Rhinoplasty and Other Nasal Surgeries (for Louisiana Only)

Policy Number: CS107LA.Q
Effective Date: January 1, 2024

Instructions for Use

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Application

This Medical Policy only applies to the state of Louisiana.

Coverage Rationale

Lysis of intranasal Synechia is considered Reconstructive and medically necessary when:
- There is a documented Functional Impairment (e.g., obstruction, pain or bleeding) due to intranasal Synechia (adhesions/scar bands); **and**
- The Functional Impairment will be eliminated by lysis of the Synechia.

Lysis of intranasal Synechia is not considered Reconstructive and medically necessary in all other indications.

Nasal valve procedures/repair of nasal vestibular stenosis or alar collapse are considered Reconstructive and medically necessary when all of the following criteria are present:
- Other causes have been ruled out as the primary cause of nasal obstruction (e.g., sinusitis, allergic rhinitis, vasomotor rhinitis, nasal polyposis, adenoid hypertrophy, nasopharyngeal masses, nasal septal deviation, turbinate hypertrophy and choanal atresia); **and**
- Nasal septal deviation and turbinate hypertrophy have been previously surgically treated and failed, or are not needed; **and**
- Prolonged, persistent obstructed nasal breathing due to internal and/or External Nasal Valve compromise (see Definitions section); **and**
- Internal valve compromise due to collapse of the upper lateral cartilage and/or External Nasal Valve compromise due to collapse of the alar (lower lateral) cartilage resulting in an anatomic Mechanical Nasal Airway Obstruction that is a primary contributing factor for obstructed nasal breathing; **and**
- Photos clearly document internal and/or external valve collapse as the primary cause of an anatomic Mechanical Nasal Airway Obstruction and are consistent with the clinical exam.

Nasal valve procedures/repair of nasal vestibular stenosis or alar collapse are not considered Reconstructive and Medically Necessary in all other indications.

Rhinophyma excision is considered Reconstructive and medically necessary when all of the following criteria are present:

- One of the following:
  - Prolonged, persistent obstructed nasal breathing due to rhinophyma; **or**
  - Chronic infection or bleeding unresponsive to medical management due to rhinophyma; **and**
- Photos clearly document rhinophyma as the primary cause of an anatomic Mechanical Nasal Airway Obstruction or chronic infection and are consistent with the clinical exam; **and**
- The proposed procedure is designed to correct the anatomic Mechanical Nasal Airway Obstruction and relieve the nasal airway obstruction by correcting the deformity or the proposed procedure is designed to address the chronic infection.

Rhinophyma excision is not considered Reconstructive and medically necessary in all other indications.

Rhinoplasty for congenital anomalies is considered Reconstructive and medically necessary when the following are present:

- Rhinoplasty is performed for a nasal deformity associated with congenital craniofacial anomalies including, but not limited to Pierre Robin, Apert Syndrome, Fraser Syndrome, Binder Syndrome, Goldenhar Syndrome, Nasal dermoids, Tessier Nasal Cleft (most commonly #1) or associated with a cleft lip or cleft palate

Rhinoplasty for congenital anomalies is not considered Reconstructive and medically necessary in all other indications.

Rhinoplasty–primary is considered Reconstructive and medically necessary when all of the following criteria are present:

- Prolonged, persistent obstructed nasal breathing due to nasal bone and septal deviation that are the primary causes of an anatomic Mechanical Nasal Airway Obstruction; **and**
- The nasal airway obstruction cannot be corrected by septoplasty alone as documented in the medical record; **and**
- Photos clearly document the nasal bone/septal deviation as the primary cause of an anatomic Mechanical Nasal Airway Obstruction and are consistent with the clinical exam; **and**
- The proposed procedure is designed to correct the anatomic Mechanical Nasal Airway Obstruction and relieve the nasal airway obstruction by centralizing the nasal bony pyramid (30410) and straightening the septum (30420); **and**
- One of the following is present:
  - Nasal fracture with nasal bone displacement severe enough to cause nasal airway obstruction; **or**
  - Residual large cutaneous defect following resection of a malignancy or nasal trauma; **and**
- Nasal airway obstruction is causing significant symptoms (e.g., chronic rhinosinusitis, difficulty breathing); **and**
- Obstructive symptoms persist despite conservative management for 4 weeks or greater, which includes, where appropriate, nasal steroids or immunotherapy.

Rhinoplasty–primary is not considered Reconstructive and medically necessary in all other indications.

Rhinoplasty–secondary is primarily cosmetic. **However, it is considered Reconstructive and medically necessary when all of the following criteria are present**:

- Required as treatment of a complication/residual deformity from primary surgery performed to address a Functional Impairment when a documented Functional Impairment persists due to the complication/deformity (these codes are usually cosmetic); **and**
- Photos clearly document the secondary deformity/complication as the primary cause of an anatomic Mechanical Nasal Airway Obstruction and are consistent with the clinical exam; **and**
- The proposed procedure is designed to correct the anatomic Mechanical Nasal Airway Obstruction and relieve the nasal airway obstruction by correcting the deformity or treating the complication (these codes are usually cosmetic); **and**
- Nasal airway obstruction is causing significant symptoms (e.g., chronic rhinosinusitis, difficulty breathing); **and**
- Obstructive symptoms persist despite conservative management for 4 weeks or greater, which includes, where appropriate, nasal steroids or immunotherapy.

Rhinoplasty–secondary is not considered Reconstructive and medically necessary in all other indications.

Rhinoplasty–tip is primarily cosmetic. **However, it is considered Reconstructive and medically necessary when all of the following criteria are present**:

- Prolonged, persistent obstructed nasal breathing due to tip drop that is the primary cause of an anatomic Mechanical Nasal Airway Obstruction (this code is usually cosmetic); **and**
- Photos clearly document tip drop as the primary cause of an anatomic Mechanical Nasal Airway Obstruction and are consistent with the clinical exam (acute columellar-labial angle); **and**
- The proposed procedure is designed to correct the anatomic Mechanical Nasal Airway Obstruction and relieve the nasal airway obstruction by lifting the nasal tip; **and**
- Nasal airway obstruction is causing significant symptoms (e.g., chronic rhinosinusitis, difficulty breathing); **and**
- Obstructive symptoms persist despite conservative management for 4 weeks or greater, which includes, where appropriate, nasal steroids or immunotherapy.

Rhinoplasty–tip is not considered Reconstructive and medically necessary in all other indications.

Nasal Polypectomy is considered Reconstructive and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Polypectomy, Nasal.

Click here to view the InterQual® criteria.

