Medical Coverage Policy

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Rhinoplasty, Vestibular Stenosis Repair and Septoplasty

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Overview

This Coverage Policy addresses rhinoplasty, vestibular stenosis repair and septoplasty procedures for nasal airway obstruction and for other otolaryngology conditions such as 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., 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 age 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:

- positive 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 are considered experimental, investigational and unproven:

- repair of nasal valve collapse with absorbable nasal implant(s)
- radiofrequency of nasal valve for the treatment of nasal airway obstruction (e.g., Vivaer ARC Stylus)

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)

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 the majority of 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 as a result 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 501(k) clearance intended to support cartilage in the nasal lateral wall.

The System consists of the Latera Absorbable Nasal Implant (Implant) and Accessory Delivery Device (Delivery Device). The Implant is composed of a PLLA-PDLA copolymer that is predominantly cylindrical in shape with an approximate diameter of 1mm and overall length of 24mm. 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
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 also 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 1 month postoperatively, 33.0 ± 23.4 at 3 months, 32.1 ± 24.6 at 6 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 evaluated 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 to the short follow-up time of three months and that the study is single-blinded which all 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 1 month, 32.0 ± 28.4 at 3 months, and 30.6 ± 25.8 at 6 months postoperatively; P<0.01 for all). reduction was noted 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). 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.

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 501(k) clearance 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)
Brehmer et al. (2019 conducted 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 patient completed two questionnaires measuring nasal obstruction and snoring (NOSE, 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 time 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 p[atients, lack of randomization, uncontrolled and lack of comparator, and relatively short term follow-up.

Ephrat et al. (2020) 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 6 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 6 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 6 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.

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. The presence of a septal deformity can be caused by trauma, or it may be congenital. 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, and duration, and exacerbating factors are recorded (Corey, et al., 2010; O'Handley, et al., 2010). Physical examination many 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 (Corey, et al., 2010; O'Handley, 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 various types of rhinitis, it is treated medically. This may include nasal steroids, antihistamines, leukotriene inhibitors, mucolytics, oral decongestants, topical decongestants, and 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 3 days, to prevent rebound nasal obstruction. Antibiotics are administered in the case of bacterial infection or acute rhinosinusitis (Corey, et al., 2010; O'Handley, 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 is a surgical procedure that 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.

Some 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. Generally, 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 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, et al., 2010). Septoplasty may be necessary in order 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, et al., 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, 2020).

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.

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 some years later. Surgical correction of congenital birth

defects may involve staged procedures, flaps, or grafts. Since the clefts of palate and lip vary considerably 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 (Nelson, et al., 2000). 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.

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 considered 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.

According to the American Academy of Sleep Medicine (AASM) recommendations (1999; Kapur, et al., 2017), 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	

	Contractor	Policy Name/Number	Revision Effective Date
LCD	Novitas Solutions	Cosmetic and Reconstructive Surgery (L35090)	11/7/2019
LCD	Palmetto GBA	Cosmetic and Reconstructive Surgery (L33428)	10/24/2019
LCD	Wisconsin Physician Services	Cosmetic and Reconstructive Surgery (L34698)	1/1/2021
LCD	Noridian Healthcare Solutions	Plastic Surgery (L35163) Plastic Surgery (L37020)	10/01/2019

Note: Please review the current Medicare Policy for the most up-to-date information.

Coding/Billing Information

Note: 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
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)

HCPCS Codes	Description
C9749	Repair of nasal vestibular lateral wall stenosis with implant(s) (Code deleted 12/31/2020)

Considered Experimental, Investigational, and Unproven when used to report radiofrequency of nasal valve for the treatment of nasal airway obstruction (e.g., Vivaer ARC Stylus):

CPT®* Codes	Description
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	Choanal atresia
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

ICD-10-CM Diagnosis Codes	Description
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

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

CPT®* Codes	Description
30999	Unlisted procedure, nose

***Current Procedural Terminology (CPT®) ©2020 American Medical Association: Chicago, IL.**

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