Rhinoplasty and Other Nasal Procedures (for Idaho Only)

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Instructions for Use

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Application

This Medical Policy only applies the state of Idaho, including Idaho Medicaid Plus plans.

Coverage Rationale

See Benefit Considerations

Nasal valve procedures/repair of nasal vestibular stenosis or alar collapse are considered reconstructive and medically necessary when all of the following criteria are present:

- Prolonged, persistent obstructed nasal breathing due to internal and/or External Nasal Valve compromise; **and**
- Other causes of nasal obstruction (e.g., rhinosinusitis, allergic rhinitis, vasomotor rhinitis, nasal polyposis, adenoid hypertrophy, and/or nasopharyngeal masses) have been adequately treated with maximal therapy and nasal obstruction persists; **and**
- Nasal septal deviation and turbinate hypertrophy either:
  - Are not present; **or**
  - Have been previously surgically treated; **or**
  - Are scheduled to be surgically treated at the same time as the nasal valve procedure/repair as part of the surgery plan

  and
- Documented evidence of visible collapse of the alar (lower lateral) cartilage (External Nasal Valve) and/or lateral nasal wall (internal nasal valve) with deep inspiration; **and**
- Documented evidence of subjective and audible improvement in nasal airflow during modified Cottle maneuver; **and**
- Photos clearly document either dynamic collapse of the internal and/or External Nasal Valve or anatomic deformities narrowing the internal and/or External Nasal Valve as a main cause of an anatomic Mechanical Nasal Airway Obstruction and are consistent with the clinical exam; **and**
- The surgeon has clearly described:
  - Whether the nasal valve compromise is static or dynamic; **and**
  - Whether the nasal valve compromise involves internal nasal valve, External Nasal Valve, or both; **and**
  - A plainly stated and clear surgical plan including the need for a cartilage graft

Nasal valve procedures/repair of nasal vestibular stenosis or alar collapse are not considered reconstructive and medically necessary in all other indications.

Rhinophyma excision is considered reconstructive and medically necessary when all of the following criteria are present:
- One of the following:
  - Prolonged, persistent obstructed nasal breathing due to rhinophyma; **or**
  - Chronic infection or bleeding unresponsive to medical management due to rhinophyma

  and
- Photos clearly document rhinophyma as the primary cause of an anatomic Mechanical Nasal Airway Obstruction or chronic infection and are consistent with the clinical exam; **and**
- The proposed procedure is designed to correct the anatomic Mechanical Nasal Airway Obstruction and relieve the nasal airway obstruction by correcting the deformity or the proposed procedure is designed to address the chronic infection

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

Rhinoplasty for congenital anomalies is considered reconstructive and medically necessary when the following are present:
- Rhinoplasty is performed for a nasal deformity associated with congenital craniofacial anomalies including, but not limited to Pierre Robin, Apert syndrome, Fraser syndrome, Binder syndrome, Goldenhar syndrome, nasal dermoids, Tessier nasal cleft (most commonly no.1), or associated with a cleft lip or cleft palate

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

Rhinoplasty–primary is considered reconstructive and medically necessary when all of the following criteria are present:
- The indication for surgery is one of the following:
  - Prolonged, persistent obstructed nasal breathing due to nasal bone and septal deviation that are the primary causes of an anatomic Mechanical Nasal Airway Obstruction; **or**
  - Nasal fracture with nasal bone displacement severe enough to cause nasal airway obstruction; **or**
  - Residual large cutaneous defect following resection of a malignancy or nasal trauma

  and
- The nasal airway obstruction cannot be corrected by septoplasty alone as documented in the medical record; **and**
- Photos clearly document the nasal bone/septal deviation as the primary cause of an anatomic Mechanical Nasal Airway Obstruction and are consistent with the clinical exam; **and**
- The proposed procedure is designed to correct the anatomic Mechanical Nasal Airway Obstruction and relieve the nasal airway obstruction by centralizing the nasal bony pyramid and straightening the septum; **and**
- Nasal airway obstruction is causing significant symptoms (e.g., Chronic Rhinosinusitis, difficulty breathing); **and**
- Obstructive symptoms persist despite conservative management for 4 weeks or greater, which includes, where appropriate, nasal steroids or immunotherapy

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

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

Rhinoplasty–revision is not considered reconstructive and medically necessary in all other indications.

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

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

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

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

Click here to view the InterQual® criteria.

Nasal polypectomy is not considered reconstructive and medically necessary in all other indications.

The following procedures are considered unproven and not medically necessary due to insufficient evidence of safety and/or efficacy:

- Absorbable polylactic acid nasal cartilage support implants [e.g., Latera Absorbable Nasal Implant (Stryker)] for supporting nasal upper and lower lateral cartilage
- Nasal septal swell body (NSB) reduction for the treatment of nasal obstruction posterior nasal nerve or sphenopalatine ganglion ablation using any method [such as radiofrequency or cryoablation (e.g., RhinAer, ClariFix)] for the treatment of chronic rhinitis
- Radiofrequency treatment of nasal valves for the treatment of nasal airway obstruction (e.g., VivAer ARC Stylus)

Definitions

The following definitions may not apply to all plans. Refer to the federal, state, and contractual requirements that supersede the definitions below.

Acute Rhinosinusitis (ARS): ARS is a clinical condition characterized by inflammation of the mucosa of the nose and paranasal sinuses with associated sudden onset of symptoms of purulent nasal drainage accompanied by nasal obstruction, facial pain/pressure/fullness, or both, of up to 4 weeks duration [American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) clinical indicators for endoscopic sinus surgery for adults. 2012, Updated 2021].

Chronic Rhinosinusitis (CRS): CRS is one of the more prevalent chronic illnesses in the United States and is an inflammatory process that involves the paranasal sinuses and persists for longer than 12 weeks (Rosenfeld et al., 2015).

External Nasal Valve: The caudal septum, along with lower lateral cartilage, alar rim, and nostril sill contribute to the External Nasal Valve (Rohrich, 2009).

Functional or Physical or Physiological Impairment: A Functional or Physical or Physiological Impairment causes deviation from the normal function of a tissue or organ. This results in a significantly limited, impaired, or delayed capacity to move, coordinate actions, or perform physical activities and is exhibited by difficulties in one or more of the following areas: physical and motor tasks; independent movement; performing basic life functions (Medicare, 2023).

Mechanical Nasal Airway Obstruction: Trouble breathing through the nose (not snoring) due to a bony or cartilaginous deformity (Corey, 2009).

Prolonged, Persistent Nasal Airway Obstruction: Trouble breathing through the nose (not snoring) that has not responded to six weeks of medical management such as nasal steroids, antihistamines, and decongestants. Elimination of drug-induced rhinitis, including Rhinitis Medicamentosa as a cause for airway obstruction (Corey, 2009).

Rhinitis Medicamentosa (RM): A condition of rebound nasal congestion brought on by extended use of topical decongestants (e.g., oxymetazoline, phenylephrine, xylometazoline, and naphazoline nasal sprays) that constrict blood vessels in the lining of the nose. It classifies as a subset of drug-induced rhinitis (Wahid, 2022).

Recurrent Acute Rhinosinusitis (RARS): RARS has been defined as four episodes per year of Acute Rhinosinusitis with distinct symptom free intervals between episodes (Rosenfeld et al., 2015).

Applicable Codes

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

Note: All nasal surgical claims may be subject to coding review. The following codes may be cosmetic; review is required to determine if considered cosmetic or reconstructive.