Nasal Polypectomy is not considered Reconstructive and medically necessary in all other indications.

Nasal Septal Swell Body (NSB) reduction for the treatment of nasal obstruction is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy.

Absorbable polylactic acid nasal cartilage support implants [e.g., Latera Absorbable Nasal Implant (Stryker)] are unproven and not medically necessary for supporting nasal upper and lower lateral cartilage due to insufficient evidence of safety and/or efficacy.

Definitions

Check the definitions within the federal, state, and contractual requirements that supersede the definitions below.

Congenital Anomaly: A physical developmental defect that is present at the time of birth, and that is identified within the first twelve months of birth.

Cosmetic Procedures: Procedures or services that change or improve appearance without significantly improving Physiological Function.

External Nasal Valve: The caudal septum, along with lower lateral cartilage, alar rim, and nostril sill contribute to the external nasal valve.

Functional or Physical or Physiological Impairment: A Functional or Physical or Physiological Impairment causes deviation from the normal function of a tissue or organ. This results in a significantly limited, impaired, or delayed capacity to move, coordinate actions, or perform physical activities and is exhibited by difficulties in one or more of the following areas: physical and motor tasks; independent movement; performing basic life functions.

Mechanical Nasal Airway Obstruction: Trouble breathing through the nose (not snoring) due to a bony or cartilaginous deformity.

Prolonged, Persistent Nasal Airway Obstruction: Trouble breathing through the nose (not snoring) that has not responded to six weeks of medical management such as nasal steroids, antihistamines, and decongestants. Elimination of Rhinitis Medicamentosa as a cause for airway obstruction.

Reconstructive Procedures: Reconstructive Procedures when the primary purpose of the procedure is either of the following:
- Treatment of a medical condition
- Improvement or restoration of physiologic function

Reconstructive Procedures include surgery or other procedures which are related to an Injury, Sickness or Congenital Anomaly. The primary result of the procedure is not a changed or improved physical appearance.

Procedures that correct an anatomical Congenital Anomaly without improving or restoring physiologic function are considered Cosmetic Procedures. The fact that you may suffer psychological consequences or socially avoidant behavior as a result of an Injury, Sickness or Congenital Anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a reconstructive procedure.

Rhinitis Medicamentosa (RM): A condition of rebound nasal congestion brought on by extended use of topical decongestants (e.g., oxymetazoline, phenylephrine, xylometazoline, and naphazoline nasal sprays) and certain oral medications (e.g., sympathomimetic amines and various 2-imidazolines) that constrict blood vessels in the lining of the nose.

Synechia: An adhesion of parts, typically the nasal side wall to the septum.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Coding Clarifications:

- All nasal surgical claims may be subject to coding review. The following codes may be cosmetic; review is required to determine if considered cosmetic or reconstructive.
- Utilize CPT/HCPCS codes 30999 and L8699 to report absorbable nasal implants and the associated procedure rather than CPT code 30465.

CPT Code	Description
30117	Excision or destruction (e.g., laser) of intranasal lesion; internal approach
30120	Excision or surgical planning of skin of nose for rhinophyma
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
30460	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip only
30462	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip, septum, osteotomies
30465	Repair of nasal vestibular stenosis (e.g., spreader grafting, lateral nasal wall reconstruction)
30468	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)
30469	Repair of nasal valve collapse with low energy, temperature-controlled (ie, radiofrequency) subcutaneous/submucosal remodeling
30560	Lysis intranasal synechia
30999	Unlisted procedure, nose
31237	Nasal/sinus endoscopy, surgical; with biopsy, polypectomy or debridement (separate procedure)
31242	Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve

CPT Code	Description
31243	Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve
*L8699	Prosthetic implant, not otherwise specified

Codes labeled with an asterisk (*) are not on the State of Louisiana Medicaid Fee Schedule and therefore are not covered by the State of Louisiana Medicaid Program.

Description of Services

Rhinoplasty: A surgical procedure of the nose for reconstructive reasons to improve a nasal deformity, or a damaged nasal structure or to replace lost tissue, while maintaining or improving the physiological function of the nose. It can also be done for cosmetic purposes to correct or improve the external appearance of the nose.

Lysis Intranasal Synechia: A procedure that cuts bands of tissue that form between fused tissues in the nose.

Nasal Valve Procedures/Repair of Nasal Vestibular Stenosis or Alar Collapse: Surgical procedures to correct nasal valve or vestibule impairment caused by aging, congenital anomaly, or prior nasal surgery to restore the nasal airway.

Rhinophyma Excision: The surgical removal of nasal bumps, known as rhinophyma. In advanced cases, the condition may cause functional impairment, such as airway obstruction, and surgical removal is necessary to restore the airway.

Rhinoplasty for Congenital Anomalies: A rhinoplasty procedure to address a medical condition present at or from birth that significantly deviates from the common structure or function of the nose or nasal airway; these procedures are most commonly done to treat cleft lip and palate abnormalities, or for removal of a nasal dermoid.

Rhinoplasty–Primary: The first rhinoplasty operation performed on a nose.

Rhinoplasty–Secondary: Any subsequent or revision rhinoplasty surgeries performed on a nose.

Rhinoplasty–Tip: A surgical procedure of the tip of the nose to improve nasal function by repairing an existing defect or to enhance the appearance.

Nasal Polypectomy: A surgical procedure to remove polyps located in the nasal passages.

Nasal Septal Swell Body (NSB) Reduction: A procedure to address the symptoms of chronic rhinitis, chronic sinusitis, or nasal obstruction by decreasing the size of an enlarged NSB. Several methods of reducing enlarged NSBs have been used. The NSB is a thickened mucosa of the anterior nasal septum superior to the inferior turbinate and anterior to the middle turbinate. The NSB is also referred to in medical literature as nasal septal turbinate (NST), septal turbinate, Kiesselbach's body, septal swell body (SSB), nasal septal body, septal body, nasal swell body, swell body, septal erectile body, septal cavernous body, anterior septum tuberculum, and intumenscentia septi nasi anterior. The nasal vestibular body (NVB) is also described as a dynamic swell body situated inferior and anterior to the head of the inferior turbinate. It is felt that the NSB can impact nasal resistance because of its location in the internal valve area.

Absorbable Nasal Cartilage Support Implant: A synthetic nasal graft made out of polylactic acid (to stimulate collage production) that absorbs over two years, leaving behind a collagen track to support the nasal valve for the treatment of nasal congestion. It is not a drug eluting nasal stent. Latera (Stryker, Inc) is the only Food and Drug Administration (FDA) approved absorbable nasal implant at this time.

