Medical Coverage Policy

Effective Date.....11/12/2023
Next Review Date.....05/15/2024
Coverage Policy Number..... 0119

Rhinoplasty, Vestibular Stenosis Repair and Septoplasty

Table of Contents

Related Coverage Resources

Balloon Sinus Ostial Dilation for Chronic Sinusitis and Eustachian Tube Dilation
Gender Dysphoria Treatment
Orthognathic Surgery
Surgical Treatments for Obstructive Sleep Apnea

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted

for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses rhinoplasty, vestibular stenosis repair and septoplasty procedures for nasal airway obstruction and for other otolaryngology conditions related to cleft lip and cleft palate repair.

Coverage Policy

Coverage for rhinoplasty varies across plans and may be subject to the provisions of a cosmetic and/or reconstructive surgery benefit and may be governed by state and/or federal mandates. Refer to the customer's benefit plan document for coverage details.

Rhinoplasty & Vestibular Stenosis Repair

Rhinoplasty is considered medically necessary for ANY of the following indications:

- Correction or repair of a nasal deformity secondary to a cleft lip/palate or other severe congenital craniofacial deformity (e.g., maxillonasal dysplasia, Binder's syndrome, facial clefts) in a child five years of age or younger.
- Correction or repair of a nasal deformity secondary to a cleft lip/palate or other severe congenital craniofacial deformity (e.g., maxillonasal dysplasia, Binder's syndrome, facial clefts) in a child that is six years of age or older that is causing a functional impairment (i.e., nasal obstruction, inadequate airflow, feeding difficulties) when BOTH of the following criteria are met:
    - photographic evidence of the anatomical abnormality including frontal, lateral and worm's eye view (e.g., nasal base)
    - the functional impairment is expected to be resolved by the rhinoplasty

- Correction or repair of a nasal deformity secondary to trauma that is causing a functional impairment (i.e., nasal obstruction, inadequate airflow) and ALL of the following criteria are met:
    - nasal airway obstruction is poorly responsive to a recent six-week trial of conservative medical management (e.g., topical/nasal corticosteroids, antihistamines)
    - photographic evidence of the anatomical abnormality including frontal, lateral and worm's eye view (e.g., nasal base)
    - the functional impairment has either not resolved after previous septoplasty/turbinectomy or would not be expected to resolve with a septoplasty/turbinectomy alone
    - the functional impairment is expected to be resolved by the rhinoplasty

Vestibular stenosis repair is considered medically necessary when there is chronic nasal obstruction due to vestibular stenosis (i.e., collapsed internal valves) and there is demonstration of improvement of the airway by EITHER of the following methods:

- Cottle maneuver
- lateralization of the upper lateral cartilage from inside the nose with an object (e.g., cotton swab or nasal speculum)

Each of the following procedures is considered experimental, investigational and unproven:

- repair of nasal valve collapse with absorbable nasal implant(s) (e.g., Latera)
- radiofrequency of nasal valve for the treatment of nasal airway obstruction (e.g., VivAer ARC Stylus)
- posterior nasal nerve ablation using radiofrequency or cryoablation for the treatment of chronic rhinitis (e.g., RhinAer, ClariFix)

Rhinoplasty or vestibular stenosis repair when performed for EITHER of the following indications is considered cosmetic in nature and/or not medically necessary:

- solely for the purpose of changing appearance
- as a primary treatment for an obstructive sleep disorder when the above criteria for approval have not been met

Septoplasty

Septoplasty is considered medically necessary when performed for ANY of the following indications:

- septal deviation causing nasal airway obstruction resulting in prolonged or chronic nasal breathing difficulty or mouth breathing that has proved poorly responsive to a recent trial of conservative medical management (e.g., topical/nasal corticosteroids, antihistamines)
- recurrent epistaxis related to a septal deformity
- performed in association with a covered cleft lip or cleft palate repair
- obstructed nasal breathing due to septal deformity or deviation that has proved poorly responsive to medical management lasting at least six weeks and is interfering with the effective use of medically necessary continuous positive airway pressure (CPAP) for the treatment of an obstructive sleep disorder (i.e., obstructive sleep apnea with an apnea/hypopnea index [AHI] ≥ 15 as documented by polysomnography or home/portable sleep study)

Septoplasty for any indication not listed above is not covered or reimbursable.

Balloon dilation septoplasty for treatment of septal deviation is considered experimental, investigational and unproven.

General Background

The anatomy of the nose is made up of two main structural layers: the outer layer which contains the nasal soft tissues, lower lateral (alar) cartilages (lateral, middle and medial crura), and the associated linings; and the inner layer which contains the bony and upper cartilaginous vaults, the nasal septum, and their associated linings. The nasal region contains several nasal muscles, two of which are clinically significant: the levator labii alaeque nasi, which keeps the nasal valve open; and the depressor septi nasi, which shortens the upper lip and decreases tip projection. The

external anatomy of the nose consists of several anatomic landmarks that includes the radix, dorsum, supratip, tip, columella, nostrils, and alar rims.

Rhinoplasty
Rhinoplasty is a surgical procedure to correct a nasal deformity or to change the appearance of the nose. Although it is typically performed for cosmetic purposes to correct or improve the external appearance of the nose, there may be situations when it is considered reconstructive in nature. Rhinoplasty may be an open or closed procedure. Nasal deformities may be congenital (e.g., cleft lip/palate) or acquired (e.g., trauma, disease, ablative surgery). Nasal traumas may result in significant functional defects and nasal obstruction. The current management for many nasal injuries is closed reduction of nasal fractures. A second operation may be needed to treat the nasal deformity secondary to trauma that is causing a functional impairment (e.g., nasal obstruction, inadequate airflow). Conservative medical management should be attempted before surgical treatment is considered. Treatment may include antihistamine and decongestant use as well as topical steroid management. After trauma, there may be limited, specific situations where the nasal obstruction cannot be expected to be corrected by a septoplasty procedure alone (Kridel, et al., 2010).

Vestibular Stenosis Repair
Vestibular stenosis or collapse of the internal valves may be a cause of nasal obstruction. The nasal valve refers to tissue that acts as a bridge between the bony skeleton and the nasal tip and can account for approximately half of the total airway resistance of the entire upper and lower respiratory tract. Nasal valve compromise may account for nasal airway obstruction. The causes of internal nasal valve obstruction may include previous surgery, trauma, facial paralysis, and cleft lip nasal deformities (Schlosser and Park, 1999). The nasal valve has internal and external components. The internal nasal valve is the narrowest portion of the nasal cavity and compromise of these components of the valve may create symptoms of nasal obstruction. Deformities of the adjacent nasal septum or loss of anatomic support structures can predispose the valve to collapse or narrowing, which may cause airway obstruction. The upper lateral cartilage at its junction with the septum may be thickened, twisted, or concave because of weakness, trauma or prior surgery.

The external valve is a laterally based space that is surrounded by the anterior nasal opening in the skull, the upper lateral cartilage and lower lateral cartilage attachments, and the caudal septum (Kridel, et al., 2010).

A consensus panel was convened by the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) to create a clinical consensus statement for the diagnosis and management of nasal valve compromise (NVC) (Rhee, et al., 2010). The statement included:

- NVC is a distinct clinical entity for patients who present with symptomatic nasal airway obstruction and is best evaluated with history and physical examination findings
- Audible improvement in nasal airflow during a Cottle maneuver (manual lateral retraction of the cheek) or manual intranasal lateralization of the lateral nasal wall is consistent with NVC
- Endoscopy and photographs may useful, but are not routinely indicated
- Radiographic studies are not useful in evaluating NVC
- Nasal steroid medication is not useful for treatment of NVC in absence of rhinitis
- Mechanical treatments (e.g., nasal strips, stents, or cones) may be useful in selected patients
- Surgical treatment is the primary mode of treatment of NVC. The panel met consensus that 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.

The Cottle maneuver is a test of nasal valve integrity. It can be performed by retracting the cheek laterally, pulling the upper lateral cartilage away from the septum and widening the internal nasal valve angle. If the patient's symptoms are relieved with this maneuver, it suggests that the cause of the nasal airway obstruction is related to the nasal valve area (e.g., dorsal septal deviation, lack of upper lateral cartilage integrity) (Chandra, et al., 2009). Another technique to evaluate the nasal valves involves using an object (e.g., cotton swab or nasal speculum) to lateralize the upper lateral cartilage from inside the nose, and the patient is asked if their symptoms are improved. This technique allows direct observation of the nasal valve area as it widens (Chandra, et al., 2009).

Latera Absorbable Nasal Implant for Nasal Vestibular Lateral Wall Stenosis
The Latera implant is designed to support the lateral nasal cartilage. It is intended to treat nasal valve collapse, which may lead to nasal obstruction and difficulty breathing. According to the vendor, it is endoscopically placed inside the nasal wall in a minimally invasive procedure by otolaryngologists or plastic surgeons using the manufacturer provided accessory delivery device. The implant is intended to support the nasal cartilage and potentially reduce the symptoms of airway obstruction. It is composed of poly l-lactic acid (PLLA) and poly dlactic acid (PDLA) copolymer materials and is designed to be absorbed by the body within approximately 18 months after implantation.

U.S. Food and Drug Administration (FDA)
June 2016, the Spirox Latera Absorbable Nasal Implant System (Spirox, Menlo Park, CA) received 510(k) clearance intended to support cartilage in the nasal lateral wall.

