Rhinoplasty and Other Nasal Procedures

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➲ Instructions for Use

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Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit 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 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 anatomical deformities narrowing the internal and/or External Nasal Valve as a main cause of an anatomical Mechanical Nasal Airway Obstruction and are consistent with the clinical examination; and

- The surgeon has clearly described:
  - Whether the nasal valve compromise is static or dynamic; and
  - Whether the nasal valve compromise involves the 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 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 anatomical Mechanical Nasal Airway Obstruction or chronic infection and are consistent with the clinical examination; and
- The proposed procedure is designed to correct the anatomical 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 syndrome, Apert syndrome, Fraser syndrome, Binder syndrome, Goldenhar syndrome, nasal dermoids, and Tessier nasal cleft (most commonly number one) 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 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 anatomical Mechanical Nasal Airway Obstruction; or
  - Nasal fracture with nasal bone displacement that is 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 anatomical Mechanical Nasal Airway Obstruction and are consistent with the clinical examination; and
- The proposed procedure is designed to correct the anatomical 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 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 anatomical Mechanical Nasal Airway Obstruction and are consistent with the clinical examination; and

- The proposed procedure is designed to correct the anatomical 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 the following criteria are present:
- Prolonged, Persistent, Obstructed nasal breathing due to tip drop that is the primary cause of an anatomical Mechanical Nasal Airway Obstruction (this code is usually cosmetic); and
- Photos clearly document tip drop as the primary cause of an anatomical Mechanical Nasal Airway Obstruction and are consistent with the clinical examination (acute columellar-labial angle); and
- The proposed procedure is designed to correct the anatomical 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 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 member specific benefit plan document for applicable definitions.

Acute Rhinosinusitis: Acute Rhinosinusitis 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 (Rosenfeld et al., 2015).

Chronic Rhinosinusitis: Chronic Rhinosinusitis 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 External Nasal Valve includes the caudal edge of the lateral crus of the lower lateral cartilage, soft tissue alae, membranous septum, and sill of the nostril. It is the entrance to the nose (Totonchi et al., 2024).

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; and 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 and Most, 2009).

Prolonged, Persistent Nasal Airway Obstruction: Trouble breathing through the nose (not snoring) that has not responded to 6 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 and Most, 2009).

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

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

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the protocol titled Medical Records Documentation Used for Reviews.

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 the member specific benefit plan document 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
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 2 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) is the only U.S. Food and Drug Administration–approved absorbable nasal implant at this time. 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 individuals 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 an individual's nose (Stryker, 2019).

Nasal septal swell body reduction: A procedure to address the symptoms of chronic rhinitis, Chronic Rhinosinusitis, or nasal obstruction by decreasing the size of an enlarged nasal septal swell body (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 the nasal septal turbinate, septal turbinate, Kiesselbach body, septal swell body, nasal septal body, septal body, nasal swell body, swell body, septal erectile body, septal cavernous body, anterior septum tuberculum, and intumescentia septi nasi anterior. The nasal vestibular body 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 benefit coverage for services that UnitedHealthcare considers cosmetic procedures, such as repair of external congenital anomalies in the absence of a Functional Impairment. Refer to the member specific benefit plan document.

UnitedHealthcare excludes cosmetic procedures from coverage, including but not limited to the following:

- Procedures that correct an anatomical congenital anomaly without improving or restoring physiological function are considered cosmetic procedures. The fact that a covered person may experience psychological consequences or socially avoidant behavior as a result of an injury, sickness, or congenital anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a reconstructive procedure.

Clinical Evidence

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

Marianetti et al. (2024) conducted a prospective, single-center, single-arm study to evaluate the efficacy of the alar extension graft for the correction of external nasal valve collapse and to evaluate the functional and aesthetic results. The study included 51 adults (23.5% male; mean age, 35.4 years) with external nasal valve collapse as the sole factor of nasal obstruction and who underwent open rhinoplasty. Rhinomanometry was performed before and after surgery, along with the completion of the Nasal Obstruction Symptom Evaluation (NOSE) and Sino-Nasal Outcome Test-20 (SNOT-20) questionnaires at baseline and at 9 months after surgery. The authors reported that 90% of the participants were subjectively satisfied with the postoperative improvement in nasal breathing and that there was significant improvement in the values of the preoperative (62 points) and postoperative (29 points) NOSE scores and SNOT-20 questionnaire scores (28 points prior to the operation and 18 points post operation). The authors also reported that rhinomanometry showed increased nasal flow, with a statistically significant difference between preoperative (515.53 ml/s) and postoperative (588.61 ml/s) results. Limitations of the study include the small study population size, single-center design, lack of a control group, and short-term follow-up. The authors concluded that the alar extension graft was proven to be effective and reliable in the surgical treatment of external nasal valve collapse, with improvement in objective and subjective breathing and good functional and aesthetic results.

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) reported that the SEG technique, which they applied for nasal projection in rhinoplasty surgery, increased the extension of the lower lateral cartilage lateral ridge and alar structures. The study included 23 patients, 18 male and five female, with mean ages of 45.5 and 39.7 years, respectively, with alar collapse, 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 reports of nasal obstruction on deep inspiration noted by the patients at their 6-month postoperative follow-up. The mean respiratory score was 152 post operation compared with 66.5 prior to the operation. The authors concluded that SEG use is effective for individuals with bilateral nasal collapse and thick-short columella that 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. Overall, 53 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 (autospreader flap) and placebo arms. Most of the included studies presented in this systematic review provided 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 individuals' outcomes. The authors concluded that proper evaluation and identification of the cause of internal valve collapse are paramount prior to selection of the preferred surgical solution. Treatment approaches should be directed at specific involved sites in the internal valve and need to be tailored toward the individual'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 individuals in each study, a stated aim to improve airway obstruction, and a minimum of a 1-month follow-up for every individual. Of these studies, one trial presented level IIIb evidence, and all other studies were classed as level IV. Seven authors presented objective measurements of nasal airflow or cross-sectional area, and four authors presented validated outcome measures. The authors concluded that there is a variety of focused surgical techniques described that deal with nasal valve collapse. They could find no RCTs on nasal valve surgery. Research in nasal valve surgery is frequently driven by a technical description of surgical technique rather than the establishment of evidence of long-term benefit in individuals. Although the understanding of the role of the nasal valve in the pathophysiology of nasal obstruction has improved vastly, the myriads of surgical techniques described reflect the uncertainty in choice of technique and in degree of benefit in individuals. Well-designed, adequately powered, prospective RCTs 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 recognizes 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 (NVD) 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 (NAO), is required to optimize patient outcomes in patients who require anatomical widening and definitive stabilization of the nasal valve.

Rhinophyma Excision

Hempel et al. 2025 published a retrospective study evaluating a combined surgical approach for treating pronounced rhinophyma using Rhinoshave followed by fractional ablative CO_2 laser therapy. Conducted at Leipzig University Hospital in 46 patients between 2016 and 2024, the method aimed to achieve precise nasal contouring while minimizing thermal damage and scarring. Results showed high patient satisfaction (92.6%), low complication rates, and a recurrence rate of 17.9%, which is significantly lower than that with shave excision alone. The technique allows for effective tissue removal, histological examination, and improved cosmetic outcomes, making it a safe and feasible option for advanced rhinophyma cases. Limitations of this study include the lack of direct comparisons with other surgical methods and the retrospective nature. Future prospective, multicenter studies are recommended to validate these findings.