Lysis of Intranasal Synechia

A prospective, multi-institutional cohort study was completed by Henriquez et al. (2013) to evaluate the impact of synechiae formation on quality-of-life (QOL) outcomes after endoscopic sinus surgery (ESS) in patients with chronic rhinosinusitis. Rhinosinusitis Disability Index (RSDI) and Chronic Sinusitis Survey (CSS) scores were measured in adult patients before and after undergoing ESS for CRS. Differences in QOL were evaluated between those who developed sinonasal synechiae and those who did not, controlling for demographic factors, medical comorbidities, and measures of disease severity at baseline. The study included a total of 286 patients who underwent ESS between July 2004 and May 2012, with 55 (19.2%) developing synechiae in the follow-up period. Patients developing synechiae reported significantly less improvement on the RSDI total scores (13.5 vs. 21.4, p = 0.008), RSDI physical sub-scores (5.3 vs. 8.3, p = 0.007), RSDI emotional sub-scores (2.9 vs. 5.8, p = 0.008), CSS total scores (14.5 vs. 21.2, p = 0.093) and CSS symptom sub-scores (19.9 vs 30.3, p = 0.069) compared to those who did not develop synechiae postoperatively. These differences persisted even after controlling for baseline differences in disease severity. The authors concluded that synechiae of the sinonasal cavity commonly occurs following ESS, particularly in those undergoing revision surgeries. Although both groups improved, the degree of QOL improvement was less in those who formed postoperative synechiae after surgery compared to those who did not. Limitations included a lack of site specific synechiae information. Furthermore, the staging system used in the study did not discriminate synechiae by location, nor did it define the difference between mild and severe.

Rhinophyma Excision

Chauhan et al. (2020) completed a systematic review comparing laser therapy, scalpel excision, and subunit treatment outcomes on patients with rhinophyma from 1946 to 2020, using an OVID Medline literature search. From a total of 351 articles, 23 met criteria for inclusion. Among 12 studies, 247 patients with a mean age of 61 years and minor to major disease (minor, n = 67; moderate (n = 64); and major (n = 87) were treated with a carbon dioxide laser in an average of 1.1 sessions. A total of 18 patients was treated, with a mean age of 62 years, and a total of 1 patient with minor, 12 with moderate, and five with major rhinophyma using the erbium: YAG (Er:YAG) laser in 1.0 sessions. A total of 108 patients underwent cold knife tangential excision among eight studies. Patients had a mean age of 61 years, treated for minor to major rhinophyma, and all required a single session for treatment. Seven patients with a mean age of 67 years underwent treatment with a Shaw scalpel, and all required a single session for treatment. Eight patients (mean age 63 years) underwent treatment with the subunit method. Four patients had external valve collapse. Four patients received alar batten cartilage grafts, all had interdomal sutures, and one patient required a skin graft. Both the complication and revision rates were 75%, but only minor revisions under local anesthetic were required and no recurrence of disease was noted. The authors concluded that the subunit method had the highest complication and revision rates followed by carbon dioxide laser therapy. Outcomes between carbon dioxide laser and scalpel therapy and electrocautery were equivalent. They also concluded that scalpel excision was a cost-effective treatment modality with less post-operative complications; however, it risked poor hemostasis intraoperatively. Patient satisfaction was common post-therapy regardless of the treatment method. Over 89% of patients would recommend undergoing treatment for rhinophyma irrespective of treatment type. Treatment options vary, and choice of treatment can be dependent on practitioner and patients' treatment goals. Reporting of quantitative and qualitative outcomes between studies is not standardized. Further research with randomized controlled trials is needed to validate these findings.

Rhinoplasty

A meta-analysis by Zhao et al. (2022) was performed to evaluate the effects of functional rhinoplasty (FRP) on nasal obstruction in patients with nasal valve problems. A total of 57 cohorts from 43 studies involving 2024 patients were included in the current meta-analysis. Level of Evidence III. The Nasal Obstruction Symptom Evaluation (NOSE) scores indicated significant improvement in nasal obstruction at the 1-month, 3-month, 6-month, 12-month, and the last follow-up with respect to the preoperative baseline. The Visual Analogue Scale (VAS) scores indicated a similar trend at the 1-month, 3-month, 6-month, and last follow-up. Nasal obstruction was demonstrated as relieved through rhino-manometry but not through peak nasal inspiratory flow (PNIF). The authors concluded that FRP may have a positive effect on nasal obstruction caused by nasal valve problems. The findings of this study need to be validated by broader, well-designed studies.

A systematic review and meta-analysis by Pfaff et al. (2021) were performed to evaluate the effects of septoplasty, septorhinoplasty, and rhinoplasty procedures on post-operative olfactory function and their relationship to nasal airflow and quality of life. Pre-operative and post-operative values for olfaction, nasal airflow, and quality of life/nasal symptoms were

analyzed. The effect size was calculated from each study and used for meta-analysis. As studies evaluated patients at different points in the postoperative period, the latest time point reported by each study was used in the meta-analysis. All included studies were Level of Evidence II. There were 25 included studies. Three studies were randomized prospective studies, seven were comparative studies, and 15 were noncomparative studies Following nasal surgery, patients experienced significant improvements in olfaction ($p < 0.001$), nasal airflow ($p < 0.001$), and quality of life/nasal symptoms ($p < 0.001$). Patients often experienced a transient decrease in olfaction immediately after surgery, followed by improvement post-operatively. Pre-operative olfactory dysfunction rates were low and post-operative dysfunction was equally low. Olfaction improvement was directly correlated with improvement in nasal airflow and quality of life. The authors concluded that functional and aesthetic nasal operations appear to improve olfaction, which is directly correlated with nasal airflow. Some studies reported a transient worsening of these measures in the immediate post-operative period, which improved at later time points. The study is limited due to a heterogeneous patient population. In addition, due to smaller sample sizes, there is an inherent risk of publication bias.

