Corporate Medical Policy

Absorbable Nasal Implant for Treatment of Nasal Valve Collapse

File Name: absorbable_nasal_implant_for_treatment_of_nasal_valve_collapse
Origination: 1/2019
Last Review: 8/2024

Description of Procedure or Service

Nasal Valve Collapse
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. Individuals with nasal valve collapse may be treated with nonsurgical interventions 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 individuals 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.

Nasal Obstruction
Nasal obstruction is defined clinically as a 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 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.

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 weak or displaced upper lateral cartilage(s). Prior nasal surgery, nasal trauma, congenital anomaly, and Mohs surgery or other skin cancer operations 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 degrees to 15 degrees 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 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 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 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.

Measuring Nasal Obstruction
Stewart et al (2004) proposed the Nasal Obstruction Symptom Evaluation as a validated sinonasal-specific health status instrument that is used to assess the impact of nasal obstruction on the quality of life of affected persons. It is a 5-item questionnaire on breathing problems: nasal congestion or stuffiness, nasal blockage or obstruction, trouble breathing through the nose, trouble sleeping, and inability to get enough air through the nose during exercise or exertion. The responses are made on a Likert-type scale ranging from 0 (not a problem) to 4 (severe problem). The range of raw scores is 0 to 20. The score is then scaled to a potential total score of 0 to 100 by multiplying the raw score by 5. A score of 100 means the worst possible problem with nasal obstruction.

The Nasal Obstruction Symptom Evaluation scale-based nasal obstruction severity classification system is proposed to classify individuals for clinical management as well as to better define study populations and describe treatment or intervention responses.

Nasal Obstruction Symptom Evaluation Severity Classification

Severity Class	**NOSE Score Range**
Mild	5-25
Moderate	30-50
Severe	55-75
Extreme	80-100

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 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.

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 individuals 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 through the 510(k) process. LATERA® is the only commercially available absorbable nasal implant for treatment of nasal valve collapse. It is a class II device indicated for supporting nasal upper and lower lateral cartilage.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

The insertion of an absorbable lateral nasal implant for the treatment of symptomatic nasal valve collapse is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Absorbable Nasal Implant for Treatment of Nasal Valve Collapse is covered

Not applicable.

When Absorbable Nasal Implant for Treatment of Nasal Valve Collapse is not covered

The insertion of an absorbable lateral nasal implant for the treatment of symptomatic nasal valve collapse is considered investigational.

Policy Guidelines

For individuals with symptomatic nasal obstruction due to internal nasal valve collapse who receive an absorbable lateral nasal valve implant, the evidence includes one randomized controlled trial with a 24-month uncontrolled follow-up phase and three 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

three 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. 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 30468, 30999

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Howard BK, Rohrich RJ. Understanding the nasal airway: principles and practice. Plast Reconstr Surg. Mar 2002;109(3):1128-1146; quiz 1145-1146. PMID 11884847

Lipan MJ, Most SP. Development of a severity classification system for subjective nasal obstruction. JAMA Facial Plast Surg. Sep-Oct 2013;15(5):358-361. PMID 23846399

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.163, 10/10/2018

Specialty Matched Consultant Advisory Panel 8/2019

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):157-163. PMID 14990910

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.163, 10/17/2019

Specialty Matched Consultant Advisory Panel 8/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.163, 10/15/2020

Specialty Matched Consultant Advisory Panel 8/2021

Specialty Matched Consultant Advisory Panel 8/2022

Specialty Matched Consultant Advisory Panel – 8/2023

Medical Director Review 8/2023

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

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. Dec 29 2021. PMID 34965603

Specialty Matched Consultant Advisory Panel – 8/2024

Medical Director Review 8/2024

Policy Implementation/Update Information

1/29/19	New policy developed. The insertion of an absorbable lateral nasal implant for the treatment of symptomatic nasal valve collapse is considered investigational. Policy noticed 1/29/2019 for effective date 4/1/2019. (sk)
11/12/19	Specialty Matched Consultant Advisory Panel review 8/21/2019. (sk)
12/8/20	References added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 8/19/2020. (sk)
12/31/20	New code 30468 added to Billing/Coding section for effective date 1/1/2021. Noted that code C9749 is deleted effective 12/31/2020. (sk)
12/14/21	Specialty Matched Consultant Advisory Panel review 8/18/2021. (sk)
2/7/23	Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 8/19/2022. (sk)
8/29/23	References updated. Specialty Matched Consultant Advisory Panel review 8/2023. Medical Director review 8/2023. (rp)
9/18/24	References updated. Specialty Matched Consultant Advisory Panel review 8/2024. Medical Director review 8/2024. (ldh)