Zheng et al. (2024) conducted a retrospective single-center study to evaluate the clinical effectiveness and recurrence rates after treating severe rhinophyma with the five-blade scratcher. The study included 28 adults (mean age, 52 years; 92.9% male) with severe rhinophyma rosacea who were assessed with the Global Flushing Severity Score, Clinician Erythema Assessment, Rhinophyma Severity Index, Glasgow Benefit Inventory, and satisfaction scores at baseline, 6 months, and 5 years post operation. The recurrence rate was calculated at 5 years post operation, and the levels of proinflammatory factors in the serum of patients were detected before and after surgery. The authors reported that the Global Flushing Severity Score, Clinician Erythema Assessment, and Rhinophyma Severity Index scores at 6 months and 5 years post operation were significantly lower than those prior to the operation, with a small number of patients (25%) reporting recurrence after surgical treatment. The authors also reported that the expression of proinflammatory factors was significantly reduced after surgery. The authors concluded that the five-blade scratcher treatment demonstrated simplicity, safety, and efficacy as well as reduced bleeding, minimized scarring, demonstrated lower recurrence rates, decreased proinflammatory factors, and improved patient satisfaction. Limitations of the study include the lack of a comparator, the single-center design, and the small sample size.

Chauhan et al. (2020) completed a systematic review comparing laser therapy, scalpel excision, and subunit treatment outcomes in individuals with rhinophyma from 1946 to 2020 using an Ovid MEDLINE literature search. From a total of 351 articles, 23 met the criteria for inclusion. Among 12 studies, 247 individuals, 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 individuals were treated, with a mean age of 62 years and a total of one individual with minor, 12 with moderate, and five with major rhinophyma using the erbium:YAG laser in 1.0 sessions. A total of 108 individuals underwent cold knife tangential excision among eight studies. Individuals had a mean age of 61 years and were treated for minor to major rhinophyma, and all required a single session for treatment. Seven individuals, with a mean age of 67 years, underwent treatment with a Shaw Scalpel, and all required a single session for treatment. Eight individuals (mean age, 63 years) underwent treatment with the subunit method. Four individuals had external valve collapse. Four individuals received alar batten cartilage grafts, all had interdomal sutures, and one individual required a skin graft. Both the complication and revision rates were 75%, but only minor revisions under a 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 postoperative complications; however, it risked poor hemostasis intraoperatively. Individuals' satisfaction was common post therapy, regardless of the treatment method. Over 89% of individuals would recommend undergoing treatment for rhinophyma, irrespective of treatment type. Treatment options vary, and choice of treatment can be dependent on practitioner and the individual's treatment goals. Reporting of quantitative and qualitative outcomes between studies is not standardized. Further research, with RCTs, is needed to validate these findings.

Rhinoplasty

The systematic review and meta-analysis by Alanazi et al. (2025) evaluated 65 studies (41 with analyzable data) on the effectiveness, outcomes, and safety of primary rhinoplasty performed during cleft lip repair and found that the combined procedure significantly improved surgical success compared with cleft repair alone (risk ratio, 1.87; $p < 0.0001$) and achieved overall goals in 73.6% of unilateral and 88% of bilateral cases, with only 14% of unilateral individuals requiring later revision. Anthropometric outcomes showed minimal differences from controls in unilateral cases but substantial differences in bilateral cases, including wider nasal width, reduced tip projection, and larger nasolabial angles, while long-term follow-up confirmed stable nasal symmetry and low complication rates. Limitations include the high heterogeneity across studies due to wide variations in deformity severity, surgical techniques, and outcome measurement methods; inconsistent follow-up durations; and limited data for bilateral cases, restricting the strength of subgroup conclusions. Overall, the findings support primary rhinoplasty as an effective and generally safe component of cleft lip repair and emphasize the need for standardized techniques and assessment tools in future research.

Yuan and An (2024) conducted a systematic review to evaluate the improvement in NAO after secondary rhinoplasty for cleft lip. The review included 29 studies (15 case series, seven prospective cohort, five retrospective cohort, and two case reports), with a total population of 1,031 individuals with cleft lip. Nasal ventilation outcomes were measured using subjective methods in 21 studies and with objective methods in eight studies. Comparison groups were included in six of the studies that used subjective methods and all of the studies that used objective methods to assess nasal ventilation outcomes. All of the studies included human individuals undergoing secondary rhinoplasty with cleft lip nasal deformity and were published between 2004 and 2023. The authors reported that all 29 studies consistently demonstrated that secondary rhinoplasty can effectively eliminate or alleviate symptoms of NAO, with improvement seen in the domains of snoring, trouble breathing through the nose, and the ability to get enough air through the nose during physical exertion. The authors also reported that it is generally recommended to perform definitive rhinoplasty after complete facial development, as it has a higher improvement rate and avoids potential subsequent anatomical changes in nasal structure; however, if severe nasal obstruction caused by caudal septal deviation is present or significant emotional distress due to peer psychological pressure is present, intermediate rhinoplasty can be considered as an early intervention. Limitations of the study include the heterogeneity of the study designs, measurement tools, and surgical techniques. The authors concluded that the review posits that secondary cleft lip rhinoplasty can effectively ameliorate NAO and recommended that larger-scale, comparative studies be conducted to address more specific inquiries, including surgical techniques and optimal measurement methodologies.

In a single-center retrospective cohort study in 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 patients (89%) 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 computed tomography or clinically present in 135 patients (32.4%); 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 an average of 6 days post trauma, with gauze removal 2 days post operation, and cast removal occurred after 7 days. The authors reported that 47 patients (11.3%) required revision rhinoplasty after fracture healing, which was performed an average of 398 days (range, 214-592 days) after the initial reduction. The authors reported that patients who experienced 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 in patients reporting airway obstruction at the time of cast removal after closed reduction. Limitations of the study include the retrospective design, inclusion of cases operated on by multiple surgeons, lack of medical records related to possible existence of airway obstruction prior to the nasal fracture, and 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 procedure. 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 on nasal obstruction in individuals with nasal valve problems. A total of 57 cohorts from 43 studies, involving 2,024 individuals, were included in the current meta-analysis (level of evidence III). NOSE scores indicated significant improvement in nasal obstruction at the 1-month, 3-month, 6-month, 12-month, and last follow-up with respect to the preoperative baseline. Visual analog 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 rhinomanometry but not through peak nasal inspiratory flow. The authors concluded that functional rhinoplasty 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) was performed to evaluate the effects of septoplasty (SPL), septorhinoplasty (SRP), and rhinoplasty procedures on postoperative olfactory function and their relationship to nasal airflow and quality of life (QOL). Preoperative and postoperative values for olfaction, nasal airflow, and QOL/nasal symptoms were analyzed. The effect size was calculated from each study and used for meta-analysis. As studies evaluated individuals 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, individuals experienced significant improvements in olfaction ($p < 0.001$), nasal airflow ($p < 0.001$), and QOL/nasal symptoms ($p < 0.001$). Individuals often experienced a transient decrease in olfaction immediately after surgery, followed by improvement post operation. Preoperative olfactory dysfunction rates were low, and postoperative dysfunction was equally low. Olfaction improvement was directly correlated with improvement in nasal airflow and QOL. 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 postoperative period, which improved at later time points. The study is limited due to a heterogeneous population of individuals. In addition, due to smaller sample sizes, there is an inherent risk of publication bias.

