DRAFT

BlueCross BlueShield of Alabama

Name of Policy:
Absorbable Nasal Implant for Treatment of Nasal Valve Collapse

Policy #:	721	Latest Review Date:	October 2018
Category:	Medical	Policy Grade:	B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

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.

Measuring Nasal Obstruction

Stewart et al (2004) proposed the Nasal Obstruction Symptom Evaluation Scale (NOSE) 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. It is a 5-item questionnaire on breathing problems; nasal congestion or stuffiness, nasal blockage or obstruction, trouble breathing through nose, trouble sleeping and, unable to get enough air through nose during exercise or exertion. The responses are made on Likert-type scale 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.

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 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.

Policy:

The insertion of an **absorbable nasal implant** for the treatment of symptomatic nasal valve collapse **does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

Blue Cross and Blue Shield of Alabama 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 Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate 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.

Key Points:

This evidence review was created in October 2018 with a search of the MEDLINE database performed through September 4, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Absorbable 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.

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 net health outcomes?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest is adults who have severe symptomatic nasal obstruction symptoms due to internal nasal valve (also known as zone 1) collapse (NCV). NCV is one of the recognized structural causes of obstructed breathing and congestion and the diagnosis is primarily clinical. NCV may be unilateral or bilateral and is typically constant with each inspiration. The condition may occur in association with prior trauma or rhinonasal surgery. Evaluation consists of clinical history to elicit alternative causes or co-occurring conditions such as obstructive sleep apnea or medication use. In addition to examination of the head and neck, Cottle's maneuver or modified Cottle's maneuver (previously described) is used to rule in NCV. Anterior rhinoscopy and nasal endoscopy are used and rule out structural abnormalities such as septal deviation or mucosal conditions such as enlarged turbinates. Radiographic studies are not generally indicated.

Interventions
The therapy being considered is unilateral or bilateral insertion of an absorbable nasal implant into the lateral nasal wall. The product is predominantly cylindrical in shape with a diameter of 1 mm and an overall length of 24 mm with a forked distal end for anchoring into the maxillary periosteum. It is composed of Poly (L-lactide-co-D-L-lactide) 70:30 copolymer which is absorbed in the body over a period of approximately 18 months. It is packaged with a 16-gauge insertion device. The available product information describes the integrity of the implant to be maintained for 12 months after implantation while a fibrous capsule forms around the device. A remodeling phase where collagen replaces the implant within the capsule persists through 24 months and is the purported mechanism of support for the lateral nasal wall support.

Comparators
The following therapies and practices are currently being used to make decisions about treating NVC: nonsurgical treatments include 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.

Outcomes
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 classified 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.

Timing
The duration of follow-up to assess early procedural outcomes is 1 month and at least 24 months would be required to evaluate durability of symptom improvement as well as to confirm the association with the purported mechanism of action of the device.

Setting
Insertion of an absorbable nasal implant is performed in the outpatient setting by an otolaryngologist or plastic surgeon.

Study Selection
No randomized comparative studies were identified to evaluate the absorbable nasal implant. The best available evidence consists of 2 nonrandomized prospective industry sponsored studies of the commercially available absorbable nasal implant. The characteristics and results of studies are summarized in Tables 3, 4, and 5.

Table 3. Summary of Key Nonrandomized Study Characteristics

Study	Study Type	Country	Dates	Participants	Treatment	Follow-Up
Stolivitzky et al (2018)	Prospective single cohort	U.S. (14 clinical sites)	Sep 2016 - Mar 2017	101	Insertion of implant[b] alone: 43 Insertion of implant[b] plus adjunctive procedure: 58	1, 3, 6 mo
San Nicoló et al (2017)	Prospective single cohort	Germany (3 clinical sites)	NR	30	Insertion of 56 lateral wall implant[b] • Bilateral: 26 • Unilateral: 4	1 wk and 1, 3, 6, 12 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/dilators, precancerous/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 Results: NOSE Score

