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Absorbable Nasal Implant for Treatment of Nasal Valve Collapse

Table of Contents

Related Policies (if applicable)
SUR706.001: Nasal and Sinus Surgery

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Coverage

The insertion of an absorbable lateral nasal implant for the treatment of symptomatic nasal valve collapse **is considered experimental, investigational and/or unproven**.

Policy Guidelines

None.

Description

Nasal valve collapse (NVC) 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 NVC 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.

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 on 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 a 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 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.

Treatment

Treatment of symptomatic nasal valve collapse includes the use of non-surgical 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.

Regulatory Status

In May 2016, LATERA® (Entellus Medical/Stryker ENT, previously Spirox) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. (2) 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 U.S. Food and Drug Administration

Product	Manufacturer	Date Cleared	501(k) No.	Product Code	Indication
LATERA® absorbable nasal implant	Spirox (part of Stryker)	2016	K161191	NHB	Supporting nasal upper and lower lateral cartilage

Rationale

Medical policies assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and 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 technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 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 (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs 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 Lateral Nasal Valve Implant

Clinical Context and Therapy Purpose

The purpose of insertion of an absorbable nasal valve implant in individuals who have symptomatic nasal valve obstruction due to nasal valve collapse (NVC) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is adults who have severe symptomatic nasal obstruction symptoms due to the internal (also known as zone 1) NVC. NVC is one of the recognized structural causes of obstructed breathing and congestion, and the diagnosis is primarily clinical. NVC may be unilateral or bilateral and is typically constant with each inspiration. The condition may occur in association with prior trauma or rhinonasal surgery. The evaluation consists of a 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, the Cottle maneuver or modified Cottle maneuver (previously described) is used to rule-in NVC. Anterior rhinoscopy and nasal endoscopy are used to rule out structural abnormalities such as septal deviation or mucosal conditions such as enlarged turbinates. Radiographic studies are not generally indicated. (3)

Interventions

The therapy being considered is a 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 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. (4)

Comparators
The following therapies and practices are currently being used to treat 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 a change in symptoms and disease status, treatment-related morbidity, functional status, and change in the QOL. 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.

Stewart et al. (2004) proposed the NOSE as a validated sinonasal-specific health status instrument that is used to assess the impact of nasal obstruction on the QOL of affected persons. (5) It is a 5-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.

The NOSE scale-based nasal obstruction severity classification 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 (Table 2). (6)

Table 2. NOSE Severity Classification

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

NOSE: Nasal Obstruction Symptom Evaluation.

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

Study Selection Criteria

- To assess efficacy outcomes, comparative controlled prospective trials, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were also included, with preference for prospective studies.
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Within each category of study design, studies with larger sample sizes and longer durations were preferred.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Randomized Controlled Trials

One sham-controlled randomized trial with 3-month follow-up has been identified (Table 3). Stolovitzky et al. (2019) randomized 137 patients with severe to extreme NOSE scores to an office-based nasal implant or sham control procedure. (7) Follow-up at 3 months showed a significant improvement in responder rate, change in NOSE score, and visual analog scale compared to the sham group, although over half of the control group also were considered responders (Table 4). Six patients (8.6% of 70) had the implant removed by 3 months and analysis was not intent-to-treat (see Tables 5 and 6). Adverse events included pain (n=4), foreign body sensation (n=3), localized swelling (n=2), inflammation (n=1), skin puncture (n=1), and vasovagal response (n=2).

Table 3. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	**Comparator**
Stolovitzky et al. (2019) (7) NCT03400787	U.S.	10	2017-2018	137 patients with severe to extreme NOSE scores after 4 weeks of medical management	Nasal implant (n=70)	Sham control with a cannula inserted into the nasal lateral wall (n=67)

NOSE: Nasal Obstruction Symptom Evaluation; RCT: randomized controlled trial; n: number (of participants); U.S.: United States.

Table 4. Summary of Key RCT Results at 3 months

Study	NOSE Responder Rate at 3 mo %[1]	Change in NOSE Score at 3 mo (SD)	Change in VAS at 3 mo (SD)	Implant Removal

Stolovitzky et al. (2019) (7) NCT03400787	N=127	N=127		
Nasal Implant	82.5	-42.4 (23.4)	-39.0 (29.7)	6/70 (8.6%)
Sham Implant	54.7	-22.7 (27.9)	-13.3 (30.0)	
p-value	0.001	<0.001	<0.001	

NOSE: Nasal Obstruction Symptom Evaluation; mo: month; RCT: randomized controlled trial; SD: standard deviation; VAS: visual analog scale.

[1] 20% decrease or decrease in 1 category on the NOSE score.