Martin et al. (2021) completed a prospective randomized controlled trial (RCT) to evaluate the subjective and objective outcome of septoplasty (SPL) and septorhinoplasty (SRP) on patient satisfaction. Patients with functional indication for SPL (n = 19) or SRP (n = 54) were included and randomized for additional turbinoplasty. Preoperative clinical symptoms were collected with SNOT-20 GAV (Sinu-nasal outcome test-20—German adapted version) and NOSE© (nasal obstruction symptom evaluation) questionnaires. The final evaluation of treatment success was performed 9 months after surgery with SNOT-20 GAV, NOSE© and a self-established feedback questionnaire. Nasal breathing and obstruction were objectively measured with rhinomanometry and acoustic rhinometry [minimum cross-sectional area 2 (MCA2)]. Minimum cross-sectional area 2 was statistically improved compared to the pre-treatment value in SPL ($p = 0.0004$) and SRP ($p = 0.0001$). Regarding MCA2 values of matched patient groups, similar findings were detected (SPL: $p = 0.0013$, SRP: $p < 0.0001$). Sinu-nasal outcome test-20 GAV and NOSE© scores were reduced after both surgical procedures (NOSE©: SPL: $p < 0.0001$, SRP: $p < 0.0001$; SNOT-20 GAV: SPL: $p = 0.0068$, SRP: $p < 0.0001$). Evaluation of patient satisfaction in a self-established feedback questionnaire revealed a motivation of 81% of patients to redo the surgery (SPL 13/16, SRP 34/42) and a notably general satisfaction of 86% for SPL and 80% for SRP. The authors concluded that rhinosurgery leads improved nasal breathing and increased disease-specific satisfaction quantitatively. Further research with randomized controlled trials is needed to validate these findings.

Floyd et al. (2017) completed a systematic review and meta-analysis of studies evaluating functional rhinoplasty outcomes with the Nasal Obstruction Symptom Evaluation (NOSE) score. A search by the authors was performed with the terms ‘‘nasal obstruction’’ and ‘‘rhinoplasty.’’ Studies were included if they evaluated the effect of functional rhinoplasty on nasal obstruction with the NOSE score. Case reports, narratives, and articles that did not use the NOSE score were excluded. Functional rhinoplasty was defined as surgery on the nasal valve. The search resulted in 665 articles. After dual-investigator independent screening, 16 articles remained. Study results were pooled with a random effects model of meta-analysis. Change in NOSE score after surgery was assessed via the mean difference between baseline and postoperative results and the standardized mean difference. Heterogeneity was assessed and reported through the I^2 statistic. Patients in the included studies had moderate to severe nasal obstructive symptoms at baseline. The NOSE scores were improved at 3-6, 6-12, and ≥ 12 months, with absolute reductions of 50 points (95% CI, 45-54), 43 points (95% CI, 36-51), and 49 points (95% CI, 39-58), respectively. All these analyses showed high heterogeneity. The authors concluded that nasal obstruction as measured by the NOSE survey is reduced by 43 to 50 points (out of 100 points) for 12 months after rhinoplasty. However, the study is limited due to a heterogeneous patient population, large variability in outcomes beyond 12 months, and the potential for bias in observational studies.

Clinical Practice Guidelines

American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS)

A clinical practice guideline developed by the AAO-HNS states that rhinoplasty is often performed to enhance function by improving nasal respiration and relieving congenital or acquired obstruction. The AAO-HNS definition of rhinoplasty documented by Ishii et al. (2017) states that rhinoplasty as a surgical procedure that alters the shape or appearance of the nose while preserving or enhancing the nasal airway. The change in appearance may be a consequence of addressing a functional abnormality (e.g., deviated septum, nasal valve compromise) and for cosmetic purposes (e.g., an incidental cosmetic procedure). The primary reason for surgery can be aesthetic, functional, or both, and it may include adjunctive procedures on the nasal septum, nasal valve, nasal turbinates, or the paranasal sinuses. When these adjunctive procedures are performed without an impact on the nasal shape or appearance, they do not meet the definition of rhinoplasty and are therefore excluded from further consideration in the guideline.

American Society of Plastic Surgeons (ASPS)

The ASPS published a Nasal Policy Statement (2021) indicating that nasal surgery is considered reconstructive surgery and medically necessary to improve nasal airway function, to treat or revise anatomic abnormalities caused by birth defects or disease, and to revise structural deformities resulting from trauma.

Nasal Valve Procedures / Repair of Nasal Vestibular Stenosis or Alar Collapse/Nasal Valve Collapse/Nasal Airway Obstruction: A randomized controlled trial (RCT) was completed by Silvers et al. (2021) to evaluate the safety and efficacy of a temperature-controlled radiofrequency (RF) device for the treatment of the nasal valve for nasal airway obstruction (NAO). The objective of the trial was to compare active device treatment against a sham procedure (control). The study included a total of 117 patients assigned to two separate groups: bilateral temperature-controlled RF treatment of the nasal valve (n = 77) or a sham procedure (n = 40), in which no RF energy was applied. The device was applied to the mucosa over the lower lateral cartilage on the lateral nasal wall. The primary endpoint was responder rate at 3 months, defined as a ≥ 20% reduction in Nasal Obstruction Symptom Evaluation (NOSE)-scale score or ≥ 1 reduction in clinical severity category. At baseline, patients had a mean NOSE-scale score of 76.7 [95% confidence interval (CI), 73.8 to 79.5] and 78.8 (95% CI, 74.2 to 83.3) (p = 0.424) in the active treatment and sham-control arms, respectively. At 3 months, the responder rate was higher in the active treatment arm [88.3% (95% CI, 79.2%-93.7%) vs 42.5% (95% CI, 28.5%-57.8%); p < 0.001]. The active treatment arm had a decrease in NOSE-scale score [mean, −42.3 (95% CI, −47.6 to −37.1) vs −16.8 (95% CI, −26.3 to −7.2); p < 0.001]. Three adverse events at least possibly related to the device and/or procedure were reported, including vasovagal reaction, headache, and nasal bleeding with mucous which all resolved. The authors concluded that temperature-controlled RF treatment of the nasal valve is safe and effective in reducing symptoms of NAO in short-term follow-up. Limitations included the lack of masking of the investigators and relatively short follow-up.

Goudakos et al. (2016) performed a systematic review to assess knowledge and evidence of management options for the treatment of nasal valve collapse. Fifty-three studies were identified and systematically reviewed. The majority (50 of 53) of the included articles were graded as level IV evidence and only one randomized trial was identified. The included randomized study reported no difference in improvement between the intervention group (auto-spreader flap) and placebo arms. Most of the included studies presented in this systematic review provide level IV evidence concerning the optimal approach for cases of nasal valve collapse. At the time of the review, research was driven by reports of techniques rather than patient outcomes. The authors concluded that proper evaluation and identification of the cause of internal valve (INV) collapse is paramount prior to selection of the preferred surgical solution. Treatment approaches should be directed at specific involved sites in the INV and need to be tailored towards the patient's specific problem. This systematic review of the literature revealed that the available evidence is based on low-level studies and focuses more on the description of various surgical techniques rather than on patient-reported outcome measures, the latter of which is recommended in future studies. Further research with randomized controlled trials (RCT) is needed to validate these findings.

