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

BCBSA Ref. Policy: 7.01.163
Effective Date: Jan. 1, 2020
Last Revised: Dec. 10, 2019
Replaces: N/A

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

Procedure | Investigational
---|---
Insertion of an absorbable lateral nasal implant | The insertion of an absorbable lateral nasal implant (eg, Latera®) for the treatment of symptomatic nasal valve collapse is considered investigational.

Coding

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

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

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 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.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in September 2019 identified an ongoing trial that might influence this review is 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>Ongoing</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. 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>Item</td>
<td>Statement</td>
<td>Level of Consensus</td>
</tr>
<tr>
<td>-----------------</td>
<td>---------------------------------------------------------------------------</td>
<td>--------------------</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 3.

**Table 3. 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>

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review
and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2020 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4555, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
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)

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Arabic):

يجب أن تكون هذه المعلومات ميزة في التعليمات التي تُستخدم في غرف الاتصال، وتجدر معرفة أن هناك تأثير إيجابي في هذه التعليمات. مثلاً، قد تتأثر النتائج الإيجابية في خدماتك معنا من خلال معرفتك بمعلوماتك الشخصية. للإبلاغ في غرف الاتصال، يمكن أن تحدث تحريات في السرية. تغطي هذه المعلومات والخدمات بشكل عام دون تكلفة إضافية. اتصل بـ 800-722-1471 (TTY: 800-842-5357) للحصول على مزيد من المعلومات.

Chinese (Chinese):

本通知有重要的讯息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知可能有重要日期。您可能需要在截止日期之前採取行動。以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):

Questo avviso contiene informazioni importanti. Questo avviso può contenere informazioni importanti sulla tua domanda o copertura attraverso Premera Blue Cross. Potrebbero esserci date chiave in questo avviso. Potrebbe essere necessario un tuo intervento entro una scadenza determinata per consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto di ottenere queste informazioni e assistenza nella tua lingua gratuitamente.

Chiamale 800-722-1471 (TTY: 800-842-5357).
Talvez seja necessário que você tome providências dentro de um ou mais períodos individuais do Premera Blue Cross. Poderão existir datas importantes neste aviso.

Informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross podem conter informações sobre datas que são importantes para você.

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

(Thailand):

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

(Thai):

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

(Portuguese):

Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

(Polski):

To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Polski wnosienia lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utraty polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie prawo do bezpłatnej informacji we własnym języku. Zadzwonite pod 800-722-1471 (TTY: 800-842-5357).

(Rusский):

Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

(Іспанські):

Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud de cobertura a través de Premera Blue Cross. Es posible que haya fechas claves en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

(Український):

Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про ваше звернення щодо страхового покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дозвоніться за номером телефону 800-722-1471 (TTY: 800-842-5357).