Bikhazi et al. (2021) reported results from a 24-month uncontrolled follow-up phase of the RCT. (8) Participants randomized to the control group were given the option to crossover to the treatment group following the 3-month randomized phase. Table 5 shows the disposition of participants and Table 6 summarizes outcomes at 24 months for the treatment and crossover participants.

Table 5. Disposition of Participants in Uncontrolled 24-month Follow-up Phase of RCT (8)

Total enrolled in randomized cohort	137 (71 treatment, 66 sham)
Sham participants undergoing crossover procedure	40 (61.0%)
Total enrolled in long-term follow-up phase	111 (7 treatment, 40 sham)
Total completing 12-month visit	90
Total completing 18-month visit	75
Total completing 24-month visit	70

RCT: randomized controlled trial.

Table 6. Summary of Key RCT Results – 24 Month Uncontrolled Crossover Phase (8)

	NOSE Responder Rate[1]	**Mean Change (SD) from Baseline in NOSE Score**	**Mean Change from Baseline in Nasal Obstruction VAS**	**Mean Change (SD) from Baseline in Epworth Sleepiness Scale**	**Device Migration/ extrusion/ retrieval**	**Total Adverse Events**
Number analyzed	60	68	NR (reported in figure)	69	111	111
	88.2% (78.1%, 94.8%)	-38.4 (25.8); p<.001	≥29.7; p<.001 at all time points	-2.6 (4.1); p<.001 Among 26 participants with abnormal baseline	10 events in 10 participants (4.5% of total implants; 9% of participants)	34 events in 26 participants

				score (> 10): -4.9 (4.1); p<.001		

NOSE: Nasal Obstruction Symptom Evaluation; NR: not reported; RCT: randomized controlled trial; SD: standard deviation; VAS: visual analog scale.
[1] 20% decrease or decrease in 1 category on the NOSE score.

Tables 7 and 8 summarize the limitations of the RCT and its uncontrolled follow-up phase. Study limitations include the lack of long-term follow-up of the control arm, significant loss of study participants to follow-up at 18 and 24 months (Table 5), and a lack of objective assessment of NVC.

Table 7. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Stolovitzky et al. (2019) (7)				6. Clinically significant difference not supported. A positive responder could still have severe symptoms.	

The study limitations stated in this table are those notable in the current literature review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[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. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 8. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Stolovitzky et al. (2019) (7)		3. Nasal examination was performed by the treating	2. In randomized phase, patients who had the implant	6. Not intent-to-treat. Six patients who had implant removal were not analyzed.		

		physician (patients were blinded). Longer-term follow-up data not blinded.	removed were excluded from analysis.	High loss to follow-up in longer-term phase.		

The study limitations stated in this table are those notable in the current literature 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 differences.

[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.

Nonrandomized Studies

No studies have compared insertion of an implant with inferior turbinate reduction and/or septoplasty. A comparative observational study of 90 individuals with nasal obstruction published in 2021 compared nasal implants to a variety of open functional rhinoplasty techniques in individuals who had also undergone septoplasty and inferior turbinate reduction. (9) However, this study was not included because of its retrospective design, follow-up of only 3 months, and heterogeneity in the indications for the interventions and the surgical techniques used.

Three prospective, single-arm cohort studies in a total of 307 individuals receiving nasal implants have evaluated outcomes at 24 months. The characteristics and results of these studies are summarized in Tables 9, 10, and 11.

Sidle, Stolovitzky, and colleagues (2019, 2021) reported outcomes from 2 post-marketing studies that enrolled a total of 277 patients with severe-to-extreme NOSE scores at 19 U.S. clinics between September 2016 and July 2017. (10-12) One of the trials (NCT02964312) was conducted in an office setting and enrolled 166 participants. The second study (NCT02952313) implanted the device in the operating room and included 113 participants. Concomitant procedures (septoplasty and/or inferior turbinate reduction) were at the discretion of the

investigators. The most recent publication from these studies (12) included data from 177 patients who were followed for 24 months under a protocol extension. NOSE scores through 24 months were reported separately for patients who received an implant alone (n = 69, NOSE = 30.4 [24.6 standard deviation {SD}]), implant plus inferior turbinate reduction (n=39, NOSE = 27.6 [23.1 SD]), or an implant combined with septoplasty and inferior turbinate reduction (n=69, NOSE = 16.0 [20.7 SD]). The data presented by Sidle et al. (2021) (12) is described in the tables below. The mean change from baseline for the 177 patients with 24-month data was -53.6 (95% confidence interval [CI], -57.0 to -50.1), with a responder rate of around 90%. Loss to follow-up in these cohorts was high, with 100 of 277 participants discontinuing the study before 24 months (44 were lost to follow-up, 17 withdrew due to lack of response, 38 withdrew or did not consent to the extension study, and 2 died). Sensitivity analysis, performed with a worst-case scenario with all missing 24-month data assigned no change from baseline, showed a mean change from baseline in the NOSE score of -34.2 (95% CI, -38.1 to -30.2), representing an improvement of 1 class.

