Valve Collapse	150	Feb 2021

NCT03793218	A Comparison of Alar Batten Graft to the Latera Nasal Implant for the Treatment of Nasal Valve Collapse	30	Nov 2021
Unpublished			
NCT02952313	Spirox Latera™‡ Implant Support of Lateral Nasal Wall Cartilage (LATERAL-OR) Study	113	Aug 2019

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

References

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13. San Nicolo M, Stelter K, Sadick H, et al. Absorbable Implant to Treat Nasal Valve Collapse. Facial Plast Surg. Apr 2017; 33(2): 233-240. PMID 28388804
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Policy History

Original Effective Date: 01/23/2019
Current Effective Date: 02/08/2021

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

Next Scheduled Review Date: 01/2022

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, 30999 Code added eff 1/1/2021: 30468
HCPCS	C1889 Code deleted eff 1/1/2021: C9749
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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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.