MEDICAL POLICY – 7.01.163
Absorbable Nasal Implant for Treatment of Nasal Valve Collapse

BCBSA Ref. Policy: 7.01.163
Effective Date: Jan. 1, 2022
Last Revised: Dec. 2, 2021
Replaces: N/A
RELATED MEDICAL POLICIES: None

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

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

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Insertion of an absorbable lateral nasal implant</strong></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>Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s) (new code effective 1/1/21)</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, 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.\(^1\)

**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 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 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 (NVC) who receive an absorbable lateral nasal valve implant, the evidence includes one RCT and two 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 patients. 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. 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.

**Ongoing and Unpublished Clinical Trials**

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 1.
Table 1. 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>NCT03793218</td>
<td>A Comparison of Alar Batten Graft to the Latera Nasal Implant for the Treatment of Nasal Valve Collapse</td>
<td>30</td>
<td>Nov 2021</td>
</tr>
<tr>
<td><strong>Unpublished</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>137</td>
<td>Dec 2020</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

*Denotes industry-sponsored or cosponsored trial.

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 U.S. professional society, an international society with U.S. 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 2010, the American Academy of Otolaryngology - Head Neck Surgery released a clinical consensus statement on the diagnosis and management of nasal valve compromise. Table 2 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 2. 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® ((Entellus Medical/Stryker ENT, previously Spirox) was cleared for marketing by the U.S. 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 3.
Table 3. Absorbable Nasal Implant Cleared by the U.S. Food and Drug Administration

<table>
<thead>
<tr>
<th>Product</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
<th>Product Code</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>NHB</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>
<tr>
<td>11/01/20</td>
<td>Coding update. Added HCPCS code C9749.</td>
</tr>
</tbody>
</table>

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ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 800-722-1471 (TTY: 711).


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