The System consists of the Latera Absorbable Nasal Implant and Accessory Delivery Device. The Implant is composed of a PLLA-PDLA copolymer that is cylindrical in shape with an approximate diameter of one mm and overall length of 24 mm. The distal end of the implant is forked to facilitate anchoring during implantation and the proximal end is narrower for increased flexibility. The disposable delivery device is comprised of a non-patient contacting handle assembly and a medical grade stainless steel 16-gauge delivery cannula. The delivery device enables placement of the implant in a minimally invasive manner.

Literature Review – Latera Absorbable Nasal Implant
Bikhazi et al. (2021) reported the long-term follow up from the treatment and crossover arms of a randomized controlled trial (RCT) of an absorbable nasal implant for dynamic nasal valve collapse (DNVC) which was originally reported by Stolovitzky (2019). A total of 137 participants (71 treatment, 66 sham) were enrolled and treated in the original randomized cohort. Cross-over was offered to qualified sham participants at three months post implant. The forty remaining sham participants underwent a crossover procedure, resulting in 111 total participants in the combined treatment and crossover arms for long-term follow-up. Of the 111 subjects implanted, 88 completed the 12 month visit and 68 completed the 24 month visit. Inclusion criteria were comprised of a baseline NOSE score ≥ 55 and a positive modified Cottle maneuver. Additionally, participants were required to have documentation of lack of benefit or tolerability of at least 4 weeks of conservative medical management (e.g., nasal steroids or antihistamines). Participants were excluded if they required concurrent nasal procedures or had undergone endoscopic sinus surgery, septoplasty, inferior turbinate reduction, or rhinoplasty within six months before enrollment. External nasal dilators were not permitted during the study. Primary outcome measures included improvement in nasal obstruction (NOSE) scores and nasal airflow. A responder was defined as a participant with at least one NOSE class improvement or a NOSE score reduction of ≥ 20% compared with baseline. Secondary measures addressed patient satisfaction, QOL and improvement in sleep quality via the Epworth Sleepiness Scale (ESS). The mean patient reported visual analog score (VAS) reduction was ≥29.7 points and statistically significant ($p < 0.001$) at all time points. As mentioned, subject participation declined over the 24-month period.

The worst-case analysis resulted in lower NOSE responder rates and changes from baseline, especially at the 18-month and 24-month visits where there were more missing values. The authors assumed no change from baseline for all missing values and the NOSE responder rates at 18 months and 24 months, respectively, were 61.1% (95% CI 51.3%, 70.3%) and 55.0% (95% CI 45.2%, 64.6%).They determined the mean change from baseline remained statistically significant at −27.3 at 18 months and −23.9 at 24 months (both p <0.001). The mean baseline ESS value for the whole participant cohort was within the normal range (ESS ≥10). While the changes in scores were statistically significant (p <0.001), the clinical impact was unclear. The authors suggested reduction in nasal symptoms possibly reduced daytime sleepiness for patients who had problems with sleep quality. A total of 34 device/ procedure-related adverse events were reported in 26 participants. The most common adverse events reported among the 111 participants included: implant migration/retrieval (9%); pain or discomfort (4.5%); bumps on nose (3.6%); foreign body sensation (3.6%). Five participants underwent re-implant after device extrusion at a median of 21 days (range 0–133 days) after the initial placement. All device/ procedure related adverse events were considered mild to moderate in severity and resolved without clinical sequelae or were ongoing but stable at study completion. Study limitations included the lack of long-term follow-up of the control arm, significant loss of study participants to follow-up at 18 and 24 months, lack of objective assessment of nasal valve collapse and uneven distribution of participants of varying race or ethnicity. The authors concluded the Latera absorbable implant was a safe and effective in-office treatment option for DNVC in patients with severe to extreme nasal obstruction with maintained symptom improvement at 24 months post placement.

Kim et al. (2020) reported on a systematic review with meta-analysis to determine the efficacy of bioabsorbable nasal implant for treating nasal obstruction caused by lateral wall insufficiency (LWI). Five studies (n=396) were included in the study. 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) were included in the analysis. The study 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 following the nasal implant, such as skin or mucosal reaction, infection, or implant retrieval, were reported with a 5% incidence rate. All adverse outcomes were resolved without significant sequelae. Compared with sham surgery, bioabsorbable nasal implants significantly improved disease specific QOL. The authors concluded that bioabsorbable nasal implants may reduce nasal wall movement and subjective symptom scores compared to preoperative status, however more randomized clinical trials must be conducted to further verify the effectiveness of bioabsorbable nasal implants. The authors noted that larger comparative studies or well-designed randomized clinical trials with outcomes based on validated patient-reported outcome measures are still required to provide more definitive recommendations.

Sidle et al. (2020) conducted a prospective, multicenter, nonrandomized study to examine 12-month outcomes for in-office treatment of dynamic nasal valve collapse (NVC) with a bioabsorbable implant. The study included 166 patients with severe-to-extreme class of Nasal Obstruction Symptom Evaluation (NOSE) scores that were treated with a bioabsorbable implant (Latera) 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 one, three, six, and 12 months postoperatively. The Lateral Wall Insufficiency (LWI) score was determined by independent physicians observing the lateral wall motion video. One hundred five patients were treated with implant alone, whereas 61 had implant + ITR. Thirty-one patients reported 41 adverse events, all of which resolved with no clinical sequelae. There was reduction in NOSE scores throughout 12 months postoperatively (77.4 ± 13.4 baseline vs. 36.2 ± 22.7 at one month postoperatively, 33.0 ± 23.4 at 3 months, 32.1 ± 24.6 at six months, and 30.3 ± 24.3 at

12 months; P<0.001). There was significant reduction in VAS scores postoperatively (69.7 ± 18.1 baseline vs. 31.3 ± 27.1 at 12 months postoperatively, P<0.001). The results were similar in patients treated with implant alone and those treated with the implant + ITR. Consistent with patient-reported outcomes, postoperative LWI scores were demonstrably lower (1.42 ± 0.09 and 0.93 ± 0.08 pre- and postoperatively, P < 0.001). The authors note that limitations of this study include that this a single-arm study comparing pre- and posttreatment measurements of symptoms and that a future randomized controlled study should be considered to further examine the device efficacy. The study was limited to 12 months and additional follow-up out to 24 months would be beneficial.

Stolovitzky et al. (2019) conducted a prospective, multicenter, single-blinded randomized controlled trial to evaluate minimally invasive procedure addressing dynamic nasal valve collapse (NVC) with a bioabsorbable implant (Latera) to support the lateral nasal wall. The study included 137 patients randomized into two arms: treatment arm (70 patients) and sham control arm (67 patients). Patients in the active treatment arm received the implant, delivered using a cannula inserted into the nasal lateral wall, and those in the sham control arm had an identical cannula inserted into the nasal lateral wall but received no implant. Outcome measures were followed through three 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). At three months (27 patients included in the final analysis: 63 treatment; 64 sham control) responder rate was 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 study is limited by short follow-up (three months) and single-blinded design (patients were blinded but physicians were aware of the assignment) which may have introduced risk of bias.

Stolovitzky et al. (2018) reported on a multicenter, nonrandomized, single-blinded study that examined six-month outcomes for treatment of lateral nasal wall insufficiency with a bioabsorbable implant. The study included 101 patients with severe-to-extreme class of Nasal Obstruction Symptom Evaluation (NOSE) scores. The 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 one, three, and six months postoperatively. The Lateral Wall Insufficiency (LWI) score was determined by independent physicians observing the lateral wall motion video. Forty-three patients were treated with implant alone, and 58 with adjunctive procedures. Seventeen patients reported 19 adverse events, which resolved with no clinical sequelae. Patients showed reduction in NOSE scores at one, three and six months postoperatively (79.5 ± 13.5 preoperatively, 34.6 ± 25.0 at one month, 32.0 ± 28.4 at three months, and 30.6 ± 25.8 at six months postoperatively; P<0.01 for all). Reduction was noted in VAS scores postoperatively (71.9 ± 18.8 preoperatively, 32.7 ± 27.1 at one month, 30.1 ± 28.3 at three months, and 30.7 ± 29.6 at six 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). Limitations of the study include nonrandomized, single arm study design with short-term follow-up.

San Nicoló et al. (2017) reported on a prospective, single cohort, nonrandomized study that evaluated the safety and effectiveness of an absorbable nasal implant with 12 months follow-up. The study included 30 subjects with Nasal Obstruction Symptom Evaluation (NOSE) score 55 and isolated NVC; 14 cases were performed in an operating suite under general anesthesia and 16

cases were performed in a clinic-based setting under local anesthesia. 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. This study is limited by the small number of subjects, lack of a comparator and lack of randomization.

San Nicoló et al. (2018) reported on follow-up of the above study (San Nicoló, et al., 2017) to assess whether the safety and effectiveness of the implant persist in these patients for 24 months after the procedure. Subjects were followed up through 24 months post-procedure. The mean preoperative NOSE score was 76.7 ± 14.8, with a range of 55 to 100. At 24 months, the mean score was 32.0 ± 29.3, reflecting an average within-patient reduction of -44.0 ± 31.1 points. There were no device-related adverse events in the 12 to 24 months period. There were five subjects who exited the study prior to the 24-month follow-up.

Professional Societies/Organizations
In January 2022, the American Rhinologic Society (ARS) issued a position statement in support of the use of a bioabsorbable implants to treat patients presenting with nasal airway obstruction due to nasal valve collapse.

