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Medical Policy Manual Surgery, Policy No. 209

Absorbable Nasal Implant for Treatment of Nasal Valve Collapse

Effective: March 1, 2019

Next Review: November 2019
Last Review: November 2018

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

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.

MEDICAL POLICY CRITERIA

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

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Rhinoplasty, Surgery, Policy No. 12.28
2. Surgeries for Snoring, Obstructive Sleep Apnea Syndrome and Upper Airway Resistance Syndrome in Adults, Surgery, Policy No. 166

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.[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 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.[2] It is a five-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.[3] 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

Severity Class	NOSE Score Range
Mild	5-25
Moderate	30-50
Severe	55-75
Extreme	80-100

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 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.

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).[4] 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 2.

Table 2. Absorbable Nasal Implant Cleared by the Food and Drug Administration

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

EVIDENCE SUMMARY

ABSORBABLE LATERAL NASAL VALVE IMPLANT

Clinical Context and Therapy Purpose

The purpose of insertion of an absorbable nasal valve implant in patients who have symptomatic nasal valve obstruction due to nasal valve collapse is to provide a treatment option that is an alternative to or an improvement on existing therapies. Existing therapies include nonsurgical treatments such as the use of externally applied adhesive strips or intranasal insertion of nasal cones. The basic mechanism of action of these treatments is to widen the nasal valve and permit increased airflow. Surgical grafting using either autologous cartilage (typically from the nasal septum, ear, or homologous irradiated rib cartilage) or a permanent synthetic implant may be performed to provide structural support to the lateral wall support defect.

The question addressed in this evidence review is: Does the use of an absorbable nasal valve implant in patients who have symptomatic nasal valve obstruction due to nasal valve collapse improve the net health outcome? The general outcomes of interest are change in symptoms and disease status, treatment-related morbidity, functional status, and change in quality of life. The Nasal Obstruction Symptom Evaluation (NOSE) score is an accepted symptom questionnaire for research purposes. The score can also be stratified to indicate the degree of severity of the nasal obstruction symptoms. The insertion of the absorbable implant is performed under local anesthesia and the adverse event profile includes mild pain, irritation, bruising and inflammation, awareness of the presence of the implant, infection, and the need for device retrieval prior to complete absorption.

Study Selection Criteria

No randomized comparative studies were identified to evaluate the absorbable nasal implant. The best available evidence consists of two nonrandomized prospective industry-sponsored studies of the commercially available absorbable nasal implant.

Nonrandomized Studies

The characteristics and results of nonrandomized studies are summarized in Tables 3, 4, and 5.

Table 3. Summary of Key Nonrandomized Study Characteristics

Study	Study Type	Country	Dates	Participants[a]	Treatment, n	Follow-Up
Stolovitzky (2018)[5]	Prospective single cohort	U.S. (14 clinical sites)	Sep 2016-Mar 2017	101	• Insertion of implantb alone: 43 • Insertion of implantb plus adjunctive procedure: 58	1, 3, 6 mo
San Nicoló (2017 and 2018)[6,7]	Prospective single cohort	Germany (3 clinical sites)	NR	30	• Insertion of 56 lateral wall implantb: • Bilateral: 26 • Unilateral: 4	1 wk and 1, 3, 6, 12, 24 mo

NOSE: Nasal Obstruction Symptom Evaluation; NR: not reported.
a Baseline inclusion criteria: NOSE score ≥55. Baseline exclusion criteria: septoplasty or turbinate reduction within 6 mo, rhinoplasty within 12 mo, recurrent nasal infection, intranasal steroids, permanent nasal implants or dilators, precancerous or cancerous lesions, radiation or chemotherapy within 24 mo.
b Absorbable polylactide implant marketed in the United States as Latera.

Table 4. Summary of Key Nonrandomized Study NOSE Score Results

Study	Baseline	1 Month	3 Months	6 Months	24 Months
Stolovitzky (2018)[5]					
N or n	101	99	97	87	

Study	Baseline	1 Month	3 Months	6 Months	24 Months
Mean score (SD)	79.5 (13.5)	34.6 (25.0)	32.0 (28.4)	30.6 (25.8)	
p[a]		<0.05	<0.01	<0.01	
Mean change from baseline (SD)		NR	NR	NR	
Response rate[b] for implant alone group[c]		90.5%	87.8%	89.2%	
San Nicoló (2017 and 2018)[6]					
N or n	30		29	30	
Mean score (SD)	76.7 (14.8)	NR	28.4	33.3	32.0 (29.3)
Mean change from baseline (SD)			-48.4 (26.9)	-43.3 (29.7)	-44.0 (31.1)
p[d]			<0.001	<0.001	
N or n		NR	29	30	
Response rate, n (%)[b]			25 (86.2)	24 (80)	

CI: confidence interval; NOSE: Nasal Obstruction Symptom Evaluation; NR: not reported; SD: standard deviation.
a Paired t tests were used to compare the mean baseline value with each of the follow-up time points to determine whether there was evidence of significant reductions in NOSE scores. CIs not reported.
b Response rate was defined as an improvement of at least 1 NOSE score category or a 20% reduction in NOSE score.
c Implant alone group was taken to be n=43 but any loss to follow-up for this subgroup was not reported for this outcome.
d Paired t tests comparing the mean preoperative NOSE score to the mean score at each follow-up time point. CIs not reported.

