Medical Coverage Policy | Absorbable Nasal Implant for Treatment of Nasal Valve Collapse



EFFECTIVE DATE: 1 | 01 | 2019

POLICY LAST UPDATED: 10 | 20 | 2021

OVERVIEW

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 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.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

The insertion of an absorbable lateral nasal implant for the treatment of symptomatic nasal valve collapse is considered not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

The insertion of an absorbable lateral nasal implant for the treatment of symptomatic nasal valve collapse is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Medicare Advantage Plans and Commercial Products

Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage

BACKGROUND

Nasal valve collapse is a readily identifiable cause of nasal obstruction. Specifically, the internal nasal valve represents the narrowest portion of the nasal airway with the upper lateral nasal cartilages present as supporting structures. The external nasal valve is an area of potential dynamic collapse that is supported by the lower lateral cartilages. Damaged or weakened cartilage will further decrease airway capacity and increase airflow resistance and may be associated with symptoms of obstruction. Patients with nasal valve collapse may be treated with nonsurgical interventions in an attempt to increase the airway capacity but severe symptoms and anatomic distortion are treated with surgical cartilage graft procedures. The placement of an absorbable implant to support the lateral nasal cartilages has been proposed as an alternative to more invasive grafting procedures in patients with severe nasal obstruction. The concept is that the implant may provide support to the lateral nasal wall prior to resorption and then stiffen the wall with scarring as it is resorbed.

For individuals with symptomatic nasal obstruction due to internal nasal valve collapse who receive an absorbable lateral 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 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 1 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, eg, 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 (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 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.

CODING

Medicare Advantage Plans and Commercial Products

The following code(s) is not covered/not medically necessary:

C9749 Repair of nasal vestibular lateral wall stenosis with implant(s) implant placement

30468 Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)

Note: Physician work for the nasal implant placement would be billed with the unlisted CPT code 30999 (Unlisted procedure, nose). While some providers may use CPT 30465 (Repair of nasal vestibular stenosis [eg, spreader grafting, lateral nasal wall reconstruction]) for this service; the unlisted code is most appropriate.

RELATED POLICIES

None

PUBLISHED

Provider Update, December 2021 Provider Update, December 2020 Provider Update, January 2019

REFERENCES:

- 1. Howard BK, Rohrich RJ. Understanding the nasal airway: principles and practice. Plast Reconstr Surg. Mar 2002; 109(3): 1128-46; quiz 1145-6. PMID 11884847
- 2. Rhee JS, Weaver EM, Park SS, et al. Clinical consensus statement: Diagnosis and management of nasal valve compromise. Otolaryngol Head Neck Surg. Jul 2010; 143(1): 48-59. PMID 20620619
- 3. Fraser L, Kelly G. An evidence-based approach to the management of the adult with nasal obstruction. Clin Otolaryngol. Apr 2009; 34(2): 151-5. PMID 19413614
- 4. Stryker. Latera. http://www.spiroxmed.com/latera. Accessed August 20, 2021.
- 5. 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): 157-63. PMID 14990910
- 6. Lipan MJ, Most SP. Development of a severity classification system for subjective nasal obstruction. JAMA Facial Plast Surg. Sep-Oct 2013; 15(5): 358-61. PMID 23846399
- 7. Stolovitzky P, Senior B, Ow RA, et al. Assessment of bioabsorbable implant treatment for nasal valve collapse compared to a sham group: a randomized control trial. Int Forum Allergy Rhinol. Aug 2019; 9(8): 850-856. PMID 31226238
- 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. Nov 2018; 128(11): 2483-2489. PMID 29756407

- 9. Sidle DM, Stolovitzky P, Ow RA, et al. Twelve-month outcomes of a bioabsorbable implant for in-office treatment of dynamic nasal valve collapse. Laryngoscope. May 2020; 130(5): 1132-1137. PMID 31254279 10. Sidle DM, Stolovitzky P, O'Malley EM, et al. Bioabsorbable Implant for Treatment of Nasal Valve Collapse with or without Concomitant Procedures. Facial Plast Surg. Apr 14 2021. PMID 33853139 11. San Nicolo M, Stelter K, Sadick H, et al. Absorbable Implant to Treat Nasal Valve Collapse. Facial Plast Surg. Apr 2017; 33(2): 233-240. PMID 28388804
- 12. San Nicolo M, Stelter K, Sadick H, et al. A 2-Year Follow-up Study of an Absorbable Implant to Treat Nasal Valve Collapse. Facial Plast Surg. Oct 2018; 34(5): 545-550. PMID 30227454

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