Martin et al. (2021) completed a prospective RCT to evaluate the subjective and objective outcome of SPL and SRP on participant satisfaction. Participants with functional indication for SPL (n = 19) or SRP (n = 54) were included and randomized for additional turbinoplasty. Preoperative clinical symptoms were collected with the SNOT-20 German Adapted Version (GAV) and NOSE questionnaires. The final evaluation of treatment success was performed 9 months after surgery with the SNOT-20 GAV, the 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)]. MCA2 was statistically improved compared with the pretreatment value in SPL ($p = 0.0004$) and SRP ($p = 0.0001$). Regarding MCA2 values of matched participant groups, similar findings were detected (SPL: $p = 0.0013$; SRP: $p < 0.0001$). SNOT-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 participant satisfaction in a self-established feedback questionnaire revealed a motivation of 81% in participants 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 to improved nasal breathing and increased disease-specific satisfaction quantitatively. Further research, with RCTs, 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 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 (SMD). Heterogeneity was assessed and reported through the I^2 statistic. Individuals in the included studies had moderate to severe nasal obstructive symptoms at baseline. The NOSE scores were improved at 3 to 6, 6 to 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 population of individuals, large variability in outcomes beyond 12 months, and 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 is 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 paranasal sinuses. When these adjunctive procedures are performed without an impact on 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 updated their 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 primary rhinoplasty, with or without limited SPL, should be performed at the time of the primary cleft lip surgery to address nasal distortion depending on the severity of the cleft lip, and nasal and/or septal reconstruction and skeletal correction of a retrusive mandible and/or maxilla may be done to achieve additional airway improvement. They further advise that earlier intervention, including rhinoplasty and nasal septal surgery, may be indicated for reasons of an 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 (2025).

American Society of Plastic Surgeons (ASPS)

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

Absorbable Nasal Cartilage Support Implants

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

Clark et al. (2024) conducted a retrospective single-center study to compare quantitative NOSE scores for autologous cartilage grafts (ACGs) and Latera nasal implants for nasal valve repair. The study included 63 patients who had completed NOSE surveys prior to and post operation at 1, 3, and 6 months. There were 24 patients who underwent ACG (62.5% male) and 39 (48.7% male) who received Latera nasal implants. The authors reported that there were no differences in demographic characteristics or in preoperative baseline NOSE scores between the two groups and that the mean operative times were not significantly different between groups. The authors reported that NOSE scores were significantly improved at each postoperative visit compared with baseline and that between groups, the mean NOSE scores were lower at each postoperative visit for ACG compared with Latera, with a NOSE score of 21.7 for ACG and 45.9 for Latera at 1 month, 14.5 for ACG and 39.9 for Latera at 3 months, and 8.4 for ACG and 44.2 for Latera at 6 months. Limitations of the study include the heterogeneity of concomitant procedures performed in both groups, small number of patients, and retrospective single-center design. The authors concluded that both ACG and Latera offer significant improvements in patient-reported nasal obstruction severity; however, ACG may yield more favorable subjective symptom scores.

In their Executive Summary on the Latera Absorbable Nasal Implant, ECRI (2017; updated 2024) reviewed evidence from one systematic review with meta-analysis (Kim et al., 2020, study below), two RCTs (Stolovitzky et al., 2019, and Bikhazi et al., 2022, below and also included in the Kim et al., 2020, systematic review with meta-analysis), one nonrandomized comparison study (Olson and Barrera, 2021, below), and three pretest/posttest studies and found that Latera appears to improve breathing in individuals with nasal wall collapse at the 2-year follow-up; however, they noted that the efficacy of Latera compared with that of rhinoplasty is unclear because the studies provided too few data. The authors noted that the pooled findings are at a risk of bias due to the subjective measurement tools used to assess efficacy, lack of parallel control groups, and inclusion of other treatments along with Latera. They also noted that some studies were at a high risk of bias due to a small sample size, lack of randomization, and lack of control groups. Sham-controlled double-blinded RCTs, with uniform treatment protocols and long-term follow-up (> 2 years), are needed to demonstrate the durability of Latera's benefits and to support stronger conclusions.

In an Evolving Evidence Review, Hayes (2022; updated 2025) completed a systematic search and findings summary on clinical studies, systematic reviews, and clinical practice guidelines on absorbable nasal implants. In the 2024 annual review, Hayes noted that they had identified two additional published clinical studies since the report was initially published in 2022 (including the Olson and Barrera, 2021, study below and the Clark et al., 2023, study above) to add to the two prospective pretest/posttest studies (three publications) and one RCT (two publications) that were included in the initial report. There was no change to the quality of the 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 et al., 2021, Olson and Barrera, 2021, Sidle et al., 2021, and San Nicoló et al., 2018), and three of the studies (Bikhazi et al., 2021, Olson and Barrera, 2021, and San Nicoló et al., 2017) are included in this policy below. Hayes concluded that while available published evidence suggests that absorbable nasal implants are technically reasonable to implant and are associated with reduced NAO and pain, the clinical studies and systematic reviews are 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 individuals were allowed to cross over to treatment after 3 months, so long-term comparison was not available. In other studies, Hayes noted that many individuals received adjunctive treatment with the nasal implants, which confounded the interpretation of the results.

In a follow-up of a crossover trial by Stolovitzky et al. (2019), using a case series design, Bikhazi et al. (2022) followed up 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, postimplant assessment was completed and included collection of participant-reported outcome measures using the NOSE, nasal obstruction VAS, and Epworth Sleepiness Scale (ESS) tools and adverse event (AE) 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; the mean VAS score reduction was 29.7 points or greater and statistically significant, and the mean baseline ESS value for the whole participant cohort was within the normal range for the ESS. Therefore, while the changes in scores were statistically significant ($p < 0.001$), the clinical impact was unclear. The authors noted 34 device-/procedure-related AEs 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 that the authors reported include the lack of long-term follow-up in the control arm, significant loss of study participants to follow-up at 18 months (74 participants) and 24 months (70 participants), lack of an objective assessment tool for nasal valve collapse, and uneven distribution of participants of varying race or ethnicity. The authors concluded that the use of an absorbable nasal implant is a safe and effective treatment option for dynamic nasal valve collapse in individuals with severe to extreme nasal obstruction and that the procedure provides symptom improvement through 24 months following placement.

In a single-center, retrospective, nonrandomized cohort study by Olson and Barrera (2021), the records of 90 patients, who were diagnosed with septal deviation, inferior turbinate hypertrophy, and nasal valve incompetence with lateral wall insufficiency and treated between July 2016 until January 2019, were reviewed. All patients underwent SPL 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, SPL, and inferior turbinate submucous reduction, while the other 40 patients underwent an open functional rhinoplasty with a variety of nasal valve techniques, including SPL and submucous reduction. The study groups were noted to be inequitable in that the treatment group consisted of older patients 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; the surgical approach itself, which could have also resulted in the improvements noted by the patients; and the lack of follow-up in patients beyond 6 months post procedure, resulting in unknown long-term efficacy. 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 systematic review with meta-analysis on the effectiveness of using the Latera bioabsorbable implant to treat nasal valve collapse in individuals 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 QOL post operation 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 individuals) 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 with pretreatment values and improved QOL at 12 months post operation. 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), individuals receiving bioabsorbable nasal implants (treatment group) had significantly improved disease-specific QOL. The authors concluded that bioabsorbable nasal implants may reduce nasal wall movement and subjective symptom scores compared with 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 the lack of a comparison group undergoing a different therapeutic approach in most of the included studies.