CPT Code	Description
30117	Excision or destruction (e.g., laser) of intranasal lesion; internal approach
30120	Excision or surgical planing of skin of nose for rhinophyma
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
30460	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip only
30462	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip, septum, osteotomies
30465	Repair of nasal vestibular stenosis (e.g., spreader grafting, lateral nasal wall reconstruction)
30468	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)
30469	Repair of nasal valve collapse with low energy, temperature-controlled (i.e., radiofrequency) subcutaneous/submucosal remodeling
30999	Unlisted procedure, nose
31237	Nasal/sinus endoscopy, surgical; with biopsy, polypectomy or debridement (separate procedure)
31242	Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve
31243	Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve
64999	Unlisted procedure, nervous system

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HCPCS Code	Description
L8699	Prosthetic implant, not otherwise specified

Description of Services

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

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

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

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

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

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

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

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

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

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

Benefit Considerations

Some states require coverage for services that UnitedHealthcare considers cosmetic procedures, such as repair of external congenital anomalies in the absence of a Functional Impairment. Check the federal, state, or contractual requirements for benefit coverage.

Clinical Evidence

Nasal Valve Procedures/Repair of Nasal Vestibular Stenosis or Alar Collapse/Nasal Valve Collapse/Nasal Airway Obstruction

In a single-center, retrospective study on the efficacy of septal extension graft (SEG) use in the treatment of alar collapse, Resuli et al. (2023) and reported that the SEG technique which they applied for nasal projection in rhinoplasty surgery, increased the extension of the lower lateral cartilage lateral ridge (LC) and alar structures. The study included 23 patients, 18 male and 5 female with mean ages of 45.5 and 39.7 years respectively, with alar collapse with a positive Cottle test and bilateral dynamic nasal collapse. Other causes of nasal obstruction (such as septal deviation, allergic rhinitis, turbinate hypertrophy, acute and/or chronic sinusitis, and nasal polyp) were not found in any of the patients, and facial nerve examinations were normal. The authors reported that there were no complaints of nasal obstruction on deep inspiration noted by the patients at their six-month post-operative follow-up. The mean respiratory score was 152 postoperatively, compared to 66.5 preoperatively. The authors concluded that SEG use is effective for patients with bilateral nasal collapse and thick-short columella which results in a significant increase in nasal vestibular volume.

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

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

Clinical Practice Guidelines

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

In their 2023 Position Statement on nasal valve repair, the AAO-HNS recognized surgical repair of the nasal valve as a distinct surgical procedure that can improve nasal obstruction symptoms for appropriately selected patients with nasal valve collapse. The AAO-HNS statement indicates that surgical approaches for the treatment of nasal valve dysfunction may include cartilage grafting and open surgical repair, suture suspension techniques, and implants or radiofrequency treatment aimed at stabilizing the nasal valve. It also states that surgical treatment of nasal valve collapse, along with treatment of other possible causes of nasal airway obstruction, is required to optimize patient outcomes for patients who require anatomic widening and definitive stabilization of the nasal valve.

In the 2010 Clinical Consensus Statement by the AAO-HNS, Rhee et al. reported that published literature consistently noted the benefit of surgical treatment of nasal valve collapse (NVC), but the evidence relied mostly on uncontrolled studies. The panel generally agreed upon the anatomic and functional features that define NVC and that diagnosis of NVC is best done with history and physical exam findings. The panel found that there is a lack of a "gold standard" objective test for NVC although radiographic tests such as CT or MRI are mainly used to rule out other disease processes such as sinusitis, nasal polyps, and neoplasms. While surgical treatment is the primary mode of treatment of NVC, surgical management was not reviewed by any specific surgical approach but was reviewed broad in scope. The panel met consensus with uniformly strong agreement that a surgical procedure that is targeted to support the lateral nasal wall/alar rim is a distinct entity from procedures that correct a deviated nasal septum or hypertrophied turbinate. There was consensus with agreement that, in some cases, septoplasty and/or turbinate surgery can treat NVC without surgery to support the lateral nasal wall/alar rim. With regards to medical management of NVC, the panel met consensus that nasal steroid medication is not useful for treating NVC in the absence of rhinitis, and mechanical treatments such as nasal stents may be useful in selected patients.

Rhinophyma Excision

Chauhan et al. (2020) completed a systematic review comparing laser therapy, scalpel excision, and subunit treatment outcomes on patients with rhinophyma from 1946 to 2020, using an OVID Medline literature search. From a total of 351 articles, 23 met criteria for inclusion. Among 12 studies, 247 patients with a mean age of 61 years and minor to major disease (minor, n = 67); moderate (n = 64); and major (n = 87) were treated with a carbon dioxide laser in an average of 1.1 sessions. A total of 18 patients was treated, with a mean age of 62 years, and a total of 1 patient with minor, 12 with moderate, and five with major rhinophyma using the erbium: YAG (Er:YAG) laser in 1.0 sessions. A total of 108 patients underwent cold knife tangential excision among eight studies. Patients had a mean age of 61 years, treated for minor to major rhinophyma, and all required a single session for treatment. Seven patients with a mean age of 67 years underwent treatment with a Shaw scalpel, and all required a single session for treatment. Eight patients (mean age 63 years) underwent treatment with the subunit method. Four patients had external valve collapse. Four patients received alar batten cartilage grafts, all had interdomal sutures, and one patient required a skin graft. Both the complication and revision rates were 75%, but only minor revisions under local anesthetic were required and no recurrence of disease was noted. The authors concluded that the subunit method had the highest complication and revision rates followed by carbon dioxide laser therapy. Outcomes between carbon dioxide laser and scalpel therapy and electrocautery were equivalent. They also concluded that scalpel excision was a cost-effective treatment modality with less post-operative complications;

however, it risked poor hemostasis intraoperatively. Patient satisfaction was common post-therapy regardless of the treatment method. Over 89% of patients would recommend undergoing treatment for rhinophyma irrespective of treatment type. Treatment options vary, and choice of treatment can be dependent on practitioner and patients' treatment goals. Reporting of quantitative and qualitative outcomes between studies is not standardized. Further research with randomized controlled trials is needed to validate these findings.

Rhinoplasty

In a single-center, retrospective cohort study of patients who underwent closed nasal reduction of nasal bone fractures, Besmens et al., (2023) determined the rate of rhinoplasty after fracture reduction and analyzed the factors affecting the outcome and need for revision rhinoplasty. The study included a record review of 417 consecutive patients (306 male and 111 female patients) with a median age of 30 years. There were 371 (89%) patients who had a closed fracture and 46 (11%) who had open fractures. One third of all patients (n = 139, 33.3%) had an associated nasal septum fracture and septal deviation was visible via CT or was clinically present in 135 patients (32.4%), and a dislocated septum was noted in 56 patients (13.4%). There were 46 patients who had sustained at least one prior nasal fracture and these patients were more likely to require revision rhinoplasty. Closed reduction was performed on average of 6 days post trauma with gauze removal 2 days post operatively and cast removal occurred after seven days. The authors reported that 47 patients (11.3%) required revision rhinoplasty after fracture healing, which was performed on average of 398 days (range 214 to 592 days) after the initial reduction. The authors reported that patients who suffered an additional septum fracture or septal deviation were more likely to undergo rhinoplasty and that the risk of the need for open revision rhinoplasty after fracture healing was significantly increased for patients complaining of airway obstruction at the time of cast removal after closed reduction. Limitations of the study include the retrospective design, the inclusion of cases operated on by multiple surgeons, the lack of medical records related to possible existence of airway obstruction prior to the nasal fracture and the lack of medical records for patients lost to follow up who may have undergone revision rhinoplasty elsewhere. The authors concluded that a significant number of patients will require secondary revision rhinoplasty even though closed reduction of nasal fractures is frequently considered a straightforward procedures. The authors recommended prospective studies to support the findings of their investigation.