San Nicoló et al. (2017, 2018) reported 24-month outcomes for 30 patients who were treated at 3 clinical sites in Germany. (13, 14) In this study, 13.3% of patients had the implant removed.

The improvement in symptoms was consistent across the 3 studies, with a mean change of over 40 points from baseline on the NOSE score. The 24-month outcomes are the most relevant, as resorption and remodeling are expected to occur within that time frame.

Table 9. Summary of Prospective, Single-Arm Study Characteristics

Study	Study Type	Country	Dates	Participants[a]	Treatment, n	Follow-Up
Sidle et al. (2019) (11) NCT02952313 NCT02964312	Two prospective single-arm cohorts	U.S. (19 clinical sites)	2016-2019	277 patients with severe to extreme nasal obstruction (NOSE score $\geq$ 55) and a positive Cottle maneuver	· Insertion of implant[b] alone (n=109) · Insertion of implant[b] plus inferior turbinate reduction (n=67) · Insertion of implant[b] plus septoplasty plus inferior turbinate reduction (n=101)	24 mo
San Nicoló et al. (2017, 2018) (13, 14)	Prospective single-arm cohort	Germany (3 clinical sites)	NR	30	Insertion of 56 lateral wall implant[b]:	1 wk and 1, 3, 6, 12, 24 mo

					· Bilateral: 26 · Unilateral: 4	

NOSE: Nasal Obstruction Symptom Evaluation; NR: not reported; mo: month; n: number; wk: week.
[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 U. S. as Latera.

Table 10. Summary of Prospective, Single-Arm Study NOSE Score Results

Study	1 Month	3 Months	6 Months	12 Months	18 Months	24 Months
Sidle et al. (2019) (11)						
N or n	276	267	258	232	185	177
Baseline (SD)	77.8 (13.6)	77.7 (13.5)	77.6 (13.6)	77.0 (13.5)	77.6 (13.2)	78.0 (13.1)
Mean NOSE score (SD)[a]	33.7 (23.0)	27.8 (23.4)	27.5 (24.0)	26.0 (23.9)	25.4 (24.0)	24.2 (23.6)
Mean change from baseline (95% CI)	-43.9 (-46.7 to 41.2)	-49.9 (-52.7 to -47.1)	-50.2 (-53.0 to -47.3)	-51.5 (-54.5 to -48.4)	-52.2 (-55.6 to -48.8)	-53.6 (-57.0 to -50.1)
Responder rate[b]	90.9%	93.3%	91.9%	91.4%	93.5%	93.2%
Responder rate[b] for implant alone group	90.8% (99/109)	92.5% (98/106)	92.0% (92/100)	88.3% (83/94)	94.5% (69/73)	89.9% (62/69)
San Nicoló et al. (2017, 2018) (13, 14)	**Baseline**		**3 Months**	**6 Months**	**12 Months**	**24 Months**
N or n	30		29	30	29	25
Mean score (SD)	76.7 (14.8)	NR	28.4	33.3	35.2	32.0 (29.3)
Mean change from baseline (SD)			-48.4 (26.9)	-43.3 (29.7)	-40.9 (29.2)	-44.0 (31.1)
p			<.001	<.001	<.001	

N or 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; N or n: number; NR: not reported; SD: standard deviation.

[a] Paired 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.

[b] Response rate was defined as an improvement of at least 1 NOSE score category or a 20% reduction in NOSE score.

Table 11. Summary of Prospective, Single-Arm Study Safety and Adverse Event Results

Study	1 Month	3 Months	6 Months	12 Months	24 Months
Sidle et al. (2019, 2021) (11, 12)					
Device related[a]				41 events in 31 patients	54 events in 45 patients
Device removals				17 out of 319 implants (5.3%)	22 out of 543 implants (4.0%)
San Nicoló et al. (2017, 2018) (13, 14)					
N or n	30	29	30	29	25[b]
Device tolerability, % (n)					
None/mild pain	30 (100)	29 (100)	29 (96.7)	29 (100)	24 (96.0)
Not assessed			1 (3.3)		
No cosmetic changes[c]	26 (86.7)	27 (93.1)	27 (90.0)	26 (89.7)	17 (89.5)
Device-related adverse events[d]	5	0	0	0	0

[a] foreign body sensation (6), sinus infection (1), mucous production (2), loss of smell/taste (1), skin irritation (1), hematoma (1), infection (4), pain (3), bumps (5), and implant retrievals (17)

[b] 4 patients had an additional procedure and 1 was lost to follow-up.