Sidle et al. (2019; included in the Kim et al., 2020, systematic review above) performed a prospective multicenter case series to examine 12-month outcomes for in-office treatment of dynamic nasal valve collapse with a bioabsorbable implant. Overall, 166 participants with a severe to extreme class of NOSE scores were enrolled at 16 U.S. clinics (November 2016 to July 2017). Participants were treated with a bioabsorbable implant (Latera, Spirox Inc., Redwood City, CA) to support the lateral wall, with or without concurrent inferior turbinate reduction, in an office setting. NOSE scores and the VAS were measured at baseline and 1, 3, 6, and 12 months post operation. The Lateral Wall Insufficiency score was determined by independent physicians observing the lateral wall motion video. Using a disease-specific QOL instrument and objective physical examination, the study showed that an in-office, minimally invasive procedure to stabilize the nasal wall with an absorbable implant significantly improves NAO symptoms in individuals with dynamic nasal valve collapse. The authors concluded that at 12 months, the Latera implant is safe and efficacious for selected individuals in whom dynamic nasal valve collapse is a main contributor to their NAO. Longer follow-up is needed to determine efficacy beyond 12 months. A limitation of this study is a lack of comparison with a group of participants receiving a treatment other than the Latera implant.

Stolovitzky et al. (2019; included in the Kim et al., 2020, systematic review above) conducted a multicenter, single-blinded, randomized controlled study to evaluate the safety and effectiveness of a bioabsorbable implant (Latera) to support the lateral nasal wall in nasal valve collapse. Overall, 137 participants from 10 clinics were randomized into two arms: treatment arm (70 participants) and sham control arm (67 participants). Outcome measures were followed through 3 months after the procedure. The primary end point was the responder rate (percentage of participants with reduction in clinical severity by one or more categories or ≥ 20% reduction in NOSE score). There were no statistically significant differences in participant demographics and nasal obstruction symptom measures between the two arms. Three months after the procedure, the responder rate was significantly higher in the treatment arm than the control (82.5% vs. 54.7%; $p = 0.001$). Participants 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 VAS scores (-39.0 ±29.7 vs. -13.3 ±30.0; $p < 0.0001$) than the sham control arm. In total, 17 participants reported 19 procedure-/implant-related AEs, 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 participants' nasal obstruction symptoms. However, there are limitations of this study. This study reported short-term follow-up data up to 3 months only. However, previous studies of the bioabsorbable implant have shown that individuals' responses to treatment stabilized at 3 months and were consistent with data observed at the 12-month, 18-month, and 24-month follow-ups. This is a single-blinded study in which all participants were blinded but physicians were aware of the assignment, which may have introduced a risk of bias. Additionally, eight participants in the implant group (11%) were excluded after randomization due to protocol deviation and implant retrieval, and the data were analyzed per protocol rather than using intent to treat, which could have introduced biases in the findings.

Stolovitzky et al. (2018; included in Kim et al., 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. Overall, 101 participants with a severe to extreme class of NOSE scores were enrolled at 14 U.S. clinics. Some participants appear to overlap with those in Sidle et al. (2020), discussed above. Participants were treated with a bioabsorbable implant designed to support the lateral wall, with or without concurrent SPL and/or turbinate reduction procedure(s). NOSE scores and the VAS were measured at baseline and months 1, 3, and 6 post operation. The Lateral Wall Insufficiency score was determined by independent physicians observing the lateral wall motion video. In total, 43 participants were treated with implants alone, whereas 58 had adjunctive procedures. Overall, 17 participants reported 19 AEs, all of which resolved with no clinical sequelae. Participants had a significant reduction in NOSE scores at 1, 3, and 6 months post operation (79.5 ±13.5 prior to operation; 34.6 ±25.0 at 1 month, 32.0 ±28.4 at 3 months, and 30.6 ±25.8 at 6 months post operation; $p < 0.01$ for all). They also had a significant reduction in VAS scores post operation (71.9 ±18.8 prior to operation; 32.7 ±27.1 at 1 month, 30.1 ±28.3 at 3 months, and 30.7 ±29.6 at 6 months post operation; $p < 0.01$ for all). These results were similar in participants treated with the implant alone compared with those treated with the implant and adjunctive procedures. Consistent with participant-reported outcomes, postoperative Lateral Wall Insufficiency scores were demonstrably lower (1.83 ±0.10 and 1.30 ±0.11 prior to and post operation; $p < 0.01$). The authors concluded that stabilization of the lateral nasal wall with a bioabsorbable implant improves individuals' 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 is also limited by the lack of a comparison group that did not receive the studied implant.

San Nicoló et al. (2017; included in the Kim et al., 2020, systematic review above) conducted a prospective case series to evaluate the safety and effectiveness of an absorbable implant for lateral cartilage support in participants with nasal valve collapse with 12 months of follow-up. Overall, 30 participants with a NOSE score of ≥ 55 and isolated nasal valve collapse 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. Participants were followed up through 12 months post procedure. Overall, 56 implants were placed in 30 participants. 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-participant reduction of -40.9 ±31.2 points. The majority (76%) of the participants 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 participants required retrieval within 30 days post procedure and resulted in no clinical sequelae. The authors concluded that this study demonstrates the safety and effectiveness of an absorbable implant for lateral cartilage support in participants with nasal valve collapse at 12 months post procedure. Well-designed, randomized clinical trials, with larger participant populations and longer follow-up periods, are needed to further assess absorbable nasal implants. This study is limited by the lack of a comparison group.

Clinical Practice Guidelines

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

In a 2025 update on their position statement on the use of biomaterials in sinonasal procedures, the AAO-HNS states that they support the use of use of U.S. Food and Drug Administration–approved biomaterials such as implants, stents, and packing material in sinonasal procedures to improve patient outcomes and reduce complications. These items have applications, including hemostasis, maintenance of sinus outflow patency, and reduction of recurrent polyposis. The AAO-HNS recommends that the final decision regarding the use of these biomaterials should be determined by the treating physician, factoring in the best-available scientific evidence, surgeon experience, clinical situation, and individual patient preference. The position statement also states that (1) updated studies continue to support the statistically significant efficacy of drug-eluting implants in maintaining sinus outlet patency following surgery compared with other standard nasal dressings in nearly all clinical situations and that (2) this intervention should not be delayed by requirements to try stepwise less invasive or less expensive therapies, as findings can be evident at 2 to 4 weeks in patients.

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 QOL in those with NAO due to nasal valve collapse, based on their review of the San Nicoló et al. (2017), Stolovitzky et al. (2018), and Stolovitzky et al. (2019) studies included above.