A meta-analysis by Zhao et al. (2022) was performed to evaluate the effects of functional rhinoplasty (FRP) on nasal obstruction in patients with nasal valve problems. A total of 57 cohorts from 43 studies involving 2,024 patients were included in the current meta-analysis (Level of Evidence III). The Nasal Obstruction Symptom Evaluation (NOSE) scores indicated significant improvement in nasal obstruction at the 1-month, 3-month, 6-month, 12-month, and the last follow-up with respect to the preoperative baseline. The Visual Analogue Scale (VAS) scores indicated a similar trend at the 1-month, 3-month, 6-month, and last follow-up. Nasal obstruction was demonstrated as relieved through rhino-manometry but not through peak nasal inspiratory flow (PNIF). The authors concluded that FRP may have a positive effect on nasal obstruction caused by nasal valve problems. The findings of this study need to be validated by broader, well-designed studies.

A systematic review and meta-analysis by Pfaff et al. (2021) were performed to evaluate the effects of septoplasty, septorhinoplasty, and rhinoplasty procedures on post-operative olfactory function and their relationship to nasal airflow and quality of life. Pre-operative and post-operative values for olfaction, nasal airflow, and quality of life/nasal symptoms were analyzed. The effect size was calculated from each study and used for meta-analysis. As studies evaluated patients at different points in the postoperative period, the latest time point reported by each study was used in the meta-analysis. All included studies were Level of Evidence II. There were 25 included studies. Three studies were randomized prospective studies, seven were comparative studies, and 15 were noncomparative studies Following nasal surgery, patients experienced significant improvements in olfaction ($p < 0.001$), nasal airflow ($p < 0.001$), and quality of life/nasal symptoms ($p < 0.001$). Patients often experienced a transient decrease in olfaction immediately after surgery, followed by improvement post-operatively. Pre-operative olfactory dysfunction rates were low and post-operative dysfunction was equally low. Olfaction improvement was directly correlated with improvement in nasal airflow and quality of life. The authors concluded that functional and aesthetic nasal operations appear to improve olfaction, which is directly correlated with nasal airflow. Some studies reported a transient worsening of these measures in the immediate post-operative period, which improved at later time points. The study is limited due to a heterogeneous patient population. In addition, due to smaller sample sizes, there is an inherent risk of publication bias.

Martin et al. (2021) completed a prospective randomized controlled trial (RCT) to evaluate the subjective and objective outcome of septoplasty (SPL) and septorhinoplasty (SRP) on patient satisfaction. Patients with functional indication for SPL (n = 19) or SRP (n = 54) were included and randomized for additional turbinoplasty. Preoperative clinical symptoms were collected with SNOT-20 GAV (Sinu-nasal outcome test-20 – German adapted version) and NOSE© (nasal obstruction symptom evaluation) questionnaires. The final evaluation of treatment success was performed 9 months after surgery with SNOT-20 GAV, NOSE© and a self-established feedback questionnaire. Nasal breathing and obstruction were objectively measured with rhinomanometry and acoustic rhinometry [minimum cross-sectional area 2 (MCA2)].

Minimum cross-sectional area 2 was statistically improved compared to the pre-treatment value in SPL ($p = 0.0004$) and SRP ($p = 0.0001$). Regarding MCA2 values of matched patient groups, similar findings were detected (SPL: $p = 0.0013$, SRP: $p < 0.0001$). Sinu-nasal outcome test-20 GAV and NOSE© scores were reduced after both surgical procedures (NOSE©: SPL: $p < 0.0001$, SRP: $p < 0.0001$; SNOT-20 GAV: SPL: $p = 0.0068$, SRP: $p < 0.0001$). Evaluation of patient satisfaction in a self-established feedback questionnaire revealed a motivation of 81% of patients to redo the surgery (SPL 13/16, SRP 34/42) and a notably general satisfaction of 86% for SPL and 80% for SRP. The authors concluded that rhinosurgery leads improved nasal breathing and increased disease-specific satisfaction quantitatively. Further research with randomized controlled trials is needed to validate these findings.

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

Clinical Practice Guidelines

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

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

American Cleft Palate-Craniofacial Association (ACPA)

The ACPA developed standards for the evaluation and treatment of patients with cleft lip/palate or other craniofacial differences under a project funded by the U.S. Public Health Service Department of Health and Human Services. They advise that rhinoplasty and nasal septal surgery are usually advocated only after completion of nasal growth; however, primary rhinoplasty may be done at the time of the primary cleft/lip palate repair surgery depending on the severity of the nasal difference. They further advise that earlier intervention including rhinoplasty and nasal septal surgery may be indicated for reasons of airway problem or nasal tip difference and that the timing of the nasal surgery should be discussed with the patient and parents so that the goals are understood and expectations are realistic (2018).

American Society of Plastic Surgeons (ASPS)

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

Absorbable Nasal Cartilage Support Implants

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

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

In their Executive Summary on the Latera Absorbable Nasal Implant, ECRI (2022) reviewed evidence from one systematic review with meta-analysis (Kim, 2020 study below), one RCT (Bikhazi, 2021 below and also included in the Kim 2020 systematic review with meta-analysis), one non-randomized comparison study (Olson and Barrera, 2021 below) and three pretest/posttest studies and found that Latera appears to improve breathing in patients with nasal wall collapse at two-year follow-up; however, they noted that the efficacy of Latera compared to rhinoplasty is unclear because the studies provided too few data. The authors noted that the pooled findings are at risk of bias due to the subjective measurement tools used to assess efficacy, the lack of parallel control groups and the inclusion of other treatments along with Latera. They also noted that some studies were at high risk of bias due to small sample size, lack of randomization and lack of control groups. Sham-controlled, double-blind RCTs with uniform treatment protocols and long-term follow-up (> 2 years) are needed demonstrate the durability of Latera's benefits and to support stronger conclusions.

In an Evolving Evidence Review, Hayes (2022, updated 2023) completed a systematic search and findings summary on clinical studies, systematic reviews, and clinical practice guidelines on absorbable nasal implants. In the most recent update, Hayes identified two newly published comparative cohort studies (including the Olson and Barrera 2021 study below) to add to the two prospective pretest/posttest studies (3 publications), and one RCT (2 publications) that were included in the previous year's report. There was no change to the quality of available studies, which were found to be of generally very poor quality, and there was a lack of studies with control groups to demonstrate if absorbable nasal implants perform better, worse, or similar to competing technologies. No relevant clinical practice guidelines or position statements were identified from any nationally recognized medical society. Many of the included studies were the same as those reviewed in the ECRI (2022) Executive Summary above (Bikhazi, 2021, Olson and Barrera, 2021, Sidle, 2021 and San Nicoló, 2018) and three of the studies (Bikhazi, 2021, Olson and Barrera, 2021, and San Nicoló, 2017) are included in this policy below. Hayes concluded that while available published evidence suggested absorbable nasal implants were technically reasonable to implant and were associated with reduced nasal airway obstruction and pain, the clinical studies and systematic reviews were of generally very poor quality. Hayes noted that only one study had a control group to demonstrate whether absorbable nasal implants perform clinically better, worse, or similar to competing technologies; however, the control participants were allowed to crossover to treatment after 3 months so long term comparison was not available. In other studies, Hayes noted that many patients received adjunctive treatment with the nasal implants which confounded the interpretation of the results.

