Absorbable Nasal Implant for Treatment of Nasal Valve Collapse

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.

OBJECTIVE

The objective of this review is to determine whether the insertion of an absorbable lateral nasal implant for the treatment of symptomatic nasal valve collapse improves the net health outcome.

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POLICY STATEMENT

The insertion of an absorbable lateral nasal implant for the treatment of symptomatic nasal valve collapse is considered investigational.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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 the treatment of nasal valve collapse. It is a class II device and regulatory details are summarized in Table 1.

Table 1. 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>

RATIONALE

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 randomized controlled trial (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 (QOL). Overall, improvements in the Nasal Obstruction Symptom Evaluation (NOSE) 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. The duration of outcomes reporting is less than the duration of absorption of the device (18 months) and the purported completion of the tissue remodeling phase (24 months). It is noted that a follow-up to 24-months in this trial is ongoing. Longer follow-up in the prospective cohort studies is available, with 24-month follow-up reported in the smaller (n=30) of the cohort studies. 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 13% of patients required an additional procedure. As reported, adverse events appeared to be mild in severity and self-limiting, but still appeared common. At the 12 month follow-up in the larger (n=160) cohort, device retrievals occurred in 5% 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. Follow-up to 24-months in this cohort is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

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. Table 2 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 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>Adjunctive tests</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>Adjunctive tests</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>Adjunctive tests</td>
<td>Increased nasal obstruction associated with deep inspiration is consistent with NVC</td>
<td>Agreement/strong agreement</td>
</tr>
<tr>
<td>Outcome measures</td>
<td>Criterion standard test to diagnose NVC exists</td>
<td>Strong disagreement</td>
</tr>
<tr>
<td>Management</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>Management</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.

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**REFERENCES**


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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2018</td>
<td>New policy</td>
<td>The policy was created to evaluate a single commercially available absorbable nasal implant product for treatment of internal nasal valve collapse. A literature search was conducted through September 4, 2018. The policy statement is investigational.</td>
</tr>
<tr>
<td>December 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through August 12, 2019, references added. Policy statement unchanged</td>
</tr>
</tbody>
</table>

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