The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) guidelines do not address absorbable nasal implants.

Radiofrequency of nasal valve for the treatment of nasal airway obstruction (Vivaer ARC Stylus)
The Vivaer ARC Stylus (Aerin Medical, Inc., Sunnyvale, CA) is a disposable handheld device capable of delivering bipolar radiofrequency energy to tissue. The Vivaer ARC Stylus consists of a handle, shaft and treatment tip. An array of bipolar electrodes is positioned on a non-conductive tip which is attached to a handle via a non-conductive shaft. A temperature sensor is located on the tip to monitor tissue temperature. The Stylus is intended to attach to a temperature-controlled radiofrequency generator (Aerin Console) via a flexible cable. The Vivaer ARC Stylus is proposed to treat patients experiencing chronic nasal airway obstruction. During a treatment procedure, the clinician inserts the tip of the Vivaer ARC Stylus into a patient's nostril to deliver low power RF energy to the target tissue of the nasal airway. It is theorized that the low-power radiofrequency energy generates heat within the tissue, allowing the tissue to be repositioned by applying lateral pressure, and creating a coagulation lesion. As the lesion heals, the tissue retracts and stiffens which is thought to shrink and reshape the tissue to lessen the degree of obstruction.

U.S. Food and Drug Administration (FDA)
December 2017, the Vivaer ARC Stylus received 510(k) clearance (class II, K200300) for use in otorhinolaryngology (ENT) surgery for the coagulation of soft tissue in the nasal airway, to treat nasal airway obstruction by shrinking submucosal tissue, including cartilage in the internal nasal valve area.

Literature Review – Radiofrequency of nasal valve for the treatment of nasal airway obstruction (Vivaer ARC Stylus)
Silvers et al. (2021) conducted a prospective, multicenter, single-blinded, randomized controlled trial comparing temperature-controlled radiofrequency device treatment of the nasal valve (n=77) for nasal airway obstruction against a sham procedure (n=41). Inclusion criteria included: age 18 to 85 years; seeking treatment for nasal obstruction; a baseline Nasal Obstruction Symptom

Evaluation (NOSE) scale score ≥55, nasal valve collapse as the primary or a significant contributor to the nasal obstruction; a positive response to a temporary nasal dilation measure, such as the modified Cottle maneuver; and patient dissatisfaction with medical management. Key exclusion criteria included: previous surgery of the lateral nasal wall; a severe case of septal deviation; turbinate hypertrophy; polyps; or ptotic nose tip believed to be the primary contributor to the nasal obstruction symptoms and warranting surgical intervention. After administration of topical and local anesthesia, intervention patients were treated bilaterally with the Vivaer Stylus on up to four non-overlapping areas of the nasal mucosa at the junction of the upper and lower lateral cartilage on the lateral nasal wall. For the sham procedure, the stylus was applied in the same manner but without radiofrequency energy delivery, while audible tones mimicking activation of the Aerin Console were played. Patients were assessed at intervals with a physical and endoscopic exam, NOSE scale score, a 100-mm ease-of-breathing visual analog scale (VAS), and a 100-mm VAS for nasal pain. Results are through three months, but the trial is planned to continue with follow-up through two years. 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 three months, the responder rate was significantly 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 significantly greater 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 related to the device and/or procedure were reported, and all resolved. This study is limited by physicians not blinded which could have caused bias, medication use was not dictated by the protocol which could have impacted results, and short-term follow-up.

Yao et al. (2021) conducted a prospective, single-arm, open-label, multi-institutional study to evaluate the effectiveness of a low-power temperature-controlled radiofrequency procedure to treat the nasal valve and measure symptomatic improvement in patients diagnosed with nasal airway obstruction due to nasal valve collapse. Inclusions criteria included: age 18 years or older; NOSE Scale score ≥ 60; nasal valve was a primary or significant contributor to the patient's nasal obstruction as determined by the study investigator (based on clinical presentation, physical examination, nasal endoscopy); positive response to external nasal dilator strips (e.g., Breathe Right Strips), Q-Tip test (manual intranasal lateralization), use of nasal stents, or Cottle's Maneuver (manual lateral retraction of the cheek). Key exclusion criteria included: Prior surgical treatment of the nasal valve within six months; rhinoplasty, septoplasty, inferior turbinate reduction or other surgical nasal procedures within three months prior; anatomy that required an adjunctive surgical nasal procedure on the same day or three months after the study procedure; medical conditions which, in the opinion of the treating physician, would predispose the patient to poor wound healing or increased surgical risk. One hundred twenty-two patients underwent radiofrequency procedure with stylus was placed on the lateral wall of the nasal valve and treatment was applied to the mucosal tissue near the caudal end of the upper lateral cartilage at non-overlapping
loci. NOSE scale total scores at three months post-procedure were significantly improved relative to baseline, from 80.3 (± 12.6; range: 60-100) to 32.9 (± 24.2; range: 0-100), $P < 0.001$. At baseline, 100% of patients' total NOSE scale scores were in the 'extreme' (score of 80-100) or 'severe' (55-75) categories; at three months post-procedure this decreased to 18.5%. At the three-month visit, 91.6% of the patients had either a 20% improvement in NOSE scale total score relative to baseline or at least one severity category improvement. Ten adverse events that were considered related to the device or study procedure occurred, and all resolved during the study period. The study is limited due to lack of control group and short follow-up period.

Brehmer et al. (2019) conducted a prospective, nonrandomized study to evaluate the safety and efficacy of the Vivaer system for the treatment of narrowed nasal valves and to measure changes in the symptoms of nasal obstruction and snoring. The study involved 31 patients presenting with symptoms of nasal obstruction and snoring. Thirty days after the treatment, patients completed

two questionnaires measuring nasal obstruction and snoring (NOSE, Snore Outcomes Survey [SOS]). The patients´ satisfaction with the treatment was assessed 90 days after the intervention by means of a 10-point Likert scale (1 = completely dissatisfied; 10 = very satisfied). In all patients, an improvement was observed in nasal breathing measured by NOSE score, sleep quality by SOS questionnaire and quality of life as measured by EQ-5D and SNOT-22. The study is limited by the small number of participants, the lack of randomization, control group and comparator, and by the short follow-up period.

Jacobowitz et al. (2019) reported on a prospective, nonrandomized, multicenter case series to assess the safety and effectiveness of in-office bipolar radiofrequency treatment of nasal valve obstruction. The study included 50 patients with a Nasal Obstruction Symptom Evaluation scale (NOSE) score ≥60 and clinically diagnosed with dynamic or static internal nasal valve obstruction as primary or significant contributor to obstruction and were required to have a positive response to nasal mechanical dilators or lateralization maneuvers. Bilateral radio-frequency treatment was applied intranasally using a novel device (Aerin Medical's Vivaer Stylus), under local anesthesia in a single session. Safety and tolerance were assessed by event reporting, inspection and Visual Analogue Scale (VAS) for pain. Efficacy was determined using the NOSE score and patient-reported satisfaction survey at 26 weeks. No device or procedure-related serious adverse events occurred. Soreness, edema and crusting resolved by one month. The mean baseline NOSE score was 79.9 (SD 10.8, range 60-100), and all had severe or extreme obstruction. At 26 weeks, mean NOSE score was 69% lower at 24.7 (P<.0001) with 95% two-sided confidence intervals 48.5 to 61.1 for decrease. The decrease in NOSE score did not differ significantly between patients who did or did not have prior nasal surgery. Patient satisfaction mean by survey was 8.2 of 10. The study is limited by the small number of patients, lack of randomization, uncontrolled and lack of comparator, and short-term follow-up.

Ephrat et al. (2021) conducted a study to determine whether the results achieved with radiofrequency treatment at six months would be sustained through 24 months (follow-up to the above study [Jacobowitz, et al., 2019]). The study included 39 patients from original cohort of 49 patients with severe to extreme Nasal Obstruction Symptom Evaluation (NOSE) Scale scores and dynamic or static internal nasal valve obstruction as the primary or significant contributor to obstruction were studied. Patients received intranasal bilateral radiofrequency treatment in a clinical study with a follow-up to six months, and were prospectively evaluated at 12, 18, and 24 months. The patient-reported NOSE Scale score and 21 QOL questions were assessed. Clinically significant improvement from baseline in NOSE Scale score change demonstrated at six months (mean, 55.9; standard deviation [SD], 23.6; $p < 0.0001$) was maintained through 24 months (mean, 53.5; SD, 24.6; $p < 0.0001$). Responders (≥15-point improvement) consisted of 92.3% of participants at six months and 97.2% at 24 months. Responses to the QOL questions also showed improvement in patients' QOL. The authors note that it will be necessary to confirm the results of this study in additional patients as part of a planned randomized, controlled trial that may help determine the relative true treatment effect vs potential placebo effects.

Professional Societies/Organizations
The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) guidelines do not address radiofrequency of nasal valve for the treatment of nasal airway obstruction.

Posterior Nasal Nerve (PNN) Ablation/Cryotherapy for the Treatment of Chronic Rhinitis (e.g., RhinAer, ClariFix) The RhinAer procedure uses a RhinAer Stylus and an Aerin Console to perform bipolar low dose radiofrequency ablation to the nasal tissue, specifically the PNN (posterior nasal nerve). The RhinAer Stylus is a disposable handheld device which delivers bipolar radiofrequency energy to nasal tissue. It is indicated for use in otorhinolaryngology (ENT) surgery for the destruction of soft tissue in the nasal airway, including in posterior nasal nerve regions in patients with chronic rhinitis. Per the manufacturer, the procedure disrupts the posterior nasal

nerve (PNN) that triggers rhinitis and treats the full length of the turbinate. The ClariFix is a minimally invasive procedure using cryotherapy to ablate the PNN under topical or local anesthesia to treat chronic rhinitis.