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

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

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

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

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

Stolovitzky et al. [2018, included in Kim (2020) systematic review above] reported 6-month outcomes from a prospective, multicenter, single-blinded (blinded assessor) case series for treatment of nasal valve collapse due to lateral wall insufficiency. One hundred and one patients with severe-to-extreme class of Nasal Obstruction Symptom Evaluation (NOSE) scores were enrolled at 14 U.S. clinics. Some participants appear to overlap with these of Sidle, et al. (2020) discussed above. Patients were treated with a bioabsorbable implant designed to support lateral wall, with or without concurrent septoplasty and/or turbinate reduction procedure(s). NOSE scores and visual analog scale (VAS) were measured at baseline and month 1, 3, and 6 postoperatively. The Lateral Wall Insufficiency (LWI) score was determined by independent physicians observing the lateral wall motion video. Forty-three patients were treated with implants alone, whereas 58 had adjunctive procedures. Seventeen patients reported 19 AEs, all of which resolved with no clinical sequelae. Patients showed significant reduction in NOSE scores at 1, 3, and 6 months postoperatively (79.5 ±3.5 preoperatively, 34.6 ±25.0 at 1 month, 32.0 ±28.4 at 3 months, and 30.6 ±25.8 at 6 months postoperatively; $p < 0.01$ for all). They also showed significant reduction in VAS scores postoperatively (71.9 ±8.8 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 post-operatively; $p < 0.01$). The authors concluded that stabilization of the lateral nasal wall with a bioabsorbable implant improves patients' nasal obstructive symptoms over 6 months. Longer-term outcomes are needed to validate the efficacy of a bioabsorbable implant for the treatment of nasal valve collapse. This study was also limited by lack of comparison group that did not receive the studied implant.

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

Clinical Practice Guidelines

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

In a 2015 (reviewed 2021) position statement, the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) determined that the use of FDA-approved biomaterials can be utilized in sinonasal procedures to improve patient outcomes and reduce complications. These items, such as implants, stents, and packing materials, have functions including, but not limited to, local drug delivery, stenting, and hemostasis. The AAO-HNS does not consider FDA-approved biomaterials for rhinologic application to be investigational and recommends that the final decision regarding use of these biomaterials should be determined by the treating physician, factoring in best available scientific evidence, surgeon experience and the clinical situation, and individual patient preference. The references cited in the position statement do not specifically address non-steroid-releasing absorbable nasal implants, e.g., Latera.

American Rhinologic Society (ARS)

The ARS issued a position statement (2022) on the use of bioabsorbable nasal implants stating that it supports the use of a bioabsorbable nasal implant to treat nasal obstruction due to nasal valve collapse. The position paper states that this procedure should be considered as an effective option in treating nasal valve collapse and improving patient quality of life in those suffering from nasal airway obstruction due to nasal valve collapse based on their review of the San Nicolo (2017), Stolovitzky (2018) and Stolovitzky (2019) studies included above.

Nasal Septal Swell Body (NSB) Reduction

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

In their prospective, open-label, single-arm multicenter study, Pritikin et al. (2023) assessed the clinical use of a temperature-controlled radiofrequency (TCRF) device (VivAer) to treat septal swell body (SSB) hypertrophy to improve symptoms in adults with nasal airway obstruction (NAO). The study included 70 patients between 22 and 85 years old (mean age of 47.5 years, 51.4% male, 88.6% white) with severe (61.4%) or extreme (38.6%) NAO related to SBB hypertrophy. All patients received TCRF treatment in the SSB area with an average of 4.8 treatments per nostril (range 2 to 6). The primary endpoint was improvement in the Nasal Obstruction Symptom Evaluation (NOSE) score from baseline to 3 months post-procedure. One participant was lost to follow-up before the 3-month post-procedure assessment. The authors reported significant improvement in mean NOSE Scale scores from 73.5 at baseline to 27.9 at three months post-procedure with 4.3% of patients reporting no further breathing problems and 46.4% reporting mild NAO, 39.1% reporting moderate NAO, 10.1% continued to report severe NAO, and no patients reporting extreme NAO. The responder rate was reported by the authors to be 95.7%. In a subset of participants (n = 37) who underwent CT imaging to evaluate post-treatment changes in SBB size, the authors reported that the CT results at 3 months showed statistically significant reductions in SBB with the greatest reduction in the middle thickness. Limitations of the study include the study design (open-label, single arm), the homogeneity of the study population's race, lack of medication management of the participants, industry sponsorship, and the short-term follow-up. The authors concluded that the study demonstrated that TCRF treatment of SSB hypertrophy is well tolerated and effective for reducing both SSB size and symptoms of NAO at three months. The authors plan to follow the participants through 36 months post procedure.

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

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

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

Haight et al. conducted a prospective, non-randomized study of 28 patients who underwent inferior turbinate reduction alone and 28 patients who underwent inferior turbinate reduction in conjunction with NST reduction. Both cryosurgery and cautery were utilized. At 10 to 16 weeks postoperatively, there were no differences in patient symptoms or rhinometry between the two patient groups. Catalano et al. conducted a prospective study of NST RFA in 60 patients who had a history of a failed prior septoplasty and turbinate reduction. There were statistically significant reductions in nasal obstruction symptom evaluation (NOSE) scores: 41.6 at pre-treatment, 17 at month 3, and 21 at month 6. There were also statistically significant improvements in endoscopic middle turbinate visualization. There were three minor infections, one small, asymptomatic septal perforation, and five patients who required multiple treatments. Kim et al. (described in detail below) retrospectively reviewed nasal obstruction scores in 8 patients who underwent NST coblation. Utilizing a visual analog scale, an average pre-treatment score of 7.63 was reduced to 3.88 (month 3) 4.16 (month 6), and 4.63 (month 12). There were no complications reported.

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

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

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

Posterior Nasal Nerve (PNN) or Sphenopalatine Ganglion (SPG) Ablation

The quality of the body of evidence for posterior nasal nerve and for sphenopalatine ganglion ablation is insufficient to demonstrate the benefit of this procedure on long-term patents' outcomes, compared to established therapies.