A systematic review was completed by Spielmann et al. (2009) to evaluate surgical treatment strategies for nasal valve collapse. The review included 43 articles from 1970 to 2008, with at least 10 patients in each study, stated aim to improve airway obstruction, and a minimum of one month follow-up for every patient. Of these studies, one trial presented level IIIb evidence, and all other studies were classed as level IV. Seven authors present objective measurements of nasal airflow or cross-sectional area, and four authors present validated outcome measures. The authors concluded that there is a variety of focused surgical techniques described which deal with nasal valve collapse. They could find no randomized controlled trials on nasal valve surgery. Research in nasal valve surgery is frequently driven by technical description of surgical technique rather than the establishment of evidence of long-term patient benefit. Although their understanding of the role of the nasal valve in the pathophysiology of nasal obstruction has improved vastly, the myriad of surgical techniques described reflects their uncertainty in choice of technique and in degree of patient benefit. Well designed, adequately powered, prospective, randomized controlled clinical trials of a single surgical technique are needed to further describe safety and clinical outcomes.

Clinical Practice Guidelines

American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS)

In the 2010 Clinical Consensus Statement by the American Academy of Otolaryngology – Head and Neck Surgery Foundation, Rhee et al. reported that published literature consistently noted the benefit of surgical treatment of nasal valve collapse (NVC), but the evidence relied mostly on uncontrolled studies. The panel generally agreed upon the anatomic and functional features that define NVC and that diagnosis of NVC is best done with history and physical exam findings. The panel found that there is a lack of a "gold standard" objective test for NVC although radiographic tests such as CT or MRI are mainly used to rule out other

disease processes such as sinusitis, nasal polyps, and neoplasms. While surgical treatment is the primary mode of treatment of NVC, surgical management was not reviewed by any specific surgical approach but was reviewed broad in scope. The panel met consensus with uniformly strong agreement that a surgical procedure that is targeted to support the lateral nasal wall/alar rim is a distinct entity from procedures that correct a deviated nasal septum or hypertrophied turbinate. There was consensus with agreement that, in some cases, septoplasty and/or turbinate surgery can treat NVC without surgery to support the lateral nasal wall/alar rim. With regards to medical management of NVC, the panel met consensus that nasal steroid medication is not useful for treating NVC in the absence of rhinitis, and mechanical treatments such as nasal stents may be useful in selected patients.

Nasal Septal Swell Body (NSB) Reduction

Various surgical approaches have been identified for the reduction of enlarged nasal septal swell bodies including radiofrequency ablation (RFA), coblation, and the use of micro-debridement. The evidence for NSB reduction are promising, however, current published quality evidence is lacking due to small sample sizes, lack of long-term follow-up, and weak study design. Additional robust, randomized trials with long-term results are needed.

Meng et al. (2021) conducted a systematic review of the existing knowledge on recent NSB developments. The review was performed using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. PubMed, Embase, Web of Science, Ovid, Cochrane Library, and Google Scholar were used for the literature search. Of the 345 journal articles that were initially obtained in the literature search, 28 were included in the review. Three articles evaluated NSB treatment outcomes: Yu et al., Kim et al., and Catalano et al. Yu et al. (described in detail below) conducted a prospective randomized controlled study that suggested a microdebrider-assisted procedure for inferior turbinate and NSB hypertrophy was superior to turbinoplasty alone. The review notes the limitations of Yu et al. were a small sample size (26 patients) and a short follow-up period. Kim et al. (described in detail below) conducted a study on using coblation to treat patients with an abnormally thickened NSB. The review notes Kim et al. demonstrated that coblation is an effective treatment option for NSB hypertrophy. Catalano et al. treated 60 patients with a prominent NSB using radiofrequency ablation (RFA). Nose obstruction symptom evaluation scores and NSB size scores were assessed at 3 and 6 months postoperatively. Patients reported satisfactory results and improved nasal congestion. One patient developed septal perforation which required attention. The authors concluded that it is still unclear if surgical intervention of the NSB for nasal obstruction improves the long-term therapeutic effect.

Ibrahim et al. (2020) conducted a retrospective cohort study to study the nasal vestibular body (NVB), persistent nasal obstruction, and the effects of treatment with RFA. The review included 35 patients with recalcitrant nasal obstruction. Twenty-five patients (48 sides) had NVBs reduced with RFA. Another cohort of ten patients (20 sides) had untreated NVBs. Follow-up included an assessment of healing and complications post-RFA at two timepoints, early (< 1 month) and late (mean, 7.3 months). A subset of patients who underwent RFA (18 of 25 patients) were compared with the 10 untreated patients using the 22-item Sino-Nasal Outcome Test (SNOT-22) and subdomain scoring. NVBs were found successfully reduced in all 35 patients (48 of 48 sides) who had NVBs reduced with RFA at both the early and late time-points. Early sequelae of RFA, including local crusting (22 of 23 patients) and bone exposure (4 of 23 patients), resolved with complete remucosalization (23 of 23 patients) by the late timepoint. No persistent pain, sensory loss, or pyriform aperture stenosis was observed in any patient. There were significant differences in reductions between mean pre- and postoperative SNOT-22 and individual subdomain scores observed in patients who had NVBs reduced with RFA (-24 and -2) compared to the reductions in patients who had untreated NVBs (-8 and -1). The authors concluded that treatment of the NVB using RFA is safe and effective and that RFA treatment of the NVB provides complete swell body reduction and significant improvement in nasal airway function with only transient local morbidity. The study is limited by the observational nature of the retrospective design, concurrent treatments, including septoplasty and turbinate reduction in many cases, and lack of adjustment for possible confounding factors.

Moss, et al. (2019) conducted a systematic review of the nasal septal turbinate (NST) to summarize and assess existing research and to evaluate its potential as a treatment target. The review was performed using the PRISMA guidelines. Medline, Embase, Web of Science, and Cochrane databases were used for the literature search. Of the 1,069 journal articles that were initially obtained in the literature search, 24 were included in the review. Four articles evaluated NST treatment outcomes: Haight et al., Catalano et al., Kim et al. and Yu et al.