U.S. Food and Drug Administration (FDA)
September 2019, the RhinAer® Stylus (Aerin Medical Inc.) received 510(k) clearance (class II, K192471) for use otorhinolaryngology (ENT) surgery for the destruction of soft tissue in the nasal airway, including in posterior nasal nerve regions in patients with chronic rhinitis. The ClariFix device was cleared by FDA 510(k) on February 14, 2017 as a cryosurgical tool to treat adults with chronic rhinitis. The clearance was based on a study of 27 individuals and a review of related published literature regarding the use of cryosurgical ablation of tissue in the nasal passageways to treat rhinitis.

Literature Review – Radiofrequency of PNN for the treatment of chronic rhinitis (RhinAer)
In 2021 Stolovitzky et. al., published the results of a multicenter, prospective, single-blinded, randomized controlled trial (RCT), of the RhinAer procedure to determine the safety and efficacy of temperature-controlled radiofrequency (TCRF) neurolysis of the posterior nasal nerve (PNN) area for the treatment of chronic rhinitis.
Patients with 24-hour reflective Total Nasal Symptom Score (rTNSS) ≥ 6, including moderate to severe rhinorrhea and mild to severe congestion (n=117, age 18-85), were randomized 2:1 to active treatment of the PNN area with a temperature-controlled TCRF device (n=78) or a sham procedure, with no TCRF energy delivery (n=39). The primary outcome measure was responder rate at three months. A response was defined as ≥ 30% improvement (decrease) in rTNSS from baseline. Results suggested treatment with the RhinAer procedure was more effective than sham ablation in improving short-term rTNSS scores. Secondary outcomes included the mean change in rTNSS from baseline through three months and the rate of device and procedure related adverse events. Primary outcome analysis demonstrated a significantly higher responder rate in the active treatment arm than in the sham control arm: 67.5% (95% CI, 55.9-77.8%) versus 41.0% (95% CI, 25.6-57.9%), p = 0.009. Three adverse events related to the device/procedure were reported (severe nostril pain accompanied by headache and earache; severe bleeding the night following the procedure; and increased nasal congestion and sinusitis one-month post-op). All adverse events resolved. Among the limitations were a short-term follow-up period, unblinded investigators, and confounding effects of uncontrolled medication on symptom relief as measured by rTNSS. The subjects will be followed for up to two years. Investigators noted long-term follow-up is needed to demonstrate the durability of the treatment effect.

Ehmer et al. (2022) conducted a prospective, single-arm multicenter study with follow-up through 52 weeks. The study aimed to determine the outcomes of patients diagnosed with chronic refractory rhinitis and treated with temperature-controlled radiofrequency (RF) neurolysis of the posterior nasal nerve (PNN) area in a minimally invasive procedure. To be eligible for the study, participants had to have had chronic rhinitis symptoms for at least six months without adequate response to at least four weeks of treatment with intranasal steroids. Additionally, participants had to have an overall 12-hour Reflective Total Nasal Symptom Score (rTNSS) ≥ 6 with sub-scores of 2-3 for rhinorrhea, 1-3 for nasal congestion, and 0-3 for each nasal itching and sneezing. The temperature-controlled radiofrequency energy was delivered via the nasal cavity mucosa overlying the PNN region with a novel single-use, disposable, handheld device. The study resulted in 50 individuals being treated, with 47 completing the study at 52 weeks. The average rTNSS improved from 8.5 at baseline to 3.6 at 52 weeks, showing a 57.6% improvement. Similarly, improvements were noted for rTNSS sub-scores for rhinorrhea, nasal congestion, itching, sneezing, postnasal drip, and chronic cough scores. Treatment was effective regardless of rhinitis classification according to the subgroup analysis. Adverse events (AEs) were recorded in 16 individuals, with eight events considered device or procedure related. Although the study resulted in significant

improvements in symptoms of chronic rhinitis after temperature-controlled RF neurolysis of the PNN area, limitations to the study exist. Limiting factors include lack of control or blinding and possible placebo effects contributing to the reported outcomes. More extensive, controlled studies are necessary to demonstrate the device's efficacy.

Per the NIH clinical trials website, there is a clinical trial on "A Study of RhinAer ARC Stylus for Treating Chronic Rhinitis (RELIEF)" that is active, but not recruiting (Last update posted September 2022) with an estimated study completion date is August 2024 (NCT04614324).

The current published studies are industry-sponsored with 12 months or less follow-up. Further studies with long-term follow-up are needed.

Literature Review – Cryotherapy of PNN for the treatment of chronic rhinitis (ClariFix)
Chang and colleagues (2019) conducted a prospective multicenter study to evaluate the efficacy and safety of cryosurgical ablation (CSA) for the treatment of rhinitis. Ninety-eight adults, aged 21-70, with chronic, medically intractable rhinitis were treated with PNN cryoablation. Participants (aged 21 and older) with a minimum total score of 4 out of 12 on the Reflective Total Nasal Symptom Score (rTNSS), chronic moderate to severe allergic or non-allergic rhinitis symptoms and have failed medical therapy were included in the study. Excluded were participants with anatomy limiting visualization and access to the posterior nasal cavity, ocular symptoms, sinus infection, recent history of epistaxis, bleeding disorder, anticoagulation medication, Raynaud's disease, and/or pregnancy. All 98 participants underwent PNN cryoablation in-office under local anesthesia. Patients discontinued use of intranasal ipratropium 3 days prior to treatment and throughout the study period. There were no comparators. The primary clinical endpoints were post-procedure change in rTNSS relative to baseline at 1, 3, 6 and 9 month intervals and safety (adverse events). The Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) was completed at pretreatment and again at three months post-treatment. Following treatment, the total rTNSS scores were significantly improved over baseline at all post-procedure evaluations: baseline (6.1 ± 1.9), at 1 month (2.9 ± 1.9, $p<0.001$), 3 months (3.0 ± 2.3, $p<0.001$), 6 months (3.0 ± 2.1, $p<0.001$), and 9 months (3.0 ± 2.4, $p<0.001$). The authors defined the minimal clinically important difference (MCID) as a 30% reduction in baseline score. Following the procedure, 29 adverse events (AEs) related to the procedure or device were reported. Adverse events included two instances of epistaxis requiring office cautery or suction cautery in the operating room; two cases of new ostia (one uncinate process perforation and one maxillary sinus accessory os); and one case of nasal synechia. Other reported AEs were headache, eye dryness and sinus infections. The study was limited by a lack of control group, unblinded provider and patient, short term follow up period, participant loss to follow up and exclusion only for use of intranasal corticosteroids (but not other medications that would affect rhinorrhea). The authors concluded cryoablation of the PNN for chronic rhinitis was safe, could decrease nasal symptoms of rhinitis, and could improve disease-specific quality of life. They acknowledged future randomized controlled studies, perhaps incorporating a sham treatment arm, would be helpful to further validate the efficacy of PNN cryoablation.

Ow and colleagues (2021) published additional post-procedure results (12-24 months) of the prospective single-arm study above (Chang, 2019). Individuals were evaluated by office visit or phone for changes Reflective Total Nasal Symptom Scores (rTNSS) scores from baseline at 12 and 24 months. Ninety-one participants completed the study through the initial 12-month study period. Sixty-two participants consented to the long-term follow-up with 57 completing the 24-month follow-up. Significant improvements in the total rTNSS were reflected in a median change from baseline of −3.0 or −4.0 at all time points ($P < .001$). Greater than 80.0% of participants achieved the minimum clinically important difference (MCID) of improvement by ≥1 point on the rTNSS at all follow-ups. Total RQLQ scores indicated significant improvement ($P < .0001$) in quality of life. Over 77% of participants achieved the MCID (≥0.5 points) for the total RQLQ score. One participant experienced two treatment-related serious adverse events (epistaxis and retained

pledget). A total of 29 nonserious treatment-related AEs were reported in 23 participants; most events were transient and resolved with little to no intervention. This follow-up study is limited by single arm design without a concurrent control arm and loss of 30% of the participants after the 12-months. The authors concluded cryotherapy significantly and clinically improves rhinitis symptoms and quality of life with outcomes that are durable through 24 months after treatment. Randomized trials with a control or sham treatment arm evaluating outcomes are needed to evaluate the relative net health benefit of this treatment compared to standard treatment.

Hwang and colleagues (2017) reported on a series of 27 adults who were treated with the ClariFix cryoablation device for allergic and non-allergic rhinitis with or without nasal congestion symptoms despite medical therapy ≥ 3 months. Individuals were evaluated using the total nasal symptom score (TNSS) and those with a minimum rhinorrhea and/or congestion subscore of two (moderate symptoms) were included. Treatment was completed in office under topical or injected local anesthesia. TNSS mean scores decreased significantly at 7 days post-procedure compared to baseline (6.2 ± 0.5 versus 4.3 ± 0.4; $p<0.005$). At 90 days, the 27 individuals continued to report a decline in the TNSS mean score at 2.7 ± 0.4; $p<0.001$. While the TNSS scores continued to decline at 180 days (2.3 ± 0.5) and 365 days (1.9 ± 0.3), six individuals (22%) were lost to follow-up at 180 days and 12 individuals (44%) were lost to follow-up at 365 days. Subjects reported mild pain/discomfort, severe ear blockage and severe nasal dryness, all of which had improved or resolved at the 30-day follow-up. A moderate nosebleed reported approximately one-month post-procedure, was managed by electrocautery. The findings of this study were limited by its small size and the high rate of subject attrition during follow-up. In addition, as medication use was not tracked during the study, other factors for improvement in symptoms may have confounded the results. The authors concluded cryotherapy of the PNN region is safe and well tolerated.