Takashima et al. (2023) published twelve-month outcomes to the Stolovitzky (2021) industry sponsored, prospective, multicenter, patient-blinded crossover RCT below (NCT04533438). There were 116 adults (mean age of 57.5 years, 64.7% female) in the study with 77 randomized to the active treatment arm that received temperature-controlled radiofrequency (RF) neurolysis of the PNN via RhinAer®, and 39 randomized to sham procedure arm. Eligibility criteria included having chronic rhinitis of 6 months duration, and total 24-hour reflective total nasal symptom score (rTNSS) of ≥ 6, with moderate to severe symptoms of rhinorrhea (rhinorrhea sub score of 2-3) and mild to severe symptoms of nasal congestion (congestion sub score of 1-3). The sham control group was unblinded at 3 months post procedure (primary endpoint) and 27 of the 39 patients were transitioned to crossover active treatment as they still met eligibility criteria and agreed to continue participation in the trial. Those patients in the sham control group who were not eligible for crossover or did not wish to continue to participate in the trial were exited from the trial as were patients who underwent additional nasal procedures at any time during follow-up. The authors reported that the responder rate of the active treatment arm (which was superior to the sham control group at 3 months) was sustained through 12 months (with a rate of 80.6%), as was the rTNSS (improvement of 57.8%). Similarly, the distribution of postnasal drip and cough scores within the active treatment arm were also improved over baseline at all timepoints. The authors reported that the baseline characteristics of the crossover group were not significantly different from those of the active treatment group at baseline and that the mean rTNSS has followed the same course as that of the active treatment group. Limitations of the study include the lack of control of medication use, the lack of a sustained control group through trial completion, and the inclusion of patients with both allergic and nonallergic rhinitis. The authors concluded that the study demonstrated that the treatment effect of temperature-controlled RF neurolysis of the PNN area is safe and effective in reducing the symptom burden of chronic rhinitis patients through 12 months post procedure. The authors plan to follow the combined active treatment group through 2 years.

Desai et al. (2023) conducted a systematic review to assess the efficacy and adverse outcomes of cryotherapy delivered using the ClariFix™ device for the treatment of chronic rhinitis refractory to medical management. The review included 8 published studies [including the Del Signore (2022) and Chang (2020) studies below] consisting of one RCT, five prospective and two retrospective single-arm or cohort studies. There were 472 adults who had chronic rhinitis lasting > 4 weeks in total from all of the studies with the mean age in each study being between 52.3 and 60.04 years. The authors reported that seven of the studies utilized the Total Nasal Symptom Score (TNSS) and rTNSS score with an average baseline score of 7.12 and that four of the seven studies had an endpoint assessing symptom improvement after one month and three months. The authors reported that the data showed a significant reduction in scores post-treatment across all studies based on validated outcome measures as there was a significant improvement in outcome scores from baseline in all studies and at all interval times. They noted that no major adverse events were identified in any of the studies. Risk of bias was assessed by the authors with the risk of bias for the single RCT ranging from "low" to "unclear," and the cohort studies were rated as good and fair. Limitations of the study included the low quantity of published studies on the use of ClariFix cryoablation for the treatment of chronic rhinitis, the lack of comparators in most of the studies, the small sample size in four of the studies, industry sponsorship of 5 of the studies, and the variability of study reporting. The authors noted that statistical analysis of the pooled means was not able to be performed because of the lack of access to the raw data from the included studies. The authors concluded that cryotherapy provided a significant reduction in validated outcome scores for the treatment of chronic rhinitis that is refractory to medical management and is safe with only minor adverse effects reported. They, however, recommended more independent, high-quality RCTs to perform a meta-analysis analyzing the effect of cryoablation on chronic rhinitis.

In their systematic review and meta-analysis of PNN neurectomy, Balai et al. (2023) evaluated eight studies (two RCTs and six prospective, single-arm, unblinded, uncontrolled studies) with 463 participants to assess the effect of PNN neurectomy on Total Nasal Symptom Score (TNSS) in adults with chronic rhinitis. The mean age ranged from 53.3 years to 60 years and two of the studies reported results from the same patient cohort (pilot data and longer-term follow-up respectively). Four of the studies (Chang 2020, Ow 2021, Stolovitzky 2021 and Del Signore 2022) are included in this section of the policy. All six of the non-randomized studies were deemed to be at an overall moderate risk of bias with two of the studies deemed at serious risk of bias due to confounding factors and missing data due to participant attrition; one study was deemed to have serious risk of bias with 44% of the cohort lost to follow up; and the two RCTs were deemed to be at an overall low risk of bias. Interventions included cryotherapy (six studies, with five studies using ClariFix), radiofrequency (one study) or continuous wave laser (one study). The authors reported that a pooled analysis of data from the two RCTs found active treatment was associated with a significantly higher responder rate (≥ 30% reduction in TNSS from baseline) when compared to a sham control procedure although both RCTs had a short duration of follow-up and relatively high baseline TNSS suggesting a patient group with severe and refractory symptoms. With regards to the remaining six non-randomized studies, the authors reported a reduction in the average post-operative TNSS sustained over longer periods of follow-up. The authors also found a relatively high total number of reported adverse events with 125 reported from 461 procedures, although the adverse events were predominantly non-serious and transient. Limitations of the study include the broad design in the six non-RCTs and their moderate risk of bias, the racial homogeneity of the two RCTs and their patient selection criteria that required more severe symptoms at baseline than was required in the non-RCTs, the heterogeneity of the treatment approaches, and industry sponsorship of six of the eight studies. The authors concluded that there was some limited evidence suggesting that cryotherapy or radiofrequency ablation of the of the PNN can improve TNSS in adults with chronic rhinitis. The authors recommended additional prospective RCTs with larger numbers of participants and medium to long-term follow-up to draw more valid conclusions regarding the true effectiveness of PNN neurectomy.

In an industry sponsored prospective, multicenter, single-arm study of 129 adults with chronic rhinitis, Lee et al. (2022) sought to determine clinical outcomes and quality of life (QoL) following temperature-controlled radiofrequency neurolysis (TCRF) of the PNN. The study was conducted in 16 centers in the United States and Germany and included adults with chronic rhinitis symptoms > 6 months with a 24-hour reflective total nasal symptom score (rTNSS) ≥ 6, moderate to severe rhinorrhea, and mild to severe nasal congestion. All participants underwent TCRF with the RhinAer device with treatment at one to five nonoverlapping regions on each side depending on the target anatomy size. The primary endpoint was the mean change in 24h fTNSS from baseline to three months. Secondary endpoints included responder rate and the mean change in the mini rhinoconjunctivitis quality of life questionnaire (MiniRQLQ) score from baseline to three months. The authors reported that there was a mean 24h rTNSS improvement of 53.8% over baseline at 3 months (n = 128) and 62.8% improvement at 6 months (n = 123). They also reported that rhinorrhea, congestion, sneezing and itching sub scores and postnasal drip and cough scores were all significantly improved over baseline at both 3 and 6 months and that 80.3% of participants reported a minimal clinically important difference of ≥ 0.4-point improvement in the mini rhinoconjunctivitis QoL questionnaire score at 3 months with 87.7% of participants achieving such improvement at 6 months. The authors reported that there were no safety concerns or post procedure major adverse events reported. Limitations of the study include the lack of a control arm, lack of blinding, and short follow-up period. The authors concluded that TCRF neurolysis of the PNN was safe and resulted in a significant reduction in rhinitis symptoms at 3 months that was sustained/improved through 6 months with the majority of participants reporting a clinically relevant improvement in QoL at 3 and 6 months.

A 2022 Evolving Evidence Review (Hayes 2022a, updated 2023) addressed the use of ClariFix (Arrinex, Inc.) for improving the symptoms of chronic rhinitis. The review of full-text clinical studies, including one good-quality randomized controlled trial (RCT), two poor-quality single-arm studies, showed minimal support for the use of ClariFix to treat chronic rhinitis. The 2023 update included a review of the abstract only of a systematic review, which did not identify any new evidence regarding efficacy, safety or longer-term follow-up. One systematic review including a study utilizing ClariFix was identified, but no conclusions or findings specific to ClariFix were reported. There are no current clinical/society guidelines addressing ClariFix or cryoablation in general for nasal rhinitis. Therefore, Hayes concluded that the existing evidence suggest minimal or unclear support for the utilization of ClariFix at this time.