Haight et al. conducted a prospective non-randomized study of 28 patients who underwent inferior turbinate reduction alone and 28 patients who underwent inferior turbinate reduction in conjunction with NST reduction. Both cryosurgery and cautery were utilized. At 10 to 16 weeks postoperatively, there were no differences in patient symptoms or rhinometry between the two

patient groups. Catalano et al. conducted a prospective study of NST RFA in 60 patients who had a history of a failed prior septoplasty and turbinate reduction. There were statistically significant reductions in nasal obstruction symptom evaluation (NOSE) scores: 41.6 at pre-treatment, 17 at month 3, and 21 at month 6. There were also statistically significant improvements in endoscopic middle turbinate visualization. There were three minor infections, one small, asymptomatic septal perforation, and five patients who required multiple treatments. Kim et al. (described in detail below) retrospectively reviewed nasal obstruction scores in 8 patients who underwent NST coblation. Utilizing a visual analog scale, an average pre-treatment score of 7.63 was reduced to 3.88 (month 3) 4.16 (month 6), and 4.63 (month 12). There were no complications reported.

Yu et al. (described in detail below) conducted a prospective randomized controlled study of 51 patients. Of those patients, 25 underwent a microdebrider submucous turbinate reduction alone and 26 underwent a concurrent NST reduction. At 3 months postoperatively, there were multiple statistically significant advantages in the NST group, including larger nasal obstruction score improvements (2.02 versus 1.43) and pronounced improvement in total nasal volume on rhinometry (0.83 mL versus 0.36 mL). Olfaction, rhinorrhea, and sneezing were similar between both treatment groups. There were no complications found related to NST reduction. The authors concluded that evaluating the NST as a treatment target is encouraging, as 3 of the 4 treatment studies found significant benefits to surgical intervention. There was no benefit with NST cautery or cryosurgery. NST RFA, coblation, and submucosa reduction were safe and effective. However, the studies included in the review have some limitations. Haight et al. was non-randomized and included multiple treatment modalities. Yu et al. was the only prospective randomized controlled trial. Kim et al. was retrospective and included only a small sample size. Study follow-up in these studies was rarely longer than 3 to 6 months, limiting conclusions about long-term results. Future prospective studies evaluating NST treatment as an isolated and adjunct treatment are needed.

In a retrospective, case-series study, Kim and associates (2016) presented the results of coblation NSB reduction for the treatment of nasal obstruction in patients with abnormally thickened NSB. The study was conducted at a single tertiary medical center; 8 patients underwent coblation NSB reduction. Pre- and post-operative nasal functions were evaluated by acoustic rhinometry and subjective symptom scales, as well as pre-operative CT scan images and nasal endoscopic findings. The post-procedure follow-up period was 3, 6, and 12 months. The mean maximal NSB width was 16.4 ±2.2 mm on pre-operative coronal CT scan images. The mean visual analog scale score for nasal obstruction was decreased from preoperative 7.63 (±0.99) points to 3.88, 4.16, and 4.63 points at 3, 6, and 12 months, respectively. Clinical satisfaction at 1 year was reported by 75% of participants. The authors concluded that coblation can be an effective treatment modality for nasal valve narrowing in patients with abnormally thickened NSB. Limitations to this study include small sample size and study design, lacking a comparison group.

Yu and colleagues (2015) conducted a prospective randomized study to evaluate the efficacy of septal body volume reduction (SBVR) for the treatment of septal body hypertrophy. Fifty-one subjects with nasal obstruction associated with septal body and inferior turbinate hypertrophy refractory to medical therapy were included. Conventional inferior turbinoplasty (ITR) was performed on 25 subjects (control group). A combination of ITR plus concurrent bilateral microdebrider-assisted SBVR was performed on 26 patients (study group). All were followed postoperatively for 3 months. The nasal symptoms, including nasal obstruction, rhinorrhea, itching, and sneezing, had significantly improved at 3 months in both groups. However, a greater improvement in nasal obstruction and a more significant increase in nasal volume were demonstrated in the study group with no AEs encountered. The researchers concluded that combined SBVR and turbinoplasty appears to be more effective than turbinoplasty alone for the treatment of nasal obstruction in patients with inferior turbinate and septal body hypertrophy. The study design did not however allow for evaluation of the long-term efficacy and safety of the procedure.

Absorbable Nasal Cartilage Support Implants

According to the manufacturer's website, the Latera implant is used to support upper and lower lateral cartilage in the nose, reinforcing the nasal wall like traditional cartilage and polymer grafts. Supporting the cartilage in this manner may reduce nasal airway obstruction symptoms and help patients breathe better. The Latera implant supports the upper and lower lateral cartilage by anchoring above the maxilla to provide cantilever support. Through a minimally invasive procedure, the nasal implant is inserted through a small incision made inside a patient's nose. (Stryker, 2019).

Current available evidence for absorbable nasal cartilage support implants, such as Latera, are promising for the treatment of nasal airway obstruction; however, overall, the evidence is of low quality with inadequate long-term follow-up, control-group comparisons and objective measurement tools. More robust, multi-center, randomized trials with long-term results are needed to demonstrate the safety and efficacy of these devices.

In an Evolving Evidence Review, Hayes (2021) completed a systematic search and findings summary on clinical studies, systematic reviews. The three prospective pretest/posttest studies and one randomized controlled trial (RCT) that were found were reviewed in full text with study quality, number of studies, use of a comparison group and whether the studies found clear advantages in patient-oriented outcomes included. They also searched for professional guidelines and position statements to evaluate guideline recommendations and whether the guidelines were evidence based; however, no relevant clinical practice guidelines or position statements were identified. Hayes concluded that, while available published evidence suggested absorbable nasal implants were technically reasonable to implant and were associated with reduced nasal airway obstruction and pain, the clinical studies and systematic reviews were of generally very poor quality. They noted that only one study had a control group to demonstrate whether absorbable nasal implants perform clinically better, worse, or similar to competing technologies.

In a single center, retrospective, non-randomized cohort study by Olson and Barrera (2021), the records of ninety patients diagnosed with septal deviation, inferior turbinate hypertrophy and nasal valve incompetence with lateral wall insufficiency who were treated between July 2016 until January 2019 were reviewed. All patients underwent septoplasty and inferior turbinate submucous reductions with correction of the nasal wall abnormalities managed by various approaches including insertion of an absorbable nasal implant, alar batten grafts, spreader grafts, or lateral crural strut grafts. Of those 90 patients, 50 underwent bilateral placement of the absorbable nasal implant, septoplasty, and inferior turbinate submucous reduction (SMR) while the other 40 patients underwent an open functional rhinoplasty with a variety of nasal valve techniques including septoplasty and SMR. The study groups were noted to be inequitable in that the treatment group consisted of older participants and a higher proportion of men choosing the implant. The authors reported that patients in both groups had a statistically significant difference in their pre- and post-operative NOSE and SNOT-22 scoring and the delta between the pre and post NOSE and SNOT-22 testing was not significantly different either. Limitations noted by the authors beyond the retrospective, single-center design include the age and gender differences between the two groups, that the surgical approach itself could also result in the improvements noted by the patients, and that the patients were not followed beyond 6 months post-procedure, so the long-term efficacy is not known. The authors concluded that the use of an absorbable nasal implant can be equivalent to a variety of open techniques in the reduction of the patient-reported outcome measures over a limited time.

