FEP Medical Policy Manual

FEP 7.01.163 Absorbable Nasal Implant for Treatment of Nasal Valve Collapse

Effective Policy Date: January 1, 2023

Original Policy Date: January 2019

Related Policies:

None

Absorbable Nasal Implant for Treatment of Nasal Valve Collapse

Description

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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.

OBJECTIVE

The objective of this review is to determine whether the insertion of an absorbable lateral nasal implant for the treatment of symptomatic nasal valve collapse improves the net health outcome.

POLICY STATEMENT

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

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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	510(k) No.	Product Code	Indication
LATERA absorbable nasal implant	Spirox (part of Stryker)	2016	K161191	NHB	Supporting nasal upper and lower lateral cartilage

RATIONALE

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 a 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Otolaryngology-Head Neck Surgery

In 2010, the American Academy of Otolaryngology-Head Neck Surgery released a clinical consensus statement on the diagnosis and management of nasal valve compromise.[2,]No more recent guidelines were identified. Table 2 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 2. Consensus Agreement: Diagnosis and Treatment of Nasal Valve Compromise

Item	Statement	Level of Consensus
Definition	Nasal valve compromise is a distinct clinical entity separate from other anatomic reasons for nasal obstruction	Agreement/strong agreement
History and physical	Main symptom of nasal valve compromise 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 nasal valve compromise	Agreement/strong agreement
	Increased nasal obstruction associated with deep inspiration is consistent with nasal valve compromise	Agreement/strong agreement
Adjunctive tests	Criterion standard test to diagnose nasal valve compromise exists	Strong disagreement
Outcome measures	Various patient-reported outcomes (eg, 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

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2018	New policy	The policy was created to evaluate a single commercially available absorbable nasal implant product for treatment of internal nasal valve collapse. A literature search was conducted through September 4, 2018. The policy statement is investigational.
December 2019	Replace policy	Policy updated with literature review through August 12, 2019, references added. Policy statement unchanged
December 2020	Replace policy	Policy updated with literature review through September 2, 2020; no references added. Policy statement unchanged.
December 2021	Replace policy	Policy updated with literature review through August 18, 2021; reference added. Policy statement unchanged.
December 2022	Replace policy	Policy updated with literature review through August 31, 2022; reference added. Policy statement unchanged.