Nasal Septal Swell Body Reduction

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

A systematic review and meta-analysis (Kim et al., 2025) evaluated the effectiveness of septal swell body volume reduction (SSBVR) for NAO by analyzing seven studies, involving 232 individuals. SSBVR significantly improved nasal obstruction scores (SMD, 2.54; 95% CI, 1.81-3.26), cross-sectional area (SMD, -1.05; 95% CI, -1.88 to -0.21), and nasal airway resistance (SMD, -0.67; 95% CI, -0.89 to -0.45), with benefits persisting up to 12 months. Combining SSBVR with turbinate surgery yielded additional improvement in nasal obstruction compared with turbinate surgery alone, although objective measures showed no significant differences. AEs were rare (< 2%). The lack of comparison groups, high heterogeneity in early follow-up outcomes, small sample sizes, lack of standardized outcome measures, limited long-term data, and generally low methodological quality of the included studies are limitations of this study. Further RCTs, with standardized protocols and extended follow-up, are needed to confirm long-term efficacy and safety.

Pritikin et al. (2025) published 24-month results to their study, included below, that showed sustained benefits of temperature-controlled radiofrequency (TCRF) treatment for septal swell body (SSB) hypertrophy. Of the original cohort, 58 individuals completed the 24-month follow-up. The mean NOSE score dropped from 73.5 at baseline to 26.6, which is a 63.5% reduction ($p < 0.001$), while the mean numeric rating scale ease-of-breathing score fell from 6.4 to 2.2, reflecting a 65.6% improvement ($p = 0.001$). SNOT-22 total scores also declined significantly, from 48.8 to 19.8 (-58.0%; $p < 0.001$). The proportion of individuals meeting the predefined NOSE responder criteria (≥ 20% improvement or at least one severity category improvement) remained high at 78.6%, modestly lower than the 84.3% at 12 months. Importantly, no new device- or procedure-related AEs were reported between 12 and 24 months, reinforcing the long-term safety and tolerability of the procedure. The findings are limited by the lack of a comparison group and large loss to follow-up.

Pritikin et al. (2024) published 12-month follow-up results from their prospective open-label study below (Pritikin et al., 2023), with 65 participants (92.9%) completing the study assessment at 6 months and 62 participants (88.6%) completing the study assessment at 12 months. The authors reported that there was a 67.5% decrease in adjusted mean NOSE scores at 6 months and a 65.4% decrease at 12 months, which was consistent with their previously reported 3-month results. The authors also reported that there was a 62% improvement in the numeric rating scale ease-of-breathing score at 6 months and a 62.5% improvement at 12 months. The authors concluded that TCRF treatment of SSB hypertrophy showed significant and durable improvements in symptoms of nasal obstruction and congestion through 12 months post procedure. However, the findings are limited by the lack of a comparison group.

In their prospective, open-label, single-arm, multicenter study, Pritikin et al. (2023) assessed the clinical use of a TCRF device (VivAer) to treat SSB hypertrophy to improve symptoms in adults with NAO. The study included 70 participants between 22 and 85 years of age (mean age, 47.5 years; 51.4% male; 88.6% White) with severe (61.4%) or extreme (38.6%) NAO related to SSB hypertrophy. All participants received TCRF treatment in the SSB area, with an average of 4.8 treatments per nostril (range, 2-6). The primary end point was improvement in 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 3 months post procedure, with 4.3% of participants reporting no further breathing problems, 46.4% reporting mild NAO, 39.1% reporting moderate NAO, 10.1% reporting severe NAO, and no participants reporting extreme NAO. The responder rate was reported by the authors to be 95.7%. In a subset of participants (n = 37) who underwent computed tomography imaging to evaluate posttreatment changes in SSB size, the authors reported that the computed tomography results at 3 months showed statistically significant reductions in SSB, with the greatest reduction in the middle thickness. 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 3 months. The authors plan to follow up the participants through 36 months post procedure. Limitations of the study include the study design (open label, single arm), homogeneity of the study population's race, lack of medication management in the participants, industry sponsorship, and short-term follow-up.

Meng et al. (2021) conducted a systematic review of the existing knowledge on recent NSB developments. The review was performed using the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. PubMed, Embase, Web of Science, Ovid, the 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 that a microdebrider-assisted procedure for inferior turbinate and NSB hypertrophy was superior to turbinoplasty alone. The review noted that the limitations of Yu et al. were a small sample size (26 individuals) and a short follow-up period. Kim et al. (described in detail below) conducted a study on using coblation to treat individuals with an abnormally thickened NSB. The review noted that Kim et al. demonstrated that coblation is an effective treatment option for NSB hypertrophy. Catalano et al. treated 60 individuals with a prominent NSB using RFA. NOSE scores and NSB size scores were assessed at 3 and 6 months post operation. Individuals reported satisfactory results and improved nasal congestion. One individual developed septal perforation that 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. Overall, 25 patients (48 sides) had NVBs reduced with RFA. Another cohort of 10 patients (20 sides) had untreated NVBs. Follow-up included an assessment of healing and complications post RFA at two time points: 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 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 (four of 23 patients), resolved with complete remucosalization (23 of 23 patients) by the late time point. No persistent pain, sensory loss, or pyriform aperture stenosis was observed in any patient. There were significant differences in reductions between mean pre- and post-operative SNOT-22 and individual subdomain scores observed in patients who had NVBs reduced with RFA (-24 and -2) compared with 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 SPL 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. The 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 nonrandomized study in 28 individuals who underwent inferior turbinate reduction alone and 28 individuals who underwent inferior turbinate reduction in conjunction with NST reduction. Both cryosurgery and cautery were used. At 10 to 16 weeks post operation, there were no differences in individuals' symptoms or rhinometry between the two groups of individuals.

Catalano et al. conducted a prospective study of NST RFA in 60 individuals who had a history of a failed prior SPL and turbinate reduction. There were statistically significant reductions in NOSE scores: 41.6 prior to 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 individuals who required multiple treatments. Kim et al. (described in detail below) retrospectively reviewed nasal obstruction scores in eight individuals who underwent NST coblation. With the VAS, an average pretreatment 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 in 51 individuals. Of those individuals, 25 underwent a microdebrider submucous turbinate reduction alone, and 26 underwent a concurrent NST reduction. At 3 months post operation, there were multiple statistically significant advantages in the NST group, including larger nasal obstruction score improvements (2.02 vs. 1.43) and pronounced improvement in total nasal volume on rhinometry (0.83 mL vs. 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 three of the four treatment studies found significant benefits with 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 nonrandomized and included multiple treatment modalities. Yu et al. was the only prospective RCT. 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 an abnormally thickened NSB. The study was conducted at a single tertiary medical center; eight patients underwent coblation NSB reduction. Pre- and post-operative nasal functions were evaluated by acoustic rhinometry and subjective symptom scales as well as preoperative computed tomography 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 preoperative coronal computed tomography scan images. The mean VAS 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 patients. The authors concluded that coblation can be an effective treatment modality for nasal valve narrowing in individuals with an abnormally thickened NSB. Limitations to this study include a small sample size and study design as well as the lack of 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. Overall, 51 participants with nasal obstruction associated with septal body and inferior turbinate hypertrophy refractory to medical therapy were included. Conventional inferior turbinoplasty was performed in 25 participants (control group). A combination of inferior turbinoplasty plus concurrent bilateral microdebrider-assisted SBVR was performed in 26 participants (study group). All were followed up post operation 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 individuals with inferior turbinate and septal body hypertrophy. However, the study design did not allow for evaluation of the long-term efficacy and safety of the procedure.

Posterior Nasal Nerve or Sphenopalatine Ganglion Ablation

The quality of the body of evidence for posterior nasal nerve (PNN) and sphenopalatine ganglion (SPG) ablation is insufficient to demonstrate the benefit of this procedure on long-term outcomes in individuals compared with established therapies. Most available studies are single-arm studies, and comparative studies are limited by short follow-up and/or lack of assessor masking to group assignment.