In a follow-up of a cross-over trial by Stolovitzky et al. (2019), using a case series design, Bikhazi, et al. (2021) followed 40 of the sham participants who subsequently had absorbable nasal implants placed along with the initial 71 participants in the treatment group for up to 24 months post placement. At each follow-up visit at 3, 6, 12, 18, and 24 months, post implant assessment was completed that included collection of patient-reported outcome measures using the nasal obstructive symptom evaluation (NOSE), nasal obstruction visual analog scale (VAS), and the Epworth Sleepiness Scale (ESS) tools and adverse event monitoring. The authors reported that at all follow-ups from 3 months through 24 months, 70.0% or more participants reported improvement to mild or moderate NOSE scores, mean VAS score reduction was 29.7 points or greater and statistically significant and that the mean baseline ESS value for the whole participant cohort was within the normal range for the ESS, so while the changes in scores were statistically significant ($p < 0.001$), the clinical impact was unclear. The authors noted 34 device/procedure-related adverse events in 26 participants that were mild to moderate in severity and that resolved without clinical sequelae or were ongoing but stable at study completion. Study limitations the authors reported included the lack of long-term follow-up of the control arm, significant loss of study participants to follow-up at 18 months (74 participants) and 24 months (70 participants), a lack of an objective assessment tool for nasal valve collapse and an uneven distribution of participants of varying race or ethnicity. The authors concluded that use of an absorbable nasal implant is a safe and effective treatment option for dynamic nasal valve collapse in patients with severe to extreme nasal obstruction and that the procedure provides symptom improvement through 24 months following placement.

Kim et al. (2020) conducted a systemic review and meta-analysis on the effectiveness of using the Latera bioabsorbable implant to treat nasal valve collapse in patients with nasal obstruction. Five databases (PubMed, SCOPUS, EMBASE, Web of Science, and the Cochrane Database) were independently reviewed by two researchers. The review started at the earliest time point recorded in the database to September 2019. The inclusion criteria were studies that scored endoscopic lateral wall movement and nasal obstruction related to quality of life (QOL) postoperatively before and after bioabsorbable nasal implants and those that compared the outcomes of nasal implants (treatment group) with outcomes of sham surgery (control group). Five studies (396 patients) met the inclusion criteria, four of which being case series and one including a comparison group described in detail below (Stolovitzky et al. 2019). The authors found that bioabsorbable nasal implants significantly reduced endoscopic lateral wall motion compared to pretreatment values and improved QOL at 12 months postoperatively. Most adverse effects were reported with a 5% incidence rate following nasal implant and included skin or mucosal reaction, infection, or implant retrieval. All adverse outcomes resolved without significant sequelae. In one study, compared with the sham surgery (control

group), patients receiving bioabsorbable nasal implants (treatment group) significantly improved disease specific QOL. The authors concluded bioabsorbable nasal implants may reduce nasal wall movement and subjective symptom scores compared to preoperative status. However, more randomized clinical trials should be conducted to further verify the effectiveness of bioabsorbable nasal implants. This systematic review and meta-analysis is limited by lack of comparison group undergoing a different therapeutic approach in most of the included studies.

Sidle, et al, [2019, included in Kim (2020) systematic review above] performed a prospective multicenter case series to examine 12-month outcomes for in-office treatment of dynamic nasal valve collapse (NVC) with a bioabsorbable implant. One hundred sixty-six patients with severe-to-extreme class of Nasal Obstruction Symptom Evaluation (NOSE) scores were enrolled at 16 U.S. clinics (November 2016–July 2017). Patients were treated with a bioabsorbable implant (Latera, Spirox Inc., Redwood City, CA) to support the lateral wall, with or without concurrent inferior turbinate reduction (ITR), in an office setting. NOSE scores and Visual Analog Scale (VAS) were measured at baseline and 1, 3, 6, and 12 months postoperatively. The Lateral Wall Insufficiency (LWI) score was determined by independent physicians observing the lateral wall motion video. Using a disease-specific quality-of-life instrument and objective physical examination, the study shows that an in-office, minimally invasive procedure to stabilize the nasal wall with an absorbable implant significantly improves NAO symptoms in patients with dynamic NVC. The authors concluded that at12 months, the Latera implant is safe and efficacious for selected patients in whom dynamic NVC is a main contributor to their NAO. Longer follow-up is needed to determine efficacy beyond 12 months. Limitation of this study is lack of comparison with a group of participants receiving a treatment other than the Latera implant.

Stolovitzky et al. [2019, included in Kim (2020) systematic review above] conducted a multicenter, single-blinded randomized control study to evaluate the safety and effectiveness of a bioabsorbable implant (Latera) to support the lateral nasal wall in nasal valve collapse. 137 patients from 10 clinics were randomized into 2 arms: treatment arm (70 patients) and sham control arm (67 patients). Outcome measures were followed through 3 months after the procedure. The primary endpoint was the responder rate [percentage of patients with reduction in clinical severity by ≥ 1 category or ≥ 20% reduction in Nasal Obstruction Symptom Evaluation (NOSE) score]. There were no statistically significant differences in patient demographics and nasal obstruction symptom measures between the 2 arms. Three months after the procedure, responder rate was significantly higher for the treatment arm compared to the control (82.5% vs 54.7%, $p = 0.001$). Patients in the treatment arm also had a significantly greater decrease in NOSE score (-42.4 ±23.4 vs -22.7 ±27.9, $p < 0.0001$) and significantly lower visual analogue scale (VAS) scores (-39.0 ±29.7 vs -13.3 ±30.0, $p < 0.0001$) than the sham control arm. Seventeen patients reported 19 procedure/implant-related adverse events, all of which resolved with no clinical sequelae. The authors concluded that the study did show the safety and effectiveness of the bioabsorbable implant in reducing patients' nasal obstruction symptoms. However, there are limitations of this study. This study reports short-term follow-up data up to 3 months only. However, previous studies of the bioabsorbable implant have shown that patients' response to treatment stabilized at 3 months and were consistent with data observed at 12-month, 18-month, and 24-month follow-up. This is a single-blinded study in which all patients were blinded but physicians were aware of the assignment, which may have introduced risk of bias. Additionally, 8 participants in the implant group (11%) were excluded after randomization due to protocol deviation and implant retrieval and the data are analyzed per protocol rather than using intent-to-treat, which could have introduced biases in the findings.