In their updated Evolving Evidence Review (Hayes 2022b, updated 2023), use of the RhinAer procedure (Aerin Medical) for treatment of chronic rhinitis was reviewed. The 2023 update included review of abstracts only for one RCT and two pretest-posttest studies [including Takashima (2023), Lee (2022) and Ehmer (2022) summarized in this policy]. Two of these studies reported longer-term follow-up data on the studies included in the 2022 report which included one poor quality and one fair quality study. Both of the initial studies reported that most individuals showed clinically significant relief of nasal symptoms post-treatment with RhinAer. One of these studies compared individual improvements to sham; the RhinAer group displayed improvement when compared with sham, but no studies compared RhinAer with other treatments. No relevant systematic reviews or guidelines were found. The Hayes Review notes that several clinical trials are currently underway, but at this time, evidence does not permit conclusions regarding whether outcomes of the RhinAer procedure are better, worse, or the same as any other treatment.

Del Signore et al. (2022, included in the 2022a Hayes Evolving Evidence review) directed a prospective, multicenter, 1:1 randomized, sham-controlled, patient-blinded trial to test if cryotherapy is superior to the sham procedure for reducing symptoms of chronic rhinitis. Adults with moderate to severe symptoms of chronic rhinitis and candidates for cryotherapy under local anesthesia were enrolled in the trial resulting in 61 participants per arm. The trial also applied additional requirements such as a minimum reflective Total Nasal Symptom Scores (rTNSSs) of 4 for total, 2 for rhinorrhea, and 1 for nasal congestion. Patient-reported outcome measures were assessed through the rTNSS, standardized Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ), and Nasal Obstruction Symptom Evaluation (NOSE) questionnaires at follow up visits 30- and 90-days post-procedure. The comparison between treatment and sham arms for the percentage of responders at 90 days was the primary endpoint, and responders were defined as those with a 30% or more significant reduction in rTNSS relative to baseline. The trial enrolled 133 participants at 12 U.S. investigational centers with the primary endpoint analysis, including 127 of those participants with 90-day results. Superior to the sham arm, the treatment arm at the 90-day follow-up was 73.4% responders compared to the 36.5% in the sham arm. The active arm improved rTNSS, RQLQ (s), and NOSE scores over the sham at the 90-day follow-up. Although the trial showed cryotherapy as superior to a sham procedure for improving chronic rhinitis symptoms and patient quality of life, the study had several limitations including racial homogeneity, restriction on rhinoscopies during the COVID-19 pandemic, precluded a meaningful evaluation of the objective endpoint, and short-term duration of follow-up. Future studies aiming to examine the broader racial diversity of participants, comparison to other treatments, and extended follow-up would aid in testing cryotherapy's effects on those with chronic rhinitis.

Ehmer et al. (2022, included in the 2022b Hayes Evolving Evidence Review) 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 rTNSS greater than or equal to 6 with sub-scores 2 to 3 for rhinorrhea, 1 to 3 for nasal congestion, and 0 to 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 possibly 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.

In a single-arm, prospective trial of 24 adults with chronic rhinitis that failed medical therapy, Gerka Stuyt et al. (2021) evaluated the efficacy of the cryosurgical ablation device of the PNN. The study population had an average age at the time of treatment of 60 years and were equally distributed between males and females. Patients were classified into three categories of rhinitis: non-allergic (n = 16), mixed (n = 5) and allergic rhinitis (n = 3). Prior medical therapy included saline irrigations (20.8%), anticholinergic nasal sprays (54%), antihistamines (37.5%) and intranasal corticosteroids (58.3%). Medical therapy was continued, decreased or discontinued based on the post-cryoablation symptomatology. Each patient completed the Total Nasal Symptom Score (TNSS) questionnaire (based on the previous 12 hours and 2 weeks) prior to treatment, and at 30 days, 90 days and 1-year post-treatment. The authors reported the TNSS 12-hour symptom score improved from 6.92 at baseline to 3.17 at 30 days, 2.92 at 90 days and 3.08 at 1 year post-treatment. The authors noted similar results for the 2-week scores with improvement from a baseline of 7.75 to 3.79 at 30 days, 3.88 at 90 days and 3.76 at 1 year post-treatment. The authors also reported that 64.7% of participants stated that the procedure decreased or eliminated nasal sprays. When the authors analyzed each rhinitis subgroup individually, 66.6% (8/12) of the non-allergic rhinitis, 100% (3/3) of the mixed rhinitis and 33.3% (1/3) of the allergic rhinitis patients decreased or eliminated the use of all medications. Limitations include the small sample size, the single-arm design, and the short follow-up time. The authors concluded that cryoablation of the PNN shows improvement in nasal symptoms over a 1-year period and that their findings were consistent with other published data.

Ow et al. (2021, included in the 2022a Hayes Evolving Evidence Review) conducted a prospective single-arm multicenter study to assess the long-term safety and effectiveness of the PNN cryoablation as a treatment for chronic rhinitis. Change from baseline in the rTNSS, physician assessment of improvement using the Clinical Global Impression Improvement (CG-I), Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ), and the incidence of treatment-related adverse events were the studies endpoints. Of the 100 participants enrolled at six U.S. investigational sites, in the first 12 months, ninety-one participants completed the study, and sixty-two participants consented to the long-term follow-up, with 57 completing the 24 month follow-up. The total rTNSS showed significant improvements with the median change from baseline of -3.0 or -4.0. The minimum clinically importance difference (MCID) was achieved by greater than 80% of participants on the rTNSS at all follow-ups. RQLQ scores showed a significant improvement in quality of life, with over 77% of participants achieving the MCID for the total RQLQ score. The CGI-I resulted in greater than or equal 83% of participants experiencing improvement at all visits except the 12-month follow-up (61.9%). AEs were reported in 23 participants, with one participant experiencing epistaxis and retained pledget. Although the study included a relatively large population of participants followed through 24 months after treatment using multiple validated assessments to evaluate various outcomes, the single-arm design without a concurrent control arm and the loss of nearly 30% of individuals after 12 months creates significant limitations. After the study, no significant differences were seen in rTNSS outcomes between allergic and nonallergic rhinitis participants. Furthermore, between the observed and imputed rTNSS results, there was a -1 difference in the change from baseline and a 3% difference in the percent of participants who achieved MCID.

Stolovitzky et al. (2021, included in the 2022b Hayes Evolving Evidence Review) headed a multicenter, prospective, single-blinded, RCT in which the control arm underwent a sham procedure to determine the safety and efficacy of temperature-controlled RF neurolysis of the PNN for the treatment of chronic rhinitis. In the setting of 16 otolaryngology centers, individuals with an rTNSS greater than or equal to 6 were randomized 2:1 to active treatment of the PNN area with a temperature-controlled RF or sham procedure without the delivery of RF energy. At three months, the primary endpoint responder rate showed a response greater than or equal to a 30% improvement (decrease) in rTNSS from baseline. The active treatment group showed results of average baseline rTNSS of 8.3, and the results of the sham control were 8.2. At three months in the active treatment arm, the responder rate was significantly higher, resulting in 67.5% vs. 41.0%. Additionally, the active treatment arm showed a significantly greater decrease in rTNSS than that sham arm. The authors concluded that the results of the RCT demonstrated that RF neurolysis is superior to sham control in reducing the overall symptom burden experienced by individuals with chronic rhinitis. However, the trial was pragmatic in its design as it did not demonstrate a reduction in medication use with active treatment and did not dictate medication use.