A 3-year follow-up study (initial study results noted below) was published by Lee et al. (2025), in which the initial RCTs evaluated TCRF ablation of the PNN for chronic rhinitis. Overall, 101 participants had sustained and clinically meaningful improvements in total nasal symptom burden [58% Reflective Total Nasal Symptom Score (rTNSS) reduction], rhinorrhea (55.8% reduction), cough (69% reduction), and postnasal drip (50% reduction), along with large QOL gains and significant decreases in the use of intranasal corticosteroids, anticholinergics, and decongestants; no device- or procedure-related serious AEs occurred throughout follow-up. Results remained consistent with earlier 3-month to 2-year outcomes, showing stable durability, despite known potential for nerve regrowth. Limitations include the single-arm design without a control group, reliance on self-reported symptom scores, participant attrition (21 participants lost, withdrawn, or treated elsewhere), and uncontrolled medication use, all of which may introduce bias or confound interpretation. Nonetheless, the findings support TCRF PNN ablation as a durable, safe, and minimally invasive long-term treatment option for chronic rhinitis.

Stolovitzky et al. (2025) published the 3-year follow-up results to their 2023 study, included below, that showed the long-term safety and efficacy of TCRF ablation of the PNN for treating chronic rhinitis. The study included 104 individuals aged 18 to 85 years with perennial allergic or nonallergic chronic rhinitis, of whom 59 completed the 3-year follow-up. All individuals received a single office-based TCRF treatment targeting the PNN region. The primary end point was the change in rTNSS from baseline to 36 months. The results showed a significant reduction in mean rTNSS from 8.2 at baseline to 3.5 at 3 years (57.3% improvement; $p < 0.0001$), with 79.7% of individuals classified as responders (≥ 30% improvement). The secondary outcomes included improvements in cough and postnasal drip scores and QOL, which decreased by 53.6% from baseline. Medication burden also declined, with notable reductions in corticosteroid and anticholinergic use. No severe AEs occurred, and no new device- or procedure-related events were reported after 12 months. The authors concluded that TCRF ablation of the PNN is a safe, durable, and effective minimally invasive treatment for chronic rhinitis that provides sustained symptom relief and QOL improvements through 3 years post procedure. Limitations include the attrition of the individuals at 3 years, single-arm design after the randomization period, lack of confirmatory allergy testing, and uncontrolled medication use.

A systematic review and meta-analysis (Choi et al., 2024) evaluated the effectiveness of ClariFix cryoablation of the PNN in treating chronic rhinitis. Across seven studies, involving 495 individuals, cryoablation significantly improved nasal symptoms and disease-specific QOL for both allergic and nonallergic rhinitis, with benefits persisting up to 12 months. Approximately 71% of individuals achieved a clinically meaningful reduction in symptoms, and improvements were noted in all symptom subdomains, particularly congestion. Adverse effects were generally mild and transient, including headache (20%) and postoperative pain (10%), with serious complications absent. However, limitations include the lack of comparison groups, heterogeneity in outcome measures, incomplete data for the individuals, potential publication bias, and manufacturer-sponsored studies, underscoring the need for long-term, high-quality, independent RCTs to confirm safety and efficacy.

The Yu et al. (2024) systematic review and meta-analysis assessed the efficacy and safety of TCRF neurolysis of the PNN for chronic rhinitis. Across five studies (four in meta-analysis) with 284 individuals, the pooled reduction in rTNSS at 3 months was -4.28, and responder rates (≥ 30% improvement) were 77% at 3 months and 81% at 6 months, indicating significant symptom improvement. QOL measures and secondary symptoms like postnasal drip and cough also improved, and AEs were minimal (7.4%, mostly mild nasal soreness or mucosal changes). Limitations include the high heterogeneity, lack of control groups in most studies, uncontrolled medication use, racially homogenous samples (> 89% White), short follow-up in some studies, and potential bias due to industry funding. Further large-scale, diverse RCTs, with long-term outcomes, are needed to confirm efficacy and generalizability.

Takashima et al. (2024) published the 2-year outcomes of their prospective, multicenter, participant-blinded RCT (RHINTRAC). The results included 77 of the original 104 participants in the initial active treatment arm and 27 participants from the control arm who were allowed to cross over after their 3-month follow-up visit and underwent TCRF ablation of the PNN. The authors reported that the mean baseline rTNSS was 8.2 and that the mean change at 2 years was -5.3 points, while the responder rate (> 30% improvement) was 87.3%. The authors also reported that all four components of the rTNSS (rhinorrhea, congestion, sneezing, and nasal itching) showed significant improvement over baseline, with the most improvement seen in rhinorrhea and congestion. The mini-Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) was reported by the authors to show that 81% of participants achieved a minimal clinical important difference, while 44.6% of the participants who were using chronic rhinitis medications at baseline either stopped all medication use (12.5%) or stopped/decreased (32.1%) the use of one or more medication classes at 2 years. The authors also imputed the responder statuses of the 13 participants with follow-up data who were lost to follow-up and one who withdrew and of the nine participants who had additional nasal procedures; the authors reported that this resulted in a 2-year responder rate of 79.4%. Limitations of the study include the lack of a sustained control group, lack of management of medication usage, and inclusion of participants with both allergic and nonallergic rhinitis. The authors concluded that TCRF ablation of the PNN was safe and resulted in significant and sustained reduction in chronic rhinitis symptom burden through 2 years and a substantial reduction in concomitant medication burden.

Rosi-Schumacher et al. (2023) conducted a single-center retrospective cohort study to evaluate medication usage and adverse effects of in-office PNN in adults with a history of chronic allergic or nonallergic rhinitis who have experienced failure of medical management. The study included 127 patients (60.6% female; mean age, 52.4 years; 49.6% with allergic rhinitis) with rhinitis lasting longer than 6 months who had experienced failure of medical management and had inadequate symptom relief over at least 4 weeks of treatment with nasal medications, including steroids, antihistamines, and/or anticholinergics. Patients were evaluated using the rTNSS and mini-RQLQ scores, which were compared before and after treatment. The authors reported that the mean TNSS decreased from a baseline score of 5.94 to a post procedure score of 3.44 (mean difference, -2.50) after the procedure, with clinically important decreases in 59.1% (n = 71) of patients, while the mean mini-RQLQ scores decreased from a total baseline score of 2.51 to a total score of 1.28 after the procedure. The authors also reported that 28.6% of medications were discontinued after the procedure and that

18.1% of patients reported adverse effects, with most patients reporting that headaches, facial pain, and dizziness only lasted hours to days after the procedure. The authors concluded that PNN cryoablation improved nasal symptoms and QOL in patients with chronic rhinitis, with more significant symptomatic improvement seen in those with a higher baseline TNSS. The study was limited by the single-center retrospective design, lack of a comparator, and short follow-up duration.