[c] Photographic review.

[d] 3 device retrievals, 1 hematoma, and 1 inflammation.

Study limitations are summarized in Tables 12 and 13. The lack of a comparator group inherent to the study design is a major limitation. Additionally, the indication for the nasal implant varied within the study populations or was not adequately described.

Table 12. Nonrandomized Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]

Sidle et al. (2019, 2021) (11, 12)	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 versus implant plus adjunctive surgery not described.		No comparator	6. Clinically significant difference not supported. A positive responder could still have severe symptoms.	
San Nicoló et al. (2017, 2018) (13, 14)	2. Clinical context for patient selection for absorbable implant vs alternative surgery not described 3. Study population is heterogenous: 68% had prior rhinonasal surgery.		No comparator	6. Clinically significant difference not supported. A positive responder could still have severe symptoms.	

The study limitations stated in this table are those notable in the current literature review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.

[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 differences not supported.

[e] Follow-Up key: 1. Not sufficient duration for benefits; 2. Not sufficient duration for harms.

Table 13. Nonrandomized Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Sidle et al. (2019,		1. No control and not blinded		1. Data incomplete for populations		

2021) (11, 12)		to treatment assignment.		assessed for various outcomes. 2. Missing data for patients who had device retrievals.		
San Nicoló et al. (2017, 2018) (13, 14)		1. No control and not blinded to treatment assignment.		2. Missing data for patients who had device retrievals.		

The study limitations stated in this table are those notable in the current literature 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 (NVC) who receive an absorbable lateral nasal valve implant, the evidence includes 1 randomized controlled trial (RCT) with a 24-month uncontrolled follow-up phase and 3 nonrandomized prospective, single-cohort studies. Relevant outcomes are symptoms, change in disease status, treatment-related morbidity, functional outcomes, and quality of life (QOL). Overall, improvements in nasal obstruction score have been demonstrated in study reports. Follow-up at 3 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. Twenty-four month follow-up has been reported in the 3 multicenter cohort studies and the uncontrolled crossover phase of the RCT. Loss to follow-up was high, although sensitivity analysis with a worst-case scenario supported an improvement in symptoms at 24 months. As reported, adverse events appeared to be mild in severity and self-limiting, but still common. In the larger cohorts, device retrievals or extrusions occurred in 4% of patients. 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. No studies have been identified that compared insertion of an

implant with inferior turbinate reduction and/or septoplasty. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American Academy of Otolaryngology - Head Neck Surgery

In 2023, the American Academy of Otolaryngology-Head Neck Surgery (AAO-HNS) issued a position statement on nasal valve repair stating that treatment options of nasal valve dysfunction may include implants aimed at stabilizing the nasal valve. (15) No specific recommendations were made for nasal implants. The AAO-HNS recognizes surgical repair of the nasal valve as a distinct surgical procedure that can alleviate nasal obstruction symptoms for patients who have nasal valve collapse and are suitable candidates for this intervention.

In 2010, the AAO-HNS released a clinical consensus statement on the diagnosis and management of nasal valve compromise. (2) Table 14 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 14. Consensus Agreement: Diagnosis and Treatment of NVC

Item	Statement	Level of Consensus
Definition	NVC is a distinct clinical entity separate from other anatomic reasons for nasal obstruction	Agreement/strong agreement
History and physical	Main symptom of NVC is decreased airflow as reported by the patient	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	Agreement/strong agreement
Adjunctive tests	Criterion standard test to diagnose NVC exists	Strong disagreement
Outcome measures	Various patient-reported outcomes (e.g., visual analog scales, satisfaction measures, quality of life scales) are valid indicators of successful intervention	General agreement
Management	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	Strong agreement

NVC: nasal valve compromise.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in August 2024 did not identify any trials that would likely influence this policy.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	30468
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/15/2024	Document updated with literature review. Coverage unchanged. Added references 8 and 9.
01/01/2024	Reviewed. No changes.
07/01/2022	Document updated with literature review. Coverage unchanged. Added reference 10; others removed.
02/01/2022	Document updated with literature review. Coverage unchanged. Reference 10 added, others renumbered.
06/15/2021	Document updated with literature review. Coverage unchanged. References 4, 7, 8, 11 added.
09/01/2020	Reviewed. No changes.
07/15/2019	New medical document. The insertion of an absorbable lateral nasal implant for the treatment of symptomatic nasal valve collapse is considered experimental, investigational and/or unproven.