

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



**EFFECTIVE DATE:** 1/01/2019

**POLICY LAST UPDATED:** 11/16/2022

### 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 considered 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 considered 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.

For individuals with symptomatic nasal obstruction due to internal 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 code(s) is not covered/not medically necessary:

**C9749** Repair of nasal vestibular lateral wall stenosis with implant(s) implant placement (Code Deleted 01/01/2021)

**30468** Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s) (New Code Effective 01/01/2021)

Note: Physician work for the nasal implant placement would be billed with the unlisted CPT code 30999 (Unlisted procedure, nose). While some providers may use CPT 30465 (Repair of nasal vestibular stenosis [eg, spreader grafting, lateral nasal wall reconstruction]) for this service; the unlisted code is most appropriate.

## **RELATED POLICIES**

Not applicable

## **PUBLISHED**

Provider Update, January 2023

Provider Update, December 2021

Provider Update, December 2020

Provider Update, January 2019

## **REFERENCES:**

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