Takashima et al. (2023) published the 12-month outcomes to the Stolovitzky et al. (2021) industry-sponsored, prospective, multicenter, participant-blinded, crossover RCT below (NCT04533438). There were 116 adults (mean age, 57.5 years; 64.7% female) in the study, with 77 randomized to the active treatment arm that received TCRF neurolysis of the PNN via RhinAer and 39 randomized to the sham procedure arm. The eligibility criteria included having chronic rhinitis of 6 months' duration and a total 24-hour 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 end point), and 27 of the 39 participants were transitioned to crossover active treatment, as they still met eligibility criteria and agreed to continue participation in the trial. Those participants 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 participants who underwent additional nasal procedures at any time during follow-up. The authors reported that the responder rate in 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 was also improved over baseline at all time points. 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 had followed the same course as that in the active treatment group. The authors concluded that the study demonstrated that the treatment effect of TCRF neurolysis of the PNN area is safe and effective in reducing the symptom burden in individuals with chronic rhinitis through 12 months post procedure. Limitations of the study include the lack of control of medication use, lack of a sustained control group through trial completion, and inclusion of participants with both allergic and nonallergic rhinitis.

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 eight published studies (including the Del Signore et al., 2022, study below and the Chang et al., 2020, study previously included in this policy) consisting of one RCT, five prospective studies, and two retrospective single-arm or cohort studies. There were 472 adults who had chronic rhinitis lasting more than 4 weeks in total from all 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 used the TNSS and rTNSS score, with an average baseline score of 7.12, and that four of the seven studies had an end point assessing symptom improvement after 1 month and 3 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 AEs were identified in any of the studies. The risk of bias was assessed by the authors, with the risk of bias for the single RCT ranging from low to unclear, and the observational studies were rated as good and fair. Limitations of the study include the low quantity of published studies on the use of ClariFix cryoablation for the treatment of chronic rhinitis, lack of comparators in most of the studies, small sample size in four of the studies, industry sponsorship of five of the studies, and variability of study reporting. The authors noted that a 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 provides 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. However, they 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 individuals, to assess the effect of PNN neurectomy on TNSS in adults with chronic rhinitis. The mean age ranged from 53.3 to 60 years, and two of the studies reported results from the same cohort of individuals (pilot data and longer-term follow-up, respectively). Three of the studies (Ow et al., 2021, Stolovitzky et al., 2021, and Del Signore et al., 2022) are included in this section of the policy, and one of the studies (Chang et al., 2020) was previously included in this policy. All six of the nonrandomized studies were deemed to be at an overall moderate risk of bias, with two of the studies deemed at a serious risk of bias due to confounding factors and missing data due to attrition of individuals; one study was deemed to have a 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), and continuous wave laser (one study). The authors reported that a pooled analysis of data from the two RCTs found that active treatment was associated with a significantly higher responder rate (≥ 30% reduction in TNSS from baseline) compared with a sham control procedure, although both RCTs had a short duration of follow-up and relatively high baseline TNSS, suggesting a group of individuals with severe and refractory symptoms. With regard to the remaining six nonrandomized studies, the authors reported a reduction in the average postoperative TNSS sustained over longer periods of follow-up. The authors also found a relatively high total number of reported AEs, with 125 reported from 461 procedures, although the AEs were predominantly nonserious and transient. Limitations of the study include the broad design in the six non-RCTs and their moderate risk of bias; racial homogeneity of the two RCTs and their selection criteria for individuals that required more severe symptoms at baseline than was required in the non-RCTs; 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 RFA 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 in 129 adults with chronic rhinitis, Lee et al. (2022) sought to determine clinical outcomes and QOL following TCRF neurolysis of the PNN. The study was conducted in 16 centers in the United States and Germany and included adults with chronic rhinitis symptoms of > 6 months who had a 24-hour rTNSS of ≥ 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 end point was the mean change in 24-hour rTNSS from baseline to 3 months. The secondary end points included responder rate and the mean change in the mini-RQLQ score from baseline to 3 months. The authors reported that there was a mean 24-hour rTNSS improvement of 53.8% over baseline at 3 months (n = 128) and a 62.8% improvement at 6 months (n = 123). They also reported that rhinorrhea, congestion, and sneezing and itching sub scores as well as 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 a ≥ 0.4-point improvement in mini-RQLQ 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 AEs 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 2025) 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 RCT, one poor-quality single-arm study, one poor-quality cohort study, one very poor-quality cohort study, and two poor-quality retrospective pretest-posttest 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 that used ClariFix was identified, but no conclusions or findings specific to ClariFix were reported. In the 2024 update, Hayes reviewed the abstracts of one retrospective, single-arm, pretest-posttest study and three systematic reviews (including the Desai et al., 2023, study above). In the 2025 update, Hayes reviewed two retrospective cohort studies, the first by Maddieni et al. (2025), with no significant difference between treatment groups or rhinitis subtypes; the second by Gorelik et al. (2024) showed higher bleeding event rates in the ClariFix group than in those receiving RhinAer. Hayes also added one poor-quality retrospective pretest-posttest study by Craig et al. (2025) that showed a 95% recurrence of chronic rhinitis symptoms and clear, thin rhinorrhea at approximately the 6-month posttreatment mark. However, Hayes maintained that the existing evidence suggests minimal or unclear support for the use of ClariFix at this time.

In their updated Evolving Evidence Review (Hayes 2022b; updated 2025), use of the RhinAer procedure (Aerin Medical) for the treatment of chronic rhinitis was reviewed. The 2025 update included a review of abstracts only for one RCT, two prospective single-arm studies, and one retrospective cohort study (including the Takashima et al., 2023, Lee et al., 2022, and Ehmer et al., 2022, studies 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 had clinically significant relief of nasal symptoms post treatment with RhinAer. One of these studies compared individual improvements with those with sham; the RhinAer group had improvement compared with sham. The third very poor-quality study added by Gorelik et al. compared RhinAer treatment with ClariFix cryotherapy at 3 months of follow-up and showed slightly higher improvement in RhinAer at 91.1% over ClariFix at 64.5%. The slight improvement in RhinAer treatment vs. ClariFix was only measured by subjective yes/no question surveys, rather than a validated standardized outcome measure. No relevant systematic reviews or guidelines were found. The Hayes Review noted 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 those of 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, participant-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 minimum rTNSSs of 4 for total, 2 for rhinorrhea, and 1 for nasal congestion. Participant-reported outcome measures were assessed through the rTNSS, standardized RQLQ, and NOSE questionnaires at follow-up visits 30 and 90 days post procedure. The comparison between the treatment and sham arms for the percentage of responders at 90 days was the primary end point, 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 end point 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 with 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 participant QOL, the study had several limitations, including the racial homogeneity; restriction on rhinoscopies during the COVID-19 pandemic, which precluded a meaningful evaluation of the objective end point; and short-term duration of follow-up. Future studies aiming to examine the broader racial diversity of participants, comparison with 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 in participants diagnosed with chronic refractory rhinitis and treated with TCRF neurolysis of the PNN area in a minimally invasive procedure. To be eligible for the study, participants had to have had chronic rhinitis symptoms for at least 6 months, without adequate response to at least 4 weeks of treatment with intranasal steroids. Additionally, participants had to have an overall 12-hour rTNSS greater than or equal to 6, with sub scores of 2 to 3 for rhinorrhea, 1 to 3 for nasal congestion, and 0 to 3 for each nasal itching and sneezing. The TCRF 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 participants 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. AEs were recorded in 16 participants, with eight events considered possibly device or procedure related. Although the study resulted in significant improvements in symptoms of chronic rhinitis after TCRF neurolysis of the PNN area, limitations to the study exist. Limiting factors include the lack of a control or blinding and possible placebo effects contributing to the reported outcomes. More extensive, controlled studies are necessary to demonstrate the device's efficacy.