Table 5. Summary of Key Nonrandomized Study Safety and Adverse Event Results

Study	1 Month	3 Months	6 Months	12 Months
Stolovitzky (2018)[5]				
Adverse events		99[b]		
Device relateda		19 events in 17 patients[c]		
San Nicoló (2017)[6]				
N or n	30	29	30	29
Device tolerability, % (n)				
None/mild pain	30 (100)	29(100)	29 (96.7)	29(100)
Not assessed			1 (3.3)	
Cosmetic changes[d]	26 (86.7)	27 (93.1)	27 (90.0)	26 (89.7)
Device-related adverse events[e]	5	0	0	0

a Defined as implant- or procedure-related.
b Taken to be n=99 but no specific reporting for this category.
c Total number only reported for inflammation, foreign body sensation, skin irritation, hematoma, infection, and implant retrievals.
d Photographic review.
e Three device retrievals, 1 hematoma, and 1 inflammation.

Stolovitzky (2018) reported on six-month outcomes for 101 patients with severe-to-extreme class of NOSE scores were enrolled at 14 U.S. clinics between September 2016 and March 2017. In the total cohort, 40.6% had a history of allergic rhinitis and 32.7% had a history of sinus disease. The types and rates of prior rhinologic surgeries were septoplasty (26.7%), turbinate reduction (29.7%), endoscopic sinus surgery (22.8%), and rhinoplasty (10.9%). The rate of prior septoplasty was 53.5% in the group that received the absorbable implant alone and 87.9% in the group that received implant plus adjunctive surgery. Overall, fifty-eight (57%) patients had adjunctive procedures (not expressly reported) in addition to the implant placement. In addition to the NOSE score, patients were assessed pre- and postoperatively with the Lateral Wall Insufficiency score, which is based on a review of a lateral wall motion video. Patients reported visual analog scale scores for nasal congestion at each follow-up visit.

San Nicoló (2017) reported on outcomes up to 12 months following implantation of 56 implants in 30 subjects.[6] All implanted patients had NOSE score ≥55. San Nicoló (2018) reported 24-month outcomes for the patients with initial results reported in.[7] This study reported that there were no device-related adverse events in the period of 12 to 24 months.

The purpose of the gaps tables (see Tables 6 and 7) is to display notable gaps identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of the evidence supporting the position statement.

Table 6. Relevance Gaps

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
Stolovitzky (2018)[5]	1. Patient population varied in important clinical characteristics and types and rates of prior rhinologic surgery 2. Clinical context for patient selection for absorbable implant vs implant plus adjunctive surgery not described 3. Implant plus adjunctive surgery group a subpopulation of potential intended use			6. Clinically significant difference not supported. A positive responder could still have severe symptoms.	Duration of outcomes reporting less than duration of absorption of device and purported completion of remodeling phase
San Nicoló (2017 and 2018)[6,7]	2. Clinical context for patient selection for absorbable implant vs alternative surgery not described 3. Study population is heterogenous: 68% had prior rhinonasal surgery			6. Clinically significant difference not supported. A positive responder could still have severe symptoms.	

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use. 5. Study population is subpopulation of intended use
b Intervention key: 1.Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator
c Comparator key: 1.Not clearly defined; 2.Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
d Outcomes key: 1.Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Not CONSORT reporting of harms; 4.Not established and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported
e Follow-Up key: 1. Not sufficient duration for benefits; 2. Not sufficient duration for harms.

Table 7. Summary of Key Nonrandomized Study Safety and Adverse Event Results

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Stolovitzky (2018)[5]		1. No sham control and not blinded to treatment assignment		1. Data incomplete for populations assessed for various outcomes 2. Missing data for patients who had device retrievals		
San Nicoló (2017 and 2018)[6,7]		1. No sham control and not blinded to treatment assignment		2. Missing data for patients who had device retrievals		

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

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 two 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 one 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, e.g., 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 (one month); suggesting technical experience limitations on the part of the operator or inappropriate patient selection. Only one study reported outcomes following 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.

PRACTICE GUIDELINE SUMMARY

There are no evidence-based clinical practice guidelines that recommend the use of an absorbable lateral nasal implant.

SUMMARY

There is not enough research to show that insertion of an absorbable lateral nasal implant improves health outcomes for people with symptomatic nasal valve collapse. No clinical guidelines based on research recommend the use of an absorbable lateral nasal implant. Therefore, insertion of an absorbable lateral nasal implant is considered investigational for all indications.

REFERENCES

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5. Stolovitzky, P, Sidle, DM, Ow, RA, Nachlas, NE, Most, SP. A prospective study for treatment of nasal valve collapse due to lateral wall insufficiency: Outcomes using a bioabsorbable implant. *The Laryngoscope*. 2018 May 14. PMID: 29756407
6. San Nicoló, M, Stelter, K, Sadick, H, Bas, M, Berghaus, A. Absorbable implant to treat nasal valve collapse. *Facial Plast Surg*. 2017 Apr;33(2):233-40. PMID: 28388804
7. San Nicolo, M, Stelter, K, Sadick, H, Bas, M, Berghaus, A. A 2-Year Follow-up Study of an Absorbable Implant to Treat Nasal Valve Collapse. *Facial Plast Surg*. 2018 Oct;34(5):545-50. PMID: 30227454
8. BlueCross BlueShield Association Medical Policy Reference Manual "Absorbable Nasal Implant for Treatment of Nasal Valve Collapse." Policy No. 7.01.163

CODES

NOTES: Previously, the unlisted HCPCS code C1889 was used to represent this device. However, the appropriate HCPCS code which describes the absorbable nasal implant device is C9749.

The physician work for the nasal implant placement would be billed with the unlisted CPT code 30999 - Unlisted procedure, nose. Some providers may use CPT 30465 for this service, Repair of nasal vestibular stenosis (e.g., spreader grafting, lateral nasal wall reconstruction); however the unlisted code is the appropriate code.

Codes	Number	Description
CPT	30999	Unlisted procedure, nose
HCPCS	C9749	Repair of nasal vestibular lateral wall stenosis with implant(s)

Date of Origin: *November 2018*