Study	Baseline	1 Month	3 Months	6 Months	12 Months
Stolivitzky et al (2018)					
N	101	99	97	87	
Mean score (SD)	79.5 (13.5)	34.6 (25.0)	32.0 (28.4)	30.6 (25.8)	
p[a]					
Mean change from baseline (SD)		NR	NR	NR	
Response rate b for implant alone group[c]		90.5%4	87.8%4	89.2%4	
San Nicoló et al (2017)					
N	30		29	30	29
Mean score (SD)	76.7 (14.8)	NR	28.4	33.3	35.2
Mean change from baseline (SD)			-48.4 (26.9)	-43.3 (29.7)	40.9 (29.2)
p[a]			<0.001	<0.001	<0.001
N		NR	29	30	29
Response rate, n (%)[b]			25 (86.2)	24 (80)	22 (75.9)

CI: confidence interval; NOSE: Nasal Obstruction Symptom Evaluation; NR: not reported.
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. CI not reported.
b Response rate is defined as an improvement of at least 1 NOSE score category or a 20% reduction in NOSE score.

c Implant alone group taken to be N=43 but any loss to follow-up for this subgroup 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. CI not reported.

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

Study	1 Month	3 Months	6 Months	12 Months
Stolivitzky et al (2018)				
Adverse events		99[b]		
Device related[a]		19 events in 17 patients[c]		
San Nicoló et al (2017)				
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 3 device retrievals, 1 hematoma, and 1 inflammation.

Stolovitzky (2018) reported on 6-month outcomes for a population of 101 patients with severe-to-extreme class of NOSE scores were enrolled at 14 U.S. clinics between September 2016 to 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 review of a lateral wall motion video. Patients reported VAS scores for nasal congestion at each follow-up visit.

The purpose of the gaps tables (see Tables 5 and 6) 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 evidence supporting the position statement.

Table 6. Relevance Gaps

Study	Population[a]	Intervention[b]	Comparator	Outcomes[d]	Duration of Follow-Up[e]
Stolovitzky et al (2018)	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 5.Implant plus adjunctive surgery group a subpopulation of potential intended use			6.Clinically significant difference not supported. A positive responder could still result in a patient with severe symptoms	1.Duration of outcomes reporting less than duration of absorption of device and purported completion of remodeling phase
San Nicoló et al (2017)	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 result in a patient with severe symptoms	1.Duration of outcomes reporting less than duration of absorption of device and purported completion of remodeling phase

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. Study Design and Conduct Gaps

	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e] Statistical[f]
Stolovitzky et al (2018)		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 et al (2017)		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 are treated with an absorbable nasal valve implant, the evidence includes 2 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 that were evaluated. Specifically, the types and rates of prior nasal procedures are not well described, nor are 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 the small study populations. Some patients meeting the positive responder criteria still report severe symptoms, and many patients report some loss of improvement at 1 year. Data elements are missing or difficult to determine for important outcomes. As reported, adverse events appear to be mild in severity and self-limiting, but still appear common. Device retrievals are incompletely characterized. They

occurred in 10% of patients in the primary cohort study, and it is not known, for example, if 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 (1 month); suggesting technical experience limitations on the part of the operator or inappropriate patient selection. The duration of outcomes reporting is less than the duration of absorption of the device (18 months) and the purported completion of tissue remodeling phase (24 months). Randomized clinical trials with a sham are feasible and should be performed. 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 8. 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 agreement	Inspiratory collapse of the lateral nasal wall or alar rim is 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® 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.

ITS: Home Policy provisions apply.

FEP: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

CPT Codes:

30999 Unlisted procedure, Nose

References:

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7. Stewart MG, Witsell DL, Smith TL, et al. Development and validation of the Nasal Obstruction Symptom Evaluation (NOSE) scale. Otolaryngol Head Neck Surg. Feb 2004;130(2):157-163.

8. Stolovitzky P, Sidle DM, Ow RA, et al. A prospective study for treatment of nasal valve collapse due to lateral wall insufficiency: Outcomes using a bioabsorbable implant. Laryngoscope. May 14 2018.

Policy History:

Medical Policy Panel, October 2018
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.*
Medical Policy Administration Committee, November 2018
Available for comment October 19, 2018 through December 3, 2018