Professional Societies/Organizations
In January 2023, the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) released a statement that endorsed the use of PNN ablation for the treatment of medically refractory chronic rhinitis.

In January 2022, the American Rhinologic Society (ARS) published a position statement in support of posterior nasal nerve ablation for the treatment of chronic rhinitis, including both allergic and non-allergic subtypes.

The American Academy of Allergy, Asthma, and Immunology publication, Rhinitis 2020: A Practice Parameter Update, does not reference low-temperature radiofrequency energy/ thermal ablation of nasal nerves as a treatment modality for rhinitis (Dykewicz et al.,2020).

Septoplasty
Septoplasty is the surgical correction of a deformity of the nasal septum, which is the partition that divides the nasal cavity into two chambers. Septal deformity can be congenital or caused by trauma. The initial method of assessing nasal breathing function is by taking the patient's history. This should include asking patient specifically about the symptoms of nasal obstruction. The side of obstruction, its severity, frequency, duration, and exacerbating factors are recorded (Corey, et al., 2010; O'Handley, et al., 2010). Physical examination may demonstrate the septum obstructing the nasal airway if anterior. If more posterior, nasal endoscopy or computed tomography (CT) scan may be necessary. The examination may include an assessment by the physician of the appearance of the intranasal anatomy, the cross-sectional area, and the condition of the lining tissues of the nose. The assessment may utilize the aid of a speculum and headlight or head mirror. In addition, endoscopy may be performed, typically with a small flexible scope, but sometimes with a rigid scope (O'Handley, et al., 2011; Corey, et al., 2010).

Nasal obstruction is a feeling of blockage or insufficient air flow through the nose. In cases of nasal obstruction, once the diagnosis has been established, the treatment plan is based on the diagnosis. If the nasal obstruction is secondary to one of the several types of rhinitis, it is treated medically (Han, et al., 2015). This may include nasal steroids, antihistamines, leukotriene inhibitors, mucolytics, oral decongestants, topical decongestants, and/or nasal saline. These medications may be used individually, or in various combinations. The choice of medications is determined by the severity of symptoms, patient's medical history and response to treatment. Oral steroids may be used in select severe cases but are associated with potential significant side effects. Nasal decongestant sprays are utilized for treating severe nasal congestion but should be used sparingly and never for longer than three days, to prevent rebound nasal obstruction. Antibiotics are administered in the case of bacterial infection or acute rhinosinusitis (O'Handley, et al., 2011; Corey, et al., 2010). In cases with septal deviation that is severe enough to cause symptoms of obstruction that are consistent with intranasal physical findings, septoplasty may be necessary.

The nasal turbinates, also known as concha, are thin, curved bony plates located in the nasal cavity. Hypertrophy of the turbinates can cause nasal obstruction and may lead to sinusitis (Mickelson and Benninger, 2001). Septoplasty corrects nasal septum defects or deformities by alteration, splinting, or removal of obstructing supporting structures. Resection of the turbinates may also be performed with the septoplasty.

Septoplasty and rhinoplasty procedures may involve the use of grafts, in particular grafts obtained from the septum (Flint, et al., 2010). Harvested septal cartilage may also be used for spreader grafts for stenting of the internal nasal valve angle or batten grafts for bolstering the valve area during repair of the nasal valves.

A degree of septal deviation is present in most individuals without accompanying functional impairment. In these cases, it is not considered medically necessary to correct the condition. Deviations in the septum can alter normal airflow, which may result in mucosal changes. This interference in airflow may also cause middle or inferior turbinate abnormalities. Sinus drainage may also be compromised by deviation of the septum and can result in recurrent or chronic sinusitis. The decision for septoplasty is not typically based solely on the degree of deviation alone, but rather based on the accompanying functional impairment in the form of obstructed nasal breathing and any resulting conditions, such as sinusitis. A case is considered refractory to medical management when there has been a sufficient period of treatment with antibiotics for infections, intranasal steroids, and decongestants (Mickelson and Benninger, 2001).

Rhinosinusitis is defined as symptomatic inflammation of the paranasal sinuses and nasal cavity. Sinusitis is almost always accompanied by inflammation of the contiguous nasal mucosa and therefore is referred to as rhinosinusitis. The American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) clinical practice guidelines for adult sinusitis note that rhinosinusitis can be classified by duration (Rosenfeld, et al., 2007):

- Acute: less than four weeks
- Subacute: four to twelve weeks
- Chronic: more than 12 weeks, with or without acute exacerbations
- Acute rhinosinusitis may be further classified by symptom pattern into acute bacterial rhinosinusitis (ABRS) or viral rhinosinusitis
- Recurrent acute rhinosinusitis: four or more acute episodes per year of ABRS, without persistent symptoms between episodes

Surgical intervention is not appropriate for uncomplicated ABRS but may have a role in managing recurrent ABRS and chronic rhinosinusitis when septal deviation is present and a factor in the

condition. Septal deviation is an anatomic variant that might predispose to sinus obstruction and inflammation.

There may be situations where a septal deformity may not be causing specific sinus symptoms; however, its presence is preventing surgical access to other intranasal or paranasal areas such as the sinuses or turbinates. Septoplasty may be performed to allow surgical access to these areas so that a medically necessary surgery may be successfully performed.

While the most common cause of epistaxis is idiopathic, it may also be caused by primary neoplasms and traumatic or iatrogenic causes (Simmen and Jones, 2010). Septoplasty may be necessary to allow adequate access to a vessel that is causing recurrent epistaxis. In this situation, a septal deformity may cause abnormal air turbulence, severe mucosal drying and crusting, which can lead to recurrent nosebleeds. Identification of known or suspected bleeding site should be documented when the purpose of surgery is to control epistaxis. Septoplasty may decrease the frequency of the epistaxis episodes (Simmen and Jones, 2010).

Extracorporeal septoplasty is a technique that involves removing the nasal septum, straightening the septum by various techniques, and then reimplanting the septum (Fettman, et al., 2009). It is a procedure that may be utilized to correct very severe, complex nasal deformities. The techniques for straightening the septum include the graft may be drilled, or partial thickness releasing incisions can be scored into the concave side (Fettman, et al., 2009).

Balloon Dilation Septoplasty
Balloon dilation septoplasty has been proposed for treatment of septal deviation. The procedure is proposed for mild cases of septal deviation. In this procedure, a topical anesthetic is used to anesthetize the nasal cavity. A balloon catheter is inserted into the nose and inflated to move the septum to the midline. A traditional septoplasty is the definitive treatment in patients with nasal obstruction due to septal deviation (Bhattacharyya, 2022).

The published scientific evidence for the treatment of septal deviation with balloon dilation septoplasty is lacking.

Balloon dilation septoplasty as a treatment for septal deviation is not included in professional/specialty organizations guidelines.

For information on balloon sinus ostial dilation (balloon sinuplasty) and eustachian tube balloon dilation (ETBD) procedures, please refer to the Balloon Sinus Ostial Dilation for Chronic Sinusitis and Eustachian Tube Dilation Coverage Policy.

Professional Societies/Organizations
The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) reviewed the use of medical management (four-week trial of nasal steroid) prior to septoplasty and were unable to reach consensus regarding value in assessment of surgical candidacy. In some patients, the deviated septa may be severe due to trauma. Some panel surgeons indicated in this instance no amount of medical management would alleviate the nasal obstruction. The panel agreed if the surgeon decided to proceed with a preoperative trial of medical management, such a trial does not need to be longer than 4 weeks. The panel felt due to the paucity of specific treatment duration recommendations in the literature, a 4-week trial would be clinically sufficient to assess symptomatic improvement prior to proceeding with a septoplasty (Han, et al., 2015).

Cleft Lip/Palate and Nasal Surgery
Congenital birth defects have a variety of presentations, including cleft nasal deformity, which may be associated with cleft lip and/or cleft palate, where the nasal structures are distorted and

abnormally developed. Some congenital abnormalities may not be fully evident until years later. Surgical correction of congenital birth defects may involve staged procedures, flaps, or grafts. Since the clefts of palate and lip vary in size, shape and degree of deformity, the planning of the stages of surgery should be individualized. Nasal correction associated with cleft lip/palate may be delayed until adolescence or performed at the time of initial repair. Children with cleft lip and/or palate usually have a deviated nasal septum due to the asymmetric bony base associated with the defect. Initially, the deviation may not cause airway problems due to the facial cleft providing a patent, low-resistance airway passage. As a result of the repair of the facial cleft, the nasal resistance increases, and the deviated septum may then cause nasal airway obstruction.

