Absorbable Nasal Implant for Treatment of Nasal Valve Collapse

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**

<table>
<thead>
<tr>
<th>Insertion of an absorbable lateral nasal implant</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The insertion of an absorbable lateral nasal implant (eg, Latera®) for the treatment of symptomatic nasal valve collapse is considered investigational.</td>
</tr>
</tbody>
</table>

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>Unlisted procedure, nose</td>
</tr>
<tr>
<td>30999</td>
<td>Unlisted procedure, nose</td>
</tr>
</tbody>
</table>

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Related Information

N/A

Evidence Review

**Description**

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.

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 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° 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 1. NOSE Severity Classification

<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 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.

**Summary of Evidence**

For individuals with symptomatic nasal obstruction due to internal nasal valve collapse who receive an absorbable lateral nasal valve implant, the evidence includes 2 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 1 year. Data elements are missing or difficult to determine for important outcomes. As reported, adverse events appeared to be mild in severity 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, eg, 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.

**Ongoing and Unpublished Clinical Trials**

A search of ClinicalTrials.gov in September 2018 identified an ongoing trial that might influence this review is listed in Table 2.

### Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT03400787*</td>
<td>Latera® Absorbable Nasal Implant vs. Sham Control for Lateral Nasal Valve Collapse</td>
<td>150</td>
<td>Feb 2020</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

*Denotes industry-sponsored or cosponsored trial.
Practice Guidelines and Position Statements

*American Academy of Otolaryngology - Head Neck Surgery*

The American Academy of Otolaryngology - Head Neck Surgery (2010) released a clinical consensus statement on the diagnosis and management of nasal valve compromise.\(^4\) Table 3 summarizes the key consensus statements relevant to this review. The statement also indicated that nasal endoscopy and nasal photography were both deemed useful but not routinely required.

### Table 3. Consensus Agreement: Diagnosis and Treatment of NVC

<table>
<thead>
<tr>
<th>Item</th>
<th>Statement</th>
<th>Level of Consensus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition</td>
<td>NVC is a distinct clinical entity separate from other anatomic reasons for nasal obstruction</td>
<td>Agreement/strong agreement</td>
</tr>
<tr>
<td>History and physical</td>
<td>Main symptom of NVC is decreased airflow as reported by the patient</td>
<td>Strong agreement</td>
</tr>
<tr>
<td></td>
<td>Anterior rhinoscopy can be adequate for an intranasal evaluation of the nasal valve, weak or malformed nasal cartilages</td>
<td>Agreement/strong agreement</td>
</tr>
<tr>
<td></td>
<td>Inspiratory collapse of the lateral nasal wall or alar rim is consistent with NVC</td>
<td>Agreement/strong agreement</td>
</tr>
<tr>
<td></td>
<td>Increased nasal obstruction associated with deep inspiration is consistent with NVC</td>
<td>Agreement/strong agreement</td>
</tr>
<tr>
<td>Adjunctive tests</td>
<td>Criterion standard test to diagnose NVC exists</td>
<td>Strong disagreement</td>
</tr>
<tr>
<td>Outcome measures</td>
<td>Various patient-reported outcomes (eg, visual analog scales, satisfaction measures, quality of life scales) are valid indicators of successful intervention</td>
<td>General agreement</td>
</tr>
<tr>
<td>Management</td>
<td>Nasal strips, stents, or cones can be used to treat some patients</td>
<td>Strong agreement</td>
</tr>
<tr>
<td></td>
<td>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</td>
<td>Strong agreement</td>
</tr>
</tbody>
</table>

NVC: nasal valve compromise.
Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In May 2016, LATERA® (Spirox) was cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process (Food and Drug Administration product code: NHB). LATERA® is the only commercially available absorbable nasal implant for treatment of nasal valve collapse. It is a class II device and regulatory details are summarized in Table 4.

Table 4. Absorbable Nasal Implant Cleared by the Food and Drug Administration

<table>
<thead>
<tr>
<th>Product</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>LATERA® absorbable nasal implant</td>
<td>Spirox (part of Stryker)</td>
<td>2016</td>
<td>K161191</td>
<td>Supporting nasal upper and lower lateral cartilage</td>
</tr>
</tbody>
</table>

References

History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/01/19</td>
<td>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.</td>
</tr>
</tbody>
</table>

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Toll free 855-332-4535, Fax 425-918-5992, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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800-722-1471 (TTY: 800-842-5357)

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