Absorbable Nasal Implant for Treatment of Nasal Valve Collapse

“Notification”

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Origination: 1/2019

Last CAP Review: N/A

Next CAP Review: 8/2019

Last Review: 1/2019

Policy Effective April 1, 2019

Description of Procedure or Service

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.

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 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, 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
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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.

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.

Lipan and Most (2013) developed a Nasal Obstruction Symptom Evaluation scale-based nasal obstruction severity classification system. The system is proposed as a means to classify patients for clinical management as well as to better define study populations and describe treatment or intervention responses (see Table 1).

<table>
<thead>
<tr>
<th>Severity Class</th>
<th>NOSE Score Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>5-25</td>
</tr>
<tr>
<td>Moderate</td>
<td>30-50</td>
</tr>
<tr>
<td>Severe</td>
<td>55-75</td>
</tr>
<tr>
<td>Extreme</td>
<td>80-100</td>
</tr>
</tbody>
</table>

NOSE: Nasal Obstruction Symptom Evaluation

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.
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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® (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 two nonrandomized
prospective, single-cohort industry-sponsored studies. Relevant outcomes are symptoms, change
in disease status, treatment-related morbidity, functional outcomes, and quality of life. Both
studies are limited by the heterogeneity of the populations evaluated. Specifically, the types and
rates of prior nasal procedures were not well described, nor was the clinical rationale for
alternative or adjunctive procedural interventions. Overall, improvements in the Nasal
Obstruction Symptom Evaluation score have been demonstrated in the study reports. 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 many
patients reported some loss of improvement at one year. Data elements are missing or difficult to
determine for important outcomes. As reported, adverse events appeared to be mild in severity
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and self-limiting, but still appeared common. Device retrievals are incompletely characterized. They occurred in 10% of patients in the primary cohort study, and it is not known, e.g., whether a device retrieval occurred in a patient who had only a unilateral nasal implant. 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. The duration of outcomes reporting is less than the duration of absorption of the device (18 months) and the purported completion of tissue remodeling phase (24 months). Randomized controlled trials with a sham control are feasible and should be performed. The evidence is insufficient to determine the effects of the technology on health outcomes.

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: 30999, C9749

Some providers may use 30465 for this service; however the unlisted code is appropriate.

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


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)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.