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MEDICAL POLICY – 7.01.163

Absorbable Nasal Implant for Treatment of Nasal Valve Collapse

BCBSA Ref. Policy:	7.01.163	
Effective Date:	Jan. 1, 2025	RELATED MEDICAL POLICIES:
Last Revised:	Dec. 9, 2024	None
Replaces:	N/A	

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EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Cartilage is one of the body's connective tissues. It's softer than bone yet strong enough to provide structure. Different types of cartilage are inside the nose, including cartilage that makes up the side (lateral) walls of the nose. In some cases, taking a breath in through the nose can cause the lateral cartilage to flex or collapse, causing a blockage. There are proven ways of treating blockages caused by problems with the lateral wall cartilage, including surgery to graft cartilage in this area. A newer technique to try to treat breathing problems caused by lateral wall collapse calls for implanting a device inside the nose. Over many months, the implant naturally dissolves. During the time that it takes for the implant to dissolve, the body naturally forms scar tissue where the implant is placed. Scar tissue is more fibrous than regular tissue. It's thought that natural scar tissue can then serve as permanent support for the lateral wall. These types of absorbable nasal implants are investigational (unproven). More and longer studies are needed to determine if this technique is safe and effective.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Procedure	Investigational
Insertion of an absorbable lateral nasal implant	**The insertion of an absorbable lateral nasal implant (e.g., Latera) for the treatment of symptomatic nasal valve collapse is considered investigational.**

Coding

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

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

N/A

Evidence Review

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. Individuals 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 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.

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, 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 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 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.[1]

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 one to two 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 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 individual 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 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.

Summary of Evidence

For individuals with symptomatic nasal obstruction due to internal NVC who receive an absorbable lateral nasal valve implant, the evidence includes one randomized controlled trial (RCT) with a 24-month uncontrolled follow-up phase and three nonrandomized prospective, single-cohort studies. The relevant outcomes are symptoms, change in disease status, treatment-related morbidity, functional outcomes, and quality of life. Overall, improvements in the nasal obstruction 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 reported in the three multicenter cohort studies. 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 individuals. The need for device retrievals appears to occur early in the course of follow-up (one 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.

Ongoing and Unpublished Clinical Trials

A search of **ClinicalTrials.gov** in August 2024 did not identify any trials that would likely influence this review.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Guidelines or position statements will be considered for inclusion 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 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.[15] No specific recommendations were made for nasal implants. The AAO-HNS recognizes surgical repair of the nasal valve as a distinct surgical procedure that can alleviate nasal obstruction symptoms for patients who have nasal valve collapse and are suitable candidates for this intervention.

In 2010, the AAO-HNS released a clinical consensus statement on the diagnosis and management of nasal valve compromise.[2] No more recent guidelines were identified. **Table 1** summarizes the key consensus statements relevant to this policy. The statement also indicated that nasal endoscopy and nasal photography were both deemed useful but not routinely required.

Table 1. 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

Item	Statement	Level of Consensus
	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 (e.g., 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

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In May 2016, LATERA (Entellus Medical/Stryker ENT, previously Spirox) was cleared for marketing by the US 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. It is a class II device and regulatory details are summarized in **Table 2**.

Table 2. Absorbable Nasal Implant Cleared by the US 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

References

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History

Date	Comments
04/01/19	New policy, approved March 12, 2019, effective July 4, 2019. Add to Surgery section. A literature search was conducted through September 2018. The policy statement is investigational. Added CPT 30999.
01/01/20	Interim Review, approved December 10, 2019. Policy updated with literature review through August 2019, references added. Policy statement unchanged.
11/01/20	Coding update. Added HCPCS code C9749.
01/01/21	Annual Review, approved December 1, 2020. Coding update, added CPT code 30498 (new code effective 1/1/21) Policy updated with literature review through September 2, 2020; no references added. Policy statement unchanged.
01/01/22	Annual Review, approved December 2, 2021. Policy updated with literature review through August 18, 2021; reference added. Policy statement unchanged. Removed CPT code 30999 and HCPCS code C9749.
01/01/23	Annual Review, approved December 12, 2022. Policy updated with literature review through August 31, 2022; reference added. Policy statement unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization. Removed new code date from CPT code 30468.
01/01/23	Annual Review, approved December 11, 2023. Policy updated with literature review through September 5, 2023; no references added. Policy statement unchanged.
01/01/25	Annual Review, approved December 9, 2024. Policy updated with literature review through August 12, 2024; Guidelines updated. Policy statement unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.