Additional limitations include the short three-month follow-up, lack of comparison to other treatments, and no investigator blinding during the study. Longer-term follow-up is necessary to report on the durability of treatment effects.

In a 2020 ECRI Clinical Evidence Assessment, data from 4 case series were extracted including dates from January 1, 2015, to August 14, 2020. The studies indicate that the ClariFix procedure is safe and may provide symptom relief for individuals with chronic rhinitis at three months to 1-year follow-up. However, all studies examined had limitations including risk of bias due to small sample size, and lack of controls, randomization and blinding. The assessment concluded that overall, the evidence addressing the ClariFix procedure is inconclusive and further randomized controlled trials are required to determine whether ClariFix is superior to other treatments.

Chang et al. (2020, included in the 2022a Hayes Evolving Evidence Review) conducted a prospective, multicenter, single-arm, open-label clinical trial to assess the efficacy and safety of cryoablation of the PNN for treating chronic rhinitis. The trial consisted of 98 participants from six U.S. centers with chronic allergic and non-allergic rhinitis who were instructed to discontinue intranasal ipratropium three days before treatment and for the duration of the study. The rTNSS was measured at pretreatment baseline and 1, 3, 6 and 9 months post-treatment. The RQLQ and number of AE were completed at pretreatment and three months after post-treatment. The study resulted in the successful completion of 98 procedures. rTNSS significantly improved over pretreatment baseline at 1, 3, 6, and 9 months post-procedure, with nasal congestion and rhinorrhea sub-scores improving considerably at all time points. Non-allergic and allergic rhinitis sub cohorts showed a comparable degree of improvement between groups. All RQLQ subdomains showed improvement, with significant progress over the pretreatment baseline at three months. Of the 54 Individuals who utilized intranasal medication at baseline, 19 were able to stop taking the drug after the treatment. AE were reported in 29 individuals, including headache, epistaxis, and sinusitis. The authors concludes that cryoablation of the PNN for chronic rhinitis can decrease rhinitis nasal symptoms and improve disease-specific quality of life. However, several limitations are present such as the lack of control treatment arm and potential for bias due to lack of blinding. Furthermore, inclusion criteria required a failure of 4 weeks of intranasal corticosteroids (INCS) but did not explicitly require treatment failure with ipratropium or other nonsteroidal medications. Although a significant improvement was seen in quality-of-life outcomes by RQLQ at 90 days, the RQLQ scores were not tracked beyond the 90 days, limiting the ability to ascertain the durability compared to improved rTNSS scores noted beyond 90 days.

Prasanna et al. (1997) evaluated the effectiveness of sphenopalatine ganglion (SPG) block for the relief of symptoms in chronic vasomotor rhinitis in a single-arm, single-center study with 30 patients, aged 15-45 years, who had established diagnoses of chronic rhinitis of several years duration. All participants had been receiving regular medical therapy without relief. Each participant was administered bilateral SPG block at weekly intervals for four weeks. The participants were instructed to continue other symptomatic therapies if needed. A subjective assessment of symptom relief was performed at weekly intervals with a monthly follow-up. The authors reported that all participants experienced mild discomfort (facial flushing, increased nasal congestion and breathing discomfort) for 24 hours after the first block and then reported a sense of roominess in the nose, a feeling of lightheadedness and greater ease of breathing. None of the participants reported discomfort with subsequent blocks. The number of blocks varied from two to four, depending on the subjective assessment of symptom reduction. Five participants (16.7%) needed four blocks, 20 (66.7%) had three blocks, and five (16.7%) required two blocks. Sixteen participants (53.3%) had deviated nasal septum and four participants (13.3%) had vascular congestion. The authors reported that during a follow-up of 12-20 months, no recurrence was reported in 29 of the 30 participants (96.7%) and that the one patient was symptom free for eight months before recurrence of early morning sneezing and mild difficulty breathing through the nose and was lost to follow-up. Three patients reported using antihistamines in the first week after the block due to fear of precipitating symptoms. The authors concluded that SPG block may be useful in the treatment of vasomotor rhinitis. The study is limited by lack of comparison group.

Clinical Practice Guidelines

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

In a 2023 position statement that addresses PNN ablation for the treatment of chronic rhinitis, the AAO-HNS stated that PNN neurolysis techniques such as RFA and cryotherapy thermal application methods have demonstrated clinical benefit for nasal symptoms. The position statement included a review of one multicenter, patient-blinded, sham-controlled RCT (including the Stolovinsky 2021 study above with three-month outcomes and the Takashima 2023 study above with 12-month outcomes for clinical trial NCT04533438) on radiofrequency neurolysis and one multicenter, patient-blinded, sham-controlled RCT (the Del Signore 2022 study above) on cryotherapy that evaluated the clinical benefit of these treatments on chronic rhinitis. They also reviewed five studies that included quality of life surveys that the society stated showed statistically significant improvement with treatment (3 studies, including the Ow 2021 and Chang 2020 studies above) with therapeutic effect (two studies, including the Ehmer 2022 study above). Based on their review of these studies, the AAO-HNS endorsed the use of PNN ablation for the treatment of medically-refractory chronic rhinitis.

Radiofrequency Treatment of Nasal Valves

While the use of transmucosal, temperature-controlled radiofrequency (RF) technology for the treatment of nasal airway obstruction is promising, there is a lack of published high quality, robust, multicenter RCTs with long-term results that demonstrate the safety and efficacy of this approach.

Casale et al. (2023) conducted a systematic review and meta-analysis to assess the efficacy of temperature-controlled radiofrequency (RF) to treat nasal obstruction. There were four prospective studies with 218 adults between the ages of 19 and 83 years old included in the review and analysis, including the Silvers (2021) study discussed below, with one RCT and three observational studies . All four studies followed the same protocol with bilateral treatment of the nasal valve regions in an office-based procedure under local anesthesia using the VivAer™ System. Three of the studies showed a moderate risk of bias and one had a serious risk of bias and the authors also noted that two of the four studies were industry sponsored. The authors reported that the Nasal Obstruction Symptom Evaluation (NOSE) score was reduced at three months post operatively [pre-treatment: 76.16 ±6.39; post-treatment: 31.20 ±2.73; MD: 46.13; 95% confidence interval (CI) 43.27-48.99] with moderate heterogeneity. The authors concluded that RF treatment could be useful for treating nasal valve collapse, improving significant subjective breathing symptom scores and they stated that the outcomes should be considered with caution due to the moderate heterogeneity of the results and the limited number of studies with small populations and short follow-up periods. The findings are limited by the lack of comparison group for most of the included studies. The authors recommended more extensive comparative studies and well-designed RCTs with validated patient-reported outcome measures to provide more definitive recommendations.