Stolovitzky et al. [2018, included in Kim (2020) systematic review above] reported 6-month outcomes from a prospective, multicenter, single-blinded (blinded assessor) case series for treatment of nasal valve collapse due to lateral wall insufficiency. One hundred and one patients with severe-to-extreme class of Nasal Obstruction Symptom Evaluation (NOSE) scores were enrolled at 14 U.S. clinics. Some participants appear to overlap with these of Sidle, et al (2020) discussed above. Patients were treated with a bioabsorbable implant designed to support lateral wall, with or without concurrent septoplasty and/or turbinate reduction procedure(s). NOSE scores and visual analog scale (VAS) were measured at baseline and month 1, 3, and 6 postoperatively. The Lateral Wall Insufficiency (LWI) score was determined by independent physicians observing the lateral wall motion video. Forty-three patients were treated with implants alone, whereas 58 had adjunctive procedures. Seventeen patients reported 19 AEs, all of which resolved with no clinical sequelae. Patients showed significant reduction in NOSE scores at 1, 3, and 6 months postoperatively (79.5 ±13.5 preoperatively, 34.6 ±25.0 at 1 month, 32.0 ±28.4 at 3 months, and 30.6 ± 25.8 at 6 months postoperatively; $p < 0.01$ for all). They also showed significant reduction in VAS scores postoperatively (71.9 ±18.8 preoperatively, 32.7 ±27.1 at 1 month, 30.1 ±28.3 at 3 months, and 30.7 ±29.6 at 6 months postoperatively; $p < 0.01$ for all). These results were similar in patients treated with the implant alone compared to those treated with the implant and adjunctive procedures. Consistent with patient-reported outcomes, postoperative LWI scores were demonstrably lower (1.83 ±0.10 and 1.30 ±0.11 pre- and postoperatively; $p < 0.01$). The authors concluded that stabilization of the lateral nasal wall with a bioabsorbable implant improves patients' nasal obstructive symptoms over 6 months. Longer-term outcomes are needed to

validate the efficacy of a bioabsorbable implant for the treatment of nasal valve collapse. This study was also limited by lack of comparison group that did not receive the studied implant.

San Nicolo et al. [2017, included in Kim (2020) systematic review above] conducted a prospective case series to evaluate the safety and effectiveness of an absorbable implant for lateral cartilage support in subjects with nasal valve collapse (NVC) with 12 months follow-up. Thirty subjects with Nasal Obstruction Symptom Evaluation (NOSE) score ≥ 55 and isolated NVC were treated; 14 cases were performed in an operating suite under general anesthesia and 16 cases were performed in a clinic-based setting under local anesthesia. The implant, a polylactic acid copolymer, was placed with a delivery tool within the nasal wall to provide lateral cartilage support. Subjects were followed up through 12 months post procedure. Fifty-six implants were placed in 30 subjects. The mean preoperative NOSE score was 76.7 ±14.8, with a range of 55 to 100. At 12 months, the mean score was 35.2 ±29.2, reflecting an average within-patient reduction of -40.9 ±31.2 points. The majority (76%) of the subjects were responders defined as having at least one NOSE class improvement or a NOSE score reduction of at least 20%. There were no adverse changes in cosmetic appearance at 12 months post procedure. Three implants in three subjects required retrieval within 30 days post procedure and resulted in no clinical sequelae. The authors conclude that this study demonstrates safety and effectiveness of an absorbable implant for lateral cartilage support in subjects with NVC at 12 months post procedure. Well-designed randomized clinical trials with larger patient populations and longer follow-up periods are needed to further assess absorbable nasal implants. This study is limited by lack of comparison group.

Clinical Practice Guidelines

American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS)

In a 2015 position statement, the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) determined that the use of FDA-approved biomaterials can be utilized in sinonasal procedures to improve patient outcomes and reduce complications. These items, such as implants, stents, and packing materials, have functions including, but not limited to, local drug delivery, stenting, and hemostasis. The AAO-HNS does not consider FDA-approved biomaterials for rhinologic application to be investigational and recommends that the final decision regarding use of these biomaterials should be determined by the treating physician, factoring in best available scientific evidence, surgeon experience and the clinical situation, and individual patient preference. The references cited in the position statement do not specifically address non-steroid-releasing absorbable nasal implants, e.g., Latera.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The FDA classifies devices used for rhinoplasty and other sinus surgeries under product code LRC (instrument, ENT, manual surgical). This is a broad product code category that includes a variety of devices used in ear, nose, and throat surgeries (e.g., knives, hooks, injection systems, dilation devices). Additionally, this product code is 510(k)-exempt. Although manufacturers may voluntarily submit product information via the 510(k) process, it is not a requirement. All manufacturers are, however, required to register their establishment and submit a “Device Listing” form; these records can be viewed in the Registration and Device Listing Database (search by product code, device, or manufacturer name). Refer to the following website for more information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm. (Accessed January 31, 2022).

Intranasal septal splint devices are classified by the FDA as class 1 devices under product code LYA. This category includes over 40 devices including, but not limited to, Alar Nasal Valve Stent, Spiway Endonasal Access Guide, Novashield Injectable Nasal Packing and Stent and the Macropore Ent Reconstruction Film. The FDA has exempted almost all class I devices (except for reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the Federal Registers of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with 21 CFR 874.9. Refer to the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=874. (Accessed February 7, 2022).

The Latera Absorbable Nasal Implant (Stryker) received U.S. Food and Drug Administration (FDA) clearance through the 510(k) premarket notification pathway on June 23, 2016 and is indicated for supporting nasal upper and lower lateral cartilage. The System consists of the Latera Absorbable Nasal Implant and Accessory Delivery Device and is composed of a PLLA-PDLA copolymer. The predicate device, INEX Absorbable Nasal Implant (Spiros®), was cleared by the FDA on December 4, 2015.

For additional information, see:

- https://www.accessdata.fda.gov/cdrh_docs/pdf16/k161191.pdf
- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K161191

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Policy History/Revision Information

Date	Summary of Changes
01/01/2024	**Applicable Codes** • Updated list of applicable CPT codes to reflect annual edits; added 31242 and 31243 **Supporting Information** • Archived previous policy version CS107LA.P

Instructions for Use

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