Professional Societies/Organizations
The American Cleft Palate-Craniofacial Association (ACP-CA) published consensus-based parameters for evaluation and treatment of patients with cleft lip/palate. Cleft lip deformity is always associated with nasal abnormalities (ACP-CA, 2017; Friedman, et al., 2010). The degree of the nasal abnormality is related to the severity of the cleft lip. Nasal deformities associated with incomplete cleft lips are less severe than those associated with complete lip clefts. The goals of primary rhinoplasty include closure of the nasal floor, repositioning the lower lateral cartilages, and repositioning the alar base. The practice parameters note that (ACP-CA, 2017):

- Although rhinoplasty and nasal septal surgery are usually advocated only after completion of nasal growth, earlier intervention for reasons of airway problems or nasal tip deformity may be indicated.
- Repair of the cleft lip nasal deformity can be accomplished with limited external incisions on the nose.
- The timing of nasal surgery should be discussed with the patient and parents so that the goals are understood, and expectations are realistic.
- The patency of the nasal airway should be considered when planning either nasal reconstructive procedures or secondary velopharyngeal operations such as a pharyngeal flap or other type of pharyngoplasty.
- The nasal deformity is an integral part of the cleft lip. Depending on the severity, primary nasoplasty may be done at the time of the primary lip repair.

Septoplasty and Rhinoplasty for Obstructive Sleep Apnea
There is insufficient literature found to support the efficacy of rhinoplasty as a primary treatment for obstructive sleep apnea (OSA), either performed alone or routinely as part of another procedure such as uvulopalatopharyngoplasty (UPPP). The limited number of studies contains biases related to small sample size, as well as limited follow-up and patient selection.

In a review article, Chen and Kushida (2003) noted that the exact role that obstructed nasal breathing plays in the cause of sleep disorders remains presumptive, and robust clinical studies are needed. Septoplasty may be medically necessary when there is documentation that obstructed nasal breathing due to septal deformity or deviation is causing difficulty tolerating nasal continuous positive airway pressure (CPAP) and it is refractory to medical management. Positive airway pressure (PAP) treatment is considered an effective and widespread treatment of moderate OSA.

Professional Societies/Organizations
According to the American Academy of Sleep Medicine (AASM) recommendations (Kapur, et al., 2017; AASM, 1999), OSA severity is determined by the severity of daytime sleepiness and of sleep-related obstructive breathing based on overnight monitoring. A severity level is specified for each component. The diagnosis of moderate OSA would include:

- Sleepiness: Unwanted sleepiness or involuntary sleep episodes occur during activities that require some attention, such as concerts, meetings, or presentations. Symptoms produce moderate impairment of social or occupational function.

- Sleep related obstructive breathing events: ≥ 15 and ≤ 30 events per hour

Use Outside of the US: No relevant information.

Medicare Coverage Determinations

	Contractor	Policy Name/Number	Revision Effective Date
NCD		No National Coverage Determination found	
LCD	First Coast Service Options, Inc.	Cosmetic and Reconstructive Surgery (L38914)	7/11/2021
LCD	Novitas Solutions, Inc.	Cosmetic and Reconstructive Surgery (L35090)	7/11/2021
LCD	Palmetto GBA	Cosmetic and Reconstructive Surgery (L33428)	7/29/2021
LCD	Wisconsin Physicians Service Insurance Corporation	Cosmetic and Reconstructive Surgery (L39051)	11/14/2021
LCD	Noridian Healthcare Solutions, LLC	Plastic Surgery (L35163 & L37020)	10/1/2019

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:
1. This list of codes may not be all-inclusive.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Rhinoplasty

Considered Medically Necessary only when coverage for the service is available and when criteria in the applicable policy statements listed above are met. Benefit exclusions and limitations may apply:

CPT®* Codes	Description
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

CPT®* Codes	Description
30462	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip, septum, osteotomies

Vestibular Stenosis Repair

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
30465	Repair of nasal vestibular stenosis (eg, spreader grafting, lateral nasal wall reconstruction)

Considered Experimental, Investigational and Unproven:

CPT®* Codes	Description
30468	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)
30469	Repair of nasal valve collapse with low energy, temperature controlled, (i.e., radiofrequency) subcutaneous/submucosal remodeling

Considered Experimental, Investigational, and Unproven when used to report posterior nasal nerve ablation using radiofrequency or cryoablation for the treatment of chronic rhinitis (e.g., RhinAer, Clarifix):

CPT®* Codes	Description
30469	Repair of nasal valve collapse with low energy, temperature controlled, (i.e., radiofrequency) subcutaneous/submucosal remodeling
30999	Unlisted procedure, nose

Septoplasty

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
30520	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft

ICD-10-CM Diagnosis Codes	Description
J34.2	Deviated nasal septum
J34.89	Other specified disorders of nose and nasal sinuses
M95.0	Acquired deformity of nose
Q30.3	Congenital perforated nasal septum

ICD-10-CM Diagnosis Codes	Description
Q30.8	Other congenital malformations of nose
Q30.9	Congenital malformation of nose, unspecified
Q35.1	Cleft hard palate
Q35.3	Cleft soft palate
Q35.5	Cleft hard palate with cleft soft palate
Q35.9	Cleft palate, unspecified
Q36.0	Cleft lip, bilateral
Q36.1	Cleft lip, median
Q36.9	Cleft lip, unilateral
Q37.0	Cleft hard palate with bilateral cleft lip
Q37.1	Cleft hard palate with unilateral cleft lip
Q37.2	Cleft soft palate with bilateral cleft lip
Q37.3	Cleft soft palate with unilateral cleft lip
Q37.4	Cleft hard and soft palate with bilateral cleft lip
Q37.5	Cleft hard and soft palate with unilateral cleft lip
Q37.9	Unspecified cleft palate with unilateral cleft lip
Q67.4	Other congenital deformities of skull, face, and jaw
R09.81	Nasal congestion
S02.2XXA	Fracture of nasal bones, initial encounter for closed fracture
S02.2XXB	Fracture of nasal bones, initial encounter for open fracture
S02.2XXD	Fracture of nasal bones, subsequent encounter for fracture with routine healing
S02.2XXG	Fracture of nasal bones, subsequent encounter for fracture with delayed healing
S02.2XXK	Fracture of nasal bones, subsequent encounter for fracture with nonunion
S02.2XXS	Fracture of nasal bones, sequela
S02.92XA	Unspecified fracture of facial bones, initial encounter for closed fracture
S02.92XB	Unspecified fracture of facial bones, initial encounter for open fracture
S02.92XD	Unspecified fracture of facial bones, subsequent encounter for fracture with routine healing
S02.92XG	Unspecified fracture of facial bones, subsequent encounter for fracture with delayed healing
S02.92XK	Unspecified fracture of facial bones, subsequent encounter for fracture with nonunion
S02.92XS	Unspecified fracture of facial bones, sequela
S03.1XXA	Dislocation of septal cartilage of nose, initial encounter
S03.1XXD	Dislocation of septal cartilage of nose, subsequent encounter
S03.1XXS	Dislocation of septal cartilage of nose, sequela
S09.92XA	Unspecified injury of nose, initial encounter
S09.92XD	Unspecified injury of nose, subsequent encounter
S09.92XS	Unspecified injury of nose, sequela
S09.93XA	Unspecified injury of face, initial encounter
S09.93XD	Unspecified injury of face, subsequent encounter
S09.93XS	Unspecified injury of face, sequela

Not Covered or Reimbursable:

ICD-10-CM Diagnosis Codes	Description
	All other diagnosis codes

Considered Medically Necessary when submitted with a medically necessary procedure:

CPT®* Codes	Description
20912	Cartilage graft; costochondral
21230	Graft; rib cartilage, autogenous, to face, chin, nose or ear (includes obtaining graft)
21235	Graft; ear cartilage, autogenous, to nose or ear (includes obtaining graft)

Considered Experimental/Investigational/Unproven when used to report balloon dilation septoplasty:

CPT®* Codes	Description
30999	Unlisted procedure, nose

***Current Procedural Terminology (CPT®) ©2022 American Medical Association: Chicago, IL.**

References

1. Aerin VivAer Stylus for nasal airway obstruction (website). Accessed Mar 13, 2023. Available at URL address: VivAer® | Get Nasal Airway Obstruction Treatment With VivAer

2. Aerin RhinAer procedure for chronic rhinitis (website). Accessed Mar 13, 2023. Available at URL address: Non-Invasive Chronic Rhinitis Treatment | RhinAer Procedure

3. American Academy of Otolaryngology-Head and Neck Surgery (AAO-HFNS). Position Statement: The Use of Biomaterials in Sinonasal Procedure. Sep 26, 2015. Updated Apr 21, 2021. Accessed Mar 13, 2023. Available at URL address: https://www.entnet.org/resource/position-statement-the-use-of-biomaterials-in-sinonasal-procedures/

4. American Academy of Sleep Medicine (AASM). Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. The Report of an American Academy of Sleep Medicine Task Force. Sleep. 1999 Aug 1;22(5):667-89.

5. American Cleft Palate-Craniofacial Association (ACP-CA). Parameters for evaluation and treatment of patients with cleft lip/palate or other craniofacial anomalies. Chapel Hill (NC): American Cleft Palate-Craniofacial Association; Dec 2017.

