Medical Coverage Policy | Absorbable Nasal Implant for Treatment of Nasal Valve Collapse



EFFECTIVE DATE: 01 | 01 | 2019

POLICY LAST REVIEWED: 10 | 15 | 2025

OVERVIEW

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.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

The insertion of an absorbable lateral nasal implant for the treatment of symptomatic nasal valve collapse is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

The insertion of an absorbable lateral nasal implant for the treatment of symptomatic nasal valve collapse is not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Medicare Advantage Plans and Commercial Products

Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND

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 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.

Regulatory Status

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.^{2,} LATERA® is the only commercially available absorbable nasal implant for the treatment of nasal valve collapse.

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 a nasal obstruction 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. 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 appeared 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. Twenty-four month follow-up from an additional 137 participants in the randomized crossover trial has been recently completed but has not been published. 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.

CODING

Medicare Advantage Plans and Commercial Products

The following CPT code(s) is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

30468 Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, January/December 2025 Provider Update, February 2024 Provider Update, January 2023 Provider Update, December 2021 Provider Update, December 2020

REFERENCES

- 1. Howard BK, Rohrich RJ. Understanding the nasal airway: principles and practice. Plast Reconstr Surg. Mar 2002; 109(3): 1128-46; quiz 1145-6. PMID 11884847
- 2. Rhee JS, Weaver EM, Park SS, et al. Clinical consensus statement: Diagnosis and management of nasal valve compromise. Otolaryngol Head Neck Surg. Jul 2010; 143(1): 48-59. PMID 20620619
- 3. Fraser L, Kelly G. An evidence-based approach to the management of the adult with nasal obstruction. Clin Otolaryngol. Apr 2009; 34(2): 151-5. PMID 19413614
- 4. Stryker. Latera. http://www.spiroxmed.com/latera. Accessed August 12, 2024.
- Stewart MG, Witsell DL, Smith TL, et al. Development and validation of the Nasal Obstruction Symptom Evaluation (NOSE) scale. Otolaryngol Head Neck Surg. Feb 2004; 130(2): 157-63. PMID 14990910
- 6. Lipan MJ, Most SP. Development of a severity classification system for subjective nasal obstruction. JAMA Facial Plast Surg. 2013; 15(5): 358-61. PMID 23846399
- 7. Stolovitzky P, Senior B, Ow RA, et al. Assessment of bioabsorbable implant treatment for nasal valve collapse compared to a sham group: a randomized control trial. Int Forum Allergy Rhinol. Aug 2019; 9(8): 850-856. PMID 31226238
- 8. Bikhazi N, Ow RA, O'Malley EM, et al. Long-Term Follow-up from the Treatment and Crossover Arms of a Randomized Controlled Trial of an Absorbable Nasal Implant for Dynamic Nasal Valve Collapse. Facial Plast Surg. Oct 2022; 38(5): 495-503. PMID 34965603
- 9. Olson MD, Barrera JE. A comparison of an absorbable nasal implant versus functional rhinoplasty for nasal obstruction. Am J Otolaryngol. 2021; 42(6): 103118. PMID 34171694
- 10. 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. Nov 2018; 128(11): 2483-2489. PMID 29756407
- 11. Sidle DM, Stolovitzky P, Ow RA, et al. Twelve-month outcomes of a bioabsorbable implant for in-office treatment of dynamic nasal valve collapse. Laryngoscope. May 2020; 130(5): 1132-1137. PMID 31254279

- 12. Sidle DM, Stolovitzky P, O'Malley EM, et al. Bioabsorbable Implant for Treatment of Nasal Valve Collapse with or without Concomitant Procedures. Facial Plast Surg. Oct 2021; 37(5): 673-680. PMID 33853139
- 13. San Nicoló 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
- 14. 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. Oct 2018; 34(5): 545-550. PMID 30227454
- 15. American Academy of Otolaryngology-Head and Neck Surgery. Position Statement: Nasal Valve Repair, 2023; https://www.entnet.org/resource/position-statement-nasal-valve-repair/. Accessed August 12, 2024.

----- CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.