Yao, et al. (2023) published results from their clinical study with two-year results on the use of temperature-controlled radiofrequency (TCRF) for the treatment of the nasal airway obstruction (NAO) due to nasal valve collapse (NVC). This prospective, single-arm, multicenter cohort study included 122 adults with NVC as a primary or significant contributor to their NAO who had baseline Nasal Obstruction Symptom Evaluation (NOSE) Scale 15 scores of ≥ 60. There were 101 participants who completed the 2-year follow up, of which 12 study participants underwent additional nasal procedures. The data from those who had undergone additional nasal procedures were not included in the 2-year analyses. Responders were defined as patients with ≥ 20% improvement in NOSE Scale score or ≥ 1 severity class improvement from baseline. The authors reported that the mean baseline NOSE Scale score for the 91 participants who completed the 2-year follow-up and had not undergone additional nasal procedures was 80.3 and the adjusted mean change in score at 2 years was −45.8 (a 57.0% improvement) while the 2-year responder rate was 90.1%. The authors also reported that there was significant and sustained symptom improvement in subpopulations based on sex, age, body mass index, baseline NAO severity, nasal surgery history, NVC mechanism, septal deviation, and other anatomic contributors of NAO. Limitations of the study included the lack of a control group, randomization and blinding, and racial homogeneity of the study population. The authors concluded that TCRF treatment of the internal nasal valve for NAO was well tolerated and led to significant and sustained improvement in NAO symptom severity through 2 years, including in patients with both static and dynamic NVC, septal deviation, turbinate enlargement, or prior nasal surgery.

ECRI published a Clinical Evidence Assessment (2022) on the VivAer nasal airway remodeling stylus following their review of five studies described in eight publications and reporting on 341 patients. The studies consisted of one randomized, sham-controlled trial (RCT) (Silvers, 2021 included below) and four single-arm pretest/posttest studies. They reached a low-confidence conclusion that the device worked well for reshaping the nasal airway and improving nasal breathing at three-month follow-up as the findings showed that the reported effects were clinically significant and consistent across independent studies. ECRI was not able to determine how well VivAer would perform longer-term or how it compared with conventional or other surgical devices due to the limited published evidence. ECRI stated that their confidence in the conclusions was low because the studies were at high risk of bias due to their small size, lack of parallel controls, randomization, and/or blinding, and high patient attrition at longest follow-up. They recommended larger, multi-center RCTs comparing the VivAer device to standard surgical tools and other devices and treatments for nasal collapse with longer-term outcomes to support stronger conclusions.

Jacobowitz et al. (2022) reported on 48-month follow-up data to assess the long-term durability of temperature-controlled radiofrequency (TCRF) treatment of nasal valve collapse for relief of symptoms of nasal airway obstruction. The patients in this extended 48-month follow-up study had agreed to participate after completing an initial 26-week prospective, single-arm, multicenter study with an extension to 24 months. The patients initially presented with chronic severe nasal obstruction with nasal valve collapse identified as the primary cause of nasal obstruction and had undergone bilateral treatment with the VivAer device. Assessments include the use of the Nasal Obstruction Symptom Evaluation (NOSE) scale score, which were completed in person, by telephone or through the mail at 36- and 48-months post procedure. Of the 49 patients in the initial study, 39 agreed to participate in follow-up through 24 months and 29 patients agreed to extended follow-up through 48 months. The authors reported that the baseline mean NOSE score was 81.0, the score was 21.6 at 6 months, 25.6 at 12 months, 29.3 at 18 months, 22.5 at 24 months, 32.3 at 36 months and 25.7 at 48 months. The authors also reported that 67.9% of patients had severity scores in the "no problems" or "mild" categories, 21.4% were in the “moderate” and 10.7% were in the “severe” categories which represented significant changes in the proportion of patients in each category. Based on a ≥ 15-point improvement on the NOSE score scale, 93.1% (27 of 29), 96.3% (26 of 27), 96.6% (28 of 29), 100% (27 of 27), 92.9% (26 of 28), and 96.4% (27 of 28) of patients were considered responders at the 6-, 12-, 18-, 24-, 36-, and 48-month follow-up times, respectively. Limitations of the study included the single-arm design, lack of control of medication usage, significant patient attrition relative to the primary study, small sample size and industry sponsorship. The authors concluded that significant and sustained improvements in symptoms of nasal airway obstruction were shown through 4 years following treatment of nasal valve collapse with a single TCRF procedure.

In an Evolving Evidence Review, Hayes (2021, updated 2023) reviewed four full-text clinical studies and determined there was minimal support for using the VivAer radiofrequency procedure for remodeling the nasal valve area when collapse of the nasal valve is associated with chronic nasal obstructive symptoms. Three of the four studies were single-group, non-randomized, pretest-posttest studies with small populations of 20 to 50 participants. One was found to be of very poor quality, and two were found to be of poor quality, while the RCT (Silvers, 2021 study below) was found to be fair quality and showed clinical benefit over sham at up to three months post-procedure. No systematic reviews or clinical practice guidelines were identified to include in the review.

Han, et al. (2022) completed a 12 month follow up study on a cohort from the Silvers, et al. (2021) study (below) to determine if active treatment of the nasal valve with a temperature-controlled radiofrequency (TCRF) was safe and had sustained improvements in symptoms of nasal airway obstruction through 12 months. In the initial Silvers study, 108 patients received active treatment (77 in the initial treatment group and 31 in the control group who then crossed over to receive TCRF treatment after 3 months). The authors found that, at 12 months post-treatment with TCRF, the Nasal Obstruction Symptom Evaluation (NOSE) Scale score improved from an average of 76.3 at baseline to an adjusted mean change of -40.9 at 3 months, -43.2 at 6 months and -44.9 at 12 months with a responder rate of 89.8% (n = 88) and no reported device/procedure-related serious adverse events. The use of medications, nasal strips and cones were tracked during the trial and an analysis of their use showed decreased use overall from baseline to 12 months post procedure. Limitations of their study included the fact that medication use was not defined by the protocol and could potentially have had some confounding effect on symptom relief, the small sample size, the lack of a control group that did not crossover/receive TCRF and the short length of follow up of 12 months. The authors concluded that patients who receive active TCRF device treatment of the nasal valve demonstrated that the treatment was safe and that the effect was durable through 12 months post-procedure. However, the study design did not allow comparison to the sham procedure beyond 3 months and loss-to-follow-up may have introduced biases.

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

U.S. Food and Drug Administration (FDA)

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

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

Refer to the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed October 2, 2023)

The VivAer® Stylus received 510(k) clearance in March 2020, as a Class II device 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. Refer to the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K200300. (Accessed October 2, 2023)

Intranasal septal splint devices are classified by the FDA as class 1 devices under product code LYA. This category includes over 40 devices including, but not limited to, Alar Nasal Valve Stent, Spiway Endonasal Access Guide, Novashield Injectable Nasal Packing and Stent and the Macropore Ent Reconstruction Film. The FDA has exempted almost all class I devices (except for reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the Federal Registers of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with 21 CFR 874.9. Refer to the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed October 2, 2023)

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

For additional information, refer to:

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

(Accessed October 2, 2023)

The ClariFix Device is a cryosurgical tool intended to be used for the destruction of unwanted tissue during surgical procedures, including in adults with chronic rhinitis. It received U.S. Food and Drug Administration (FDA) clearance as a Class II device through the 510(k) premarket notification pathway on February 14, 2017. Refer to the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K190356. (Accessed October 2, 2023)

U.S. Food and Drug Administration (FDA) cleared The RhinAer Stylus as a Class II device through the 510(k) premarket notification pathway on July 29, 2022. This device 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. Refer to the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K221907. (Accessed October 2, 2023)

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Policy History/Revision Information

Date	Summary of Changes
06/01/2025	• New Medical Policy

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.