6. American Rhinologic Society (ARS). ARS Position Statement: Bioabsorbable Nasal Implants Jan 2022. Accessed Mar 28, 2023. Available at URL address: Bioabsorbable Nasal Implants (american-rhinologic.org)

7. American Rhinologic Society (ARS). ARS Position Statement: Posterior Nasal Nerve Ablation. Jan 2022. Accessed Mar 28, 2023. Available at URL address: Posterior Nasal Nerve Ablation (american-rhinologic.org)

8. Antunes MB, Goldstein SA. Surgical approach to nasal valves and the midvault in patients with a crooked nose. Facial Plast Surg. 2011 Oct;27(5):422-36

9. Arosarena OA. Cleft lip and palate. Otolaryngol Clin North Am. 2007 Feb;40(1):27-60, vi.

10. Asaria J, Pepper JP, Baker SR. Key issues in nasal reconstruction. Curr Opin Otolaryngol Head Neck Surg. 2010 Aug;18(4):278-82.

11. Bezerra TF, Stewart MG, Fornazieri MA, Pilan RR, Pinna FD, Padua FG, et al. Quality of life assessment septoplasty in patients with nasal obstruction. Braz J Otorhinolaryngol. 2012 Jun;78(3):57-62.

12. Bhattacharyya N. Nasal obstruction: Diagnosis and management. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Last updated: Jan 11, 2022.

13. Bikhazi N, Ow RA, O'Malley EM, Perkins N, Sidle DM, Stolovitzky P. Long-Term Follow-up from the Treatment and Crossover Arms of a Randomized Controlled Trial of an Absorbable Nasal Implant for Dynamic Nasal Valve Collapse. Facial Plast Surg. 2022 Oct;38(5):495-503. doi: 10.1055/s-0041-1740948. Epub 2021 Dec 29. PMID: 34965603; PMCID: PMC9763033.

14. Bottini DJ, Gentile P, Arpino A, Dasero G, Cervelli V. Reconstruction of the nasal valve. J Craniofac Surg. 2007 May;18(3):516-9.

15. Brehmer D, Bodlaj R, Gerhards F. A prospective, non-randomized evaluation of a novel low energy radiofrequency treatment for nasal obstruction and snoring. Eur Arch Otorhinolaryngol. 2019;276(4):1039–1047.

16. Cannon DE, Rhee JS. Evidence-based practice: functional rhinoplasty. Otolaryngol Clin North Am. 2012 Oct;45(5):1033-43.

17. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determinations (LCDs) alphabetical index. Accessed Mar 13, 2023. Available at URL address: https://www.cms.gov/medicare-coverage-database/reports/local-coverage-proposed-lcds-alphabetical-report.aspx?proposedStatus=A&sortBy=title

18. Centers for Medicare and Medicaid Services (CMS). National Coverage Determinations (NCDs) alphabetical index. Accessed Mar 13, 2023. Available at URL address: https://www.cms.gov/medicare-coverage-database/reports/national-coverage-ncd-report.aspx?chapter=all&sortBy=title

19. Chandra RK, Patadia MO, Raviv J. Diagnosis of nasal airway obstruction. Otolaryngol Clin North Am. 2009 Apr;42(2):207-25, vii.

20. Chang MT, Song S, Hwang PH. Cryosurgical ablation for treatment of rhinitis: A prospective multicenter study. Laryngoscope. 2020 Aug;130(8):1877-1884. doi: 10.1002/lary.28301. Epub 2019 Sep 30. PMID: 31566744; PMCID: PMC7384004.

21. Chen W, Kushida CA. Nasal obstruction in sleep-disordered breathing. Otolaryngologic Clinics of North America 2003 Jun:36(3):437-460.

22. Chow AW, Benninger MS, Brook I, Brozek JL, Goldstein EJ, Hicks LA, et al. IDSA clinical practice guideline for acute bacterial rhinosinusitis in children and adults. Clin Infect Dis. 2012 Apr;54(8):e72-e112.

23. Clarifix. 2022. Chronic rhinitis finally has a real solution! Accessed Mar 22, 2023. Available at URL address: For Physicians – ClariFix

24. ClinicalTrials.gov. (2021). A Study of RhinAer ARC Stylus for Treating Chronic Rhinitis (RELIEF) [NCT04614324]. Accessed Mar 23, 2023. Available at URL address: https://www.clinicaltrials.gov/ct2/show/NCT04614324

25. Corey CL, Most SP. Treatment of nasal obstruction in the posttraumatic nose. Otolaryngol Clin North Am. 2009 Jun;42(3):567-78.

26. Corey J, Pallanch J. Evaluation of Nasal Breathing Function with Objective Airway Testing. In: Flint PW, Haughey BH, Lund VJ, Niparko JK, Richardson MA, Robbins KT, Thomas JR, editors. Cummings Otolaryngology: Head & Neck Surgery, 5th ed. Mosby, Inc. an Imprint of Elsevier; 2010.ch 42.

27. Dykewicz MS, Wallace DV, Amrol DJ, Baroody FM, Bernstein JA, Craig TJ, Dinakar C, Ellis AK, Finegold I, Golden DBK, Greenhawt MJ, Hagan JB, Horner CC, Khan DA, Lang DM, Larenas-Linnemann DES, Lieberman JA, Meltzer EO, Oppenheimer JJ, Rank MA, Shaker MS, Shaw JL, Steven GC, Stukus DR, Wang J; Chief Editor(s):; Dykewicz MS, Wallace DV; Joint Task Force on Practice Parameters:; Dinakar C, Ellis AK, Golden DBK, Greenhawt MJ, Horner CC, Khan DA, Lang DM, Lieberman JA, Oppenheimer JJ, Rank MA, Shaker MS, Stukus DR, Wang J; Workgroup Contributors:; Dykewicz MS, Wallace DV, Amrol DJ, Baroody FM, Bernstein JA, Craig TJ, Finegold I, Hagan JB, Larenas-Linnemann DES, Meltzer EO, Shaw JL, Steven GC. Rhinitis 2020: A practice parameter update. J Allergy Clin Immunol. 2020 Oct;146(4):721-767. doi: 10.1016/j.jaci.2020.07.007. Epub 2020 Jul 22. PMID: 32707227.

28. Ehmer D, McDuffie CM, Scurry WC Jr, McIntyre JB, Mehendale NH, Willis JH, Shealy RB, Watkins JP, Kakarlapudi VV. Temperature-Controlled Radiofrequency Neurolysis for the Treatment of Rhinitis. Am J Rhinol Allergy. 2022 Jan;36(1):149-156. doi: 10.1177/19458924211033400. Epub 2021 Aug 12. PMID: 34382444; PMCID: PMC8652359.

29. Ephrat M, Jacobowitz O, Driver M. Quality-of-life impact after in-office treatment of nasal valve obstruction with a radiofrequency device: 2-year results from a multicenter, prospective clinical trial. Int Forum Allergy Rhinol. 2021 Apr;11(4):755-765.

30. Fettman N, Sanford T, Sindwani R. Surgical management of the deviated septum: techniques in septoplasty. Otolaryngol Clin North Am. 2009 Apr;42(2):241-52, viii.

31. Fischer H, Gubisch W. Nasal valves--importance and surgical procedures. Facial Plast Surg. 2006 Nov;22(4):266-80.

32. Flint PW, Haughey BH, Lund VJ, Niparko JK, Richardson MA, Robbins KT, Thomas JR, editors. Cummings Otolaryngology: Head & Neck Surgery, 5th ed. Mosby, Inc. an Imprint of Elsevier; 2010.

33. Fraser L, Kelly G. An evidence-based approach to the management of the adult with nasal obstruction. Clin Otolaryngol. 2009 Apr;34(2):151-5.

34. Friedman O, Wang TD, Milczuk HA. Cleft Lip and Palate. In: Flint PW, Haughey BH, Lund VJ, Niparko JK, Richardson MA, Robbins KT, Thomas JR, editors. Cummings Otolaryngology: Head & Neck Surgery, 5th ed. Mosby, Inc. an Imprint of Elsevier; 2010.ch 34.

35. Ge NN, Rabinov CR, Crumley RL. Nasal Reconstruction. In: Flint PW, Haughey BH, Lund VJ, Niparko JK, Richardson MA, Robbins KT, Thomas JR, editors. Cummings Otolaryngology: Head & Neck Surgery, 5th ed. Mosby, Inc. an Imprint of Elsevier; 2010.ch 25.

36. Gubisch W. Extracorporeal septoplasty for the markedly deviated septum. Arch Facial Plast Surg. 2005 Jul-Aug;7(4):218-26.

37. Gubisch W. Twenty-five years' experience with extracorporeal septoplasty. Facial Plast Surg. 2006 Nov;22(4):230-9.

38. Han JK, Stringer SP, Rosenfeld RM, Archer SM, Baker DP, Brown SM, Edelstein DR, Gray ST, Lian TS, Ross EJ, Seiden AM, Setzen M, Tollefson TT, Ward PD, Welch KC, Wise SK, Nnacheta LC. Clinical Consensus Statement: Septoplasty with or without Inferior Turbinate Reduction. Otolaryngol Head Neck Surg. 2015 Nov;153(5):708-20. doi: 10.1177/0194599815606435. PMID: 26527752.

39. Hwang PH, Lin B, Weiss R, et al. Cryosurgical posterior nasal tissue ablation for the treatment of rhinitis. Int Forum Allergy Rhinol. 2017;7(10):952-956.

40. Ishii LE, Rhee JS. Are diagnostic tests useful for nasal valve compromise? Laryngoscope. 2013 Jan;123(1):7-8.

41. Ishii LE, Tollefson TT, Basura GJ, Rosenfeld RM, Abramson PJ, Chaiet SR, et al. Clinical Practice Guideline: Improving Nasal Form and Function after Rhinoplasty. Otolaryngol Head Neck Surg. 2017 Feb;156(2_suppl):S1-S30.

