For dates of service January 1, 2021, and after, refer to LCD L33428/Article A56658.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Absorbable Nasal Implant for Treatment of Nasal Valve Collapse

Policy #:	721	Latest Review Date:	October 2020
Category:	Medical	Policy Grade:	B

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

For dates of service January 1, 2021, and after, refer to LCD L33248/Article A56658.

For dates of service prior to January 1, 2021:

Blue Advantage will treat use of **absorbable nasal implant for symptomatic nasal valve collapse** as a **non-covered benefit** and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

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 non-surgical 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 on 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 variations in symptoms are 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. Upon 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 degrees in the White population. 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, increase airflow resistance and symptoms of congestion.

Physical Examination
A thorough physical examination of the nose, nasal cavity, and the nasopharynx is generally sufficient for identification of 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's 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’s maneuver. A cotton swab or curette is inserted into the nasal cavity to support the nasal cartilage and the patient reports whether there is improvement in their 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 non-surgical interventions such as the adhesive strips that are applied externally across the nose (applying the principle of the Cottle’s maneuver) or the use of nasal dilators, cones or other devices that support the lateral nasal wall internally (applying the principle of the modified Cottle’s maneuver).

Severe cases of obstruction result 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.

KEY POINTS:

This evidence review was created in October 2018 with a search of the MEDLINE database performed through September 2, 2020.

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 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 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.

Practice Guidelines and Position Statements:

American Academy of Otolaryngology—Head Neck Surgery

In 2010, the American Academy of Otolaryngology − Head Neck Surgery convened a panel to create a clinical consensus statement on the diagnosis and management of nasal valve compromise. A summary of key consensus statements is shown in Table 8. The panel also indicated that nasal endoscopy and nasal photography were both deemed useful but not routinely required.

Table 1. Consensus Agreement: Diagnosis and Treatment of NVC

Item	Level of Consensus	Statement
Definition	Agreement/strong agreement	NVC is a distinct clinical entity separate from other anatomic reasons for nasal obstruction
History and physical	Strong agreement	Main symptom of NVC is decreased airflow as reported by the patient
	Agreement/strong agreement	Anterior rhinoscopy can be adequate for an intranasal evaluation of the nasal valve, weak or malformed nasal cartilages
	Agreement/strong	Inspiratory collapse of the lateral nasal wall or alar rim is

	agreement	consistent with NVC
	Agreement/strong agreement	Increased nasal obstruction associated with deep inspiration is consistent with NVC
Adjunctive tests	Strong disagreement	Gold standard test to diagnose NVC exists
Outcome Measures	General agreement	Various patient-reported outcomes (e.g., visual analog scales, satisfaction measures, quality of life scales) are valid indicators of successful intervention.
Management	Strong agreement	Nasal strips, stents or cones can be used to treat some patients
	Strong agreement	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

NCV: nasal valve compromise.

KEY WORDS:

Latera, absorbable nasal implant, nasal valve collapse

APPROVED BY GOVERNING BODIES:

LATERA® (Stryker ENT, previously Spirox) is the only commercially available absorbable nasal implant for treatment of nasal valve collapse Food and Drug Administration product code: NHB). It is a class II device and regulatory details are summarized in Table 2.

Table 2. Absorbable Nasal Implant Cleared by FDA

Product	Manufacturer	Date Cleared	510(k) No.	Indication
LATERA® absorbable nasal implant	Spirox (part of Stryker)	May 2016	K161191	Supporting nasal upper and lower lateral cartilage

U.S. Preventative Services Task Force Recommendations

Not applicable.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

30468	Repair of nasal valve collapse using an implant **(Effective 01/01/21)**
30999	Unlisted procedure, Nose

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POLICY HISTORY:

Medical Policy Group, October 2018 (**6**): New medical policy, information regarding LATERA transferred from *MP#501 Implantable Sinus Stents and Drug-Eluting Implants for Postoperative*

Use Following Endoscopic Sinus Surgery and for Recurrent Sinus Disease. **LATERA was previously non-covered per internal processing guidelines prior to MP #501.**
Available for comment October 25 through December 9, 2018
Medical Policy Group, October 2019
Medical Policy Group, October 2020
Medical Policy Group, November 2020: 2021 Annual Coding update. Added CPT 30468 to the Current coding section.
Medical Policy Group, December 2020