42. Jacobowitz O, Driver M, Ephrat M. In-office treatment of nasal valve obstruction using a novel, bipolar radiofrequency device. Laryngoscope Investig Otolaryngol. 2019;4(2):211–217. Published 2019 Feb 4.

43. Jang YJ, Kwon M. Modified extracorporeal septoplasty technique in rhinoplasty for severely deviated noses. Ann Otol Rhinol Laryngol. 2010 May;119(5):331-5.

44. Kantas I, Balatsouras DG, Papadakis CE, Marangos N, Korres SG, Danielides V. Aesthetic reconstruction of a crooked nose via extracorporeal septoplasty. J Otolaryngol Head Neck Surg. 2008 Apr;37(2):154-9.

45. Kapur VK, Auckley DH, Chowdhuri S, Kuhlmann DC, Mehra R, Ramar K, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American

Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017 Mar 15;13(3):479-504.

46. Ketcham AS, Han JK. Complications and management of septoplasty. Otolaryngol Clin North Am. 2010 Aug;43(4):897-904.

47. Kim DH, Lee HH, Kim SH, Hwang SH. Effectiveness of using a bioabsorbable implant (Latera) to treat nasal valve collapse in patients with nasal obstruction: systemic review and meta-analysis. Int Forum Allergy Rhinol. 2020 Jun;10(6):719-725.

48. Konstantinidis I, Malliari H, Metaxas S. Nasal trauma: Primary reconstruction with open rhinoplasty. Can J Plast Surg. 2011 Fall;19(3):108-10.

49. Kridel RWH, Kelly PE, MacGregro Holzapfel A. The Nasal Septum. In: Flint PW, Haughey BH, Lund VJ, Niparko JK, Richardson MA, Robbins KT, Thomas JR, editors. Cummings Otolaryngology: Head & Neck Surgery, 5th ed. Mosby, Inc. an Imprint of Elsevier; 2010.ch 34.

50. Lee J, White WM, Constantinides M. Surgical and nonsurgical treatments of the nasal valves. Otolaryngol Clin North Am. 2009 Jun;42(3):495-511.

51. Mickelson SA, Benninger MS. The Nose and Paranasal Sinuses. In: Noble J, Levinson W., editors Textbook of primary care medicine. 3rd ed. St. Louis, MO: Mosby, Inc.; 2001. ch.179

52. Moore M, Eccles R. Objective evidence for the efficacy of surgical management of the deviated septum as a treatment for chronic nasal obstruction: a systematic review. Clin Otolaryngol. 2011 Apr;36(2):106-13.

53. Morgan NJ, MacGregor FB, Birchall MA, Lund VJ, Sittampalam Y. Racial differences in nasal fossa dimensions determined by acoustic rhinometry. Rhinology. 1995 Dec;33(4):224-8. PMID: 8919216.

54. Most SP. Anterior septal reconstruction: outcomes after a modified extracorporeal septoplasty technique. Arch Facial Plast Surg. 2006 May-Jun;8(3):202-7.

55. O'Handley JG, Tobin EJ, Shah AR. Otorhinolaryngology. In: Rakel RE, Rakel DP, editors. Textbook of Family Medicine, 8th ed. Saunders, an imprint of Elsevier Inc.: Philadelphia; 2011.

56. Ow RA, O'Malley EM, Han JK, et al. Cryosurgical ablation for treatment of rhinitis: Two-year results of a prospective multicenter study. Laryngoscope. 2021; 131(9):1952-1957.

57. Rhee JS, Arganbright JM, McMullin BT, Hannley M. Evidence supporting functional rhinoplasty or nasal valve repair: A 25-year systematic review. Otolaryngol Head Neck Surg. 2008 Jul;139(1):10-20.

58. Rhee JS, Poetker DM, Smith TL, Bustillo A, Burzynski M, Davis RE. Nasal valve surgery improves disease-specific quality of life. Laryngoscope. 2005 Mar;115(3):437-40.

59. Rhee JS, Weaver EM, Park SS, Baker SR, Hilger PA, Kriet JD, et al. Clinical consensus statement: Diagnosis and management of nasal valve compromise. Otolaryngol Head Neck Surg. 2010 Jul;143(1):48-59.

60. Rosenfeld RM, Andes D, Bhattacharyya N, Cheung D, Eisenberg S, Ganiats TG, et al. Clinical practice guideline: adult sinusitis. Otolaryngol Head Neck Surg. 2007 Sep;137(3 Suppl):S1-31.

61. San Nicoló M, Stelter K, Sadick H, Bas M, Berghaus A. A 2-Year Follow-up Study of an Absorbable Implant to Treat Nasal Valve Collapse. Facial Plast Surg. 2018 Oct;34(5):545-550.

62. San Nicoló M, Stelter K, Sadick H, Bas M, Berghaus A. Absorbable Implant to Treat Nasal Valve Collapse. Facial Plast Surg. 2017 Apr;33(2):233-240.

63. Schlosser RJ, Park SS. Functional nasal surgery. Otolaryngol Clin North Am. 1999 Feb;32(1):37-51.

64. Sidle DM, Stolovitzky P, Ow RA, Silvers S, Matheny K, Bikhazi N, et al. Twelve-month outcomes of a bioabsorbable implant for in-office treatment of dynamic nasal valve collapse. Laryngoscope. 2020 May;130(5):1132-1137.

65. Silvers SL, Rosenthal JN, McDuffie CM, Yen DM, Han JK. Temperature-controlled radiofrequency device treatment of the nasal valve for nasal airway obstruction: A randomized controlled trial. Int Forum Allergy Rhinol. 2021;11(12):1676-1684.

66. Simmen DB, Jones NS. Epistaxis. In: Flint PW, Haughey BH, Lund VJ, Niparko JK, Richardson MA, Robbins KT, Thomas JR, editors. Cummings Otolaryngology: Head & Neck Surgery, 5th ed. Mosby, Inc. an Imprint of Elsevier; 2010.ch 45.

67. Spirox Latera Absorbable Nasal Implant (website). Accessed Mar 13, 2023. Available at URL address: https://ent.stryker.com/physician-resources/clinical-studies-trials/nasal-implant

68. Stewart MG, Smith TL, Weaver EM, Witsell DL, Yueh B, Hannley MT, Johnson JT. Outcomes after nasal septoplasty: results from the Nasal Obstruction Septoplasty Effectiveness (NOSE) study. Otolaryngol Head Neck Surg. 2004 Mar;130(3):283-90.

69. Stolovitzky P, Senior B, Ow RA, Mehendale N, Bikhazi N, Sidle DM. Assessment of bioabsorbable implant treatment for nasal valve collapse compared to a sham group: a randomized control trial. Int Forum Allergy Rhinol. 2019 Aug;9(8):850-856.

70. Stolovitzky P, Sidle DM, Ow RA, Nachlas NE, Most SP. A prospective study for treatment of nasal valve collapse due to lateral wall insufficiency: Outcomes using a bioabsorbable implant. Laryngoscope. 2018 Nov;128(11):2483-2489.

71. Stolovitzky JP, Ow RA, Silvers SL, Bikhazi NB, Johnson CD, Takashima M. Effect of Radiofrequency Neurolysis on the Symptoms of Chronic Rhinitis: A Randomized Controlled Trial. OTO Open. 2021 Sep 10;5(3):2473974X211041124. doi: 10.1177/2473974X211041124. PMID: 34527852; PMCID: PMC8436321.

72. Tasca I, Ceroni Compadretti G, Sorace F. Nasal valve surgery. Acta Otorhinolaryngol Ital. 2013 Jun;33(3):196-201.

73. U.S. Food and Drug Adminstration (FDA). 510 (k) approval K161191. Latera Absorbable Nasal Implant. Jun 23, 2016. Accessed Mar 13, 2023. Available at URL address: https://www.accessdata.fda.gov/cdrh_docs/pdf16/K161191.pdf

74. U.S. Food and Drug Adminstration (FDA). 510 (k) approval K172529. Vivaer ARC Stylus. Dec 2017. Accessed Mar 13, 2023. Available at URL address: https://www.accessdata.fda.gov/cdrh_docs/pdf17/K172529.pdf

75. Velasco LC, Arima LM, Tiago RS. Assessment of symptom improvement following nasal septoplasty with or without turbinectomy. Braz J Otorhinolaryngol. 2011 Sep-Oct;77(5):577-83.

76. Wang TD. Secondary rhinoplasty in unilateral cleft nasal deformity. Facial Plast Surg. 2007 May;23(2):123-7.

77. Wilson MA, Mobley SR. Extracorporeal septoplasty: complications and new techniques. Arch Facial Plast Surg. 2011 Mar-Apr;13(2):85-90.

78. Wittkopf M, Wittkopf J, Ries WR. The diagnosis and treatment of nasal valve collapse. Curr Opin Otolaryngol Head Neck Surg. 2008 Feb;16(1):10-3.

79. Yao WC, Ow RA, Barham HP. Temperature-Controlled Radiofrequency Treatment of the Nasal Valve and Nasal Airway Obstruction: Early Results of a Prospective, Multi-Center Study. J Otolaryngol Rhinol. 2021, 7:105.

Revision Details

Type of Revision	Summary of Changes	Date
Annual	• updated to new template and formatting standards	11/12/2023