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 PNN cryoablation as a treatment for chronic rhinitis. Change from baseline in the rTNSS, physician assessment of improvement using the Clinical Global Impression of Improvement, RQLQ, and the incidence of treatment-related AEs were the study end points. Of the 100 participants enrolled at six U.S. investigational sites, in the first 12 months, 91 participants completed the study, and 62 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 was achieved by greater than 80% of participants on the rTNSS at all follow-ups. RQLQ scores showed a significant improvement in QOL, with over 77% of participants achieving the minimum clinically importance difference for the total RQLQ score. The Clinical Global Impression of Improvement resulted in greater than or equal to 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 up 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 participants after 12 months, created significant limitations. After the study, no significant differences were seen in rTNSS outcomes between participants with allergic or nonallergic rhinitis. Furthermore, between the observed and imputed rTNSS results, there was a -1 difference in the change from baseline and a 3% difference in the percentage of participants who achieved the minimum clinically importance difference.

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 TCRF neurolysis of the PNN for the treatment of chronic rhinitis. In the setting of 16 otolaryngology centers, participants with an rTNSS greater than or equal to 6 were randomized 2:1 to active treatment of the PNN area with a TCRF or sham procedure, without the delivery of radiofrequency energy. At 3 months, the primary end point 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 an average baseline rTNSS of 8.3, and the results of the sham control were 8.2. At 3 months in the active treatment arm, the responder rate was significantly higher, resulting in 67.5% vs. 41.0%. Additionally, the active treatment arm had a significantly greater decrease in rTNSS than the sham arm. The authors concluded that the results of the RCT demonstrated that radiofrequency neurolysis was superior to sham control in reducing the overall symptom burden experienced by participants 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 3-month follow-up, lack of comparison with 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 (updated 2023), data from one systematic review/meta-analysis with pooled results of symptom improvement, one RCT, and six before-and-after studies that reported on symptoms, QOL, need for medication, and AEs in individuals with chronic rhinitis treated with ClariFix that were published between January 1, 2015, through July 27, 2022, were reviewed. The studies indicated that the ClariFix procedure is safe and may provide symptom relief for individuals with chronic rhinitis, although whether its benefits are sustained long term (for more than 2 years) could not be determined from the available data. Other evidence limitations include the lack of comparators to other treatment options and high risk of bias in the six before-and-after studies due to the lack of controls, randomization and blinding, and small sample sizes. The assessment concluded that overall, ClariFix is safe and relieves symptoms of chronic rhinitis at the 3-month to 2-year follow-up, although additional RCTs, with longer follow-up periods, are needed to enable firm conclusions on the device's long-term effectiveness, as are RCTs that compare the device with other procedures to assess its comparative safety and effectiveness for treating chronic rhinitis in adults. This ECRI review included the Del Signore et al. (2022) and Ow et al. (2021) studies that are currently summarized in this policy and the Gerka Stuyt et al. (2021) study that was previously summarized in this policy.

Prasanna et al. (1997) evaluated the effectiveness of SPG block for the relief of symptoms in chronic vasomotor rhinitis in a single-arm single-center study with 30 individuals aged 15 to 45 years who had established diagnoses of chronic rhinitis of several years' duration. All individuals had been receiving regular medical therapy without relief. Each individual was administered bilateral SPG block at weekly intervals for 4 weeks. The individuals 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 individuals 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 individuals reported discomfort with subsequent blocks. The number of blocks varied from two to four, depending on the subjective assessment of symptom reduction. Five individuals (16.7%) needed four blocks, 20 (66.7%) had three blocks, and five (16.7%) required two blocks. Overall, 16 individuals (53.3%) had a deviated nasal septum, and four individuals (13.3%) had vascular congestion. The authors reported that during a follow-up of 12 to 20 months, no recurrence was reported in 29 of the 30 individuals (96.7%); the one individual was symptom free for 8 months before recurrence of early-morning sneezing and mild difficulty breathing through the nose and was lost to follow-up. Three individuals 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 the lack of a 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 states that PNN neurolysis techniques such as RFA and cryotherapy thermal application methods have demonstrated clinical benefit for nasal symptoms. The position statement includes a review of one multicenter, patient-blinded, sham-controlled RCT (including the Stolovitzky et al., 2021, study above, with 3-month outcomes, and the Takashima et al., 2023, study above, with 12-month outcomes for clinical trial NCT04533438) on radiofrequency neurolysis and one multicenter, patient-blinded, sham-controlled RCT (Del Signore et al., 2022, study above) on cryotherapy that evaluated the clinical benefit of these treatments on chronic rhinitis. They also reviewed five studies that included QOL surveys, which the society states showed statistically significant improvement with treatment (three studies, including the Ow et al., 2021, study above and the Chang et al., 2020, study previously included in this policy), with therapeutic effect (two studies, including the Ehmer et al., 2022, study above). Based on their review of these studies, the AAO-HNS has endorsed the use of PNN ablation for the treatment of medically refractory chronic rhinitis.

American Academy of Otolaryngic Allergy (AAOA)/American Rhinologic Society (ARS)

The *International Consensus Statement on Allergy and Rhinology: Allergic Rhinitis 2023* provides an updated comprehensive evidence review of allergic rhinitis, expanding to 144 topics across 10 major content areas and incorporating substantial new literature since the 2018 edition. The review summarizes multicenter, multidesign studies demonstrating that TCRF ablation of the PNN provided durable symptom improvement for chronic rhinitis, with significant reductions in rTNSS at both the 2-year and 3-year follow-ups. This included a 64.6% improvement in rTNSS at 2 years and sustained reductions in rhinorrhea, postnasal drip, cough, and QOL scores at 3 years, without serious device- or procedure-related AEs. While these results support TCRF ablation as a safe, minimally invasive option for patients with conditions refractory to medical therapy, the evidence base remains limited by single-arm open-label designs, potential selection bias, reliance on patient-reported outcomes, and a lack of long-term data beyond 3 years. Aside from one patient-blinded randomized trial demonstrating 2-year durability after crossover, most data come from prospective case series, restricting comparative effectiveness assessment and increasing susceptibility to placebo effects and regression to the mean. The scarcity of objective physiological measures further limits external validity and mechanistic insight. These gaps underscore the need for higher-quality, longitudinal, and geographically diverse randomized trials that incorporate objective end points and account for environmental and genetic modifiers to improve generalizability and long-term durability assessment.

Radiofrequency Treatment of Nasal Valves

While the use of transmucosal TCRF technology for the treatment of NAO 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.

In the Han et al. (2025) prospective, multicenter, single-arm follow-up of a single-blinded RCT with a sham control arm, the long-term safety and efficacy of TCRF treatment of the lateral nasal valve for severe or extreme NAO were assessed. The study enrolled 118 adults, of whom 108 received active TCRF treatment and 54 completed the 3-year follow-up. All participants underwent a single office-based procedure using the VivAer ARC Stylus targeting the nasal valve region. The primary end point was the change in NOSE score from baseline to 36 months. The results demonstrated a significant reduction in mean NOSE score from 76.9 at baseline to 27.1 at 3 years (64.6% improvement; $p < 0.001$), with 88.7% classified as responders (≥ 20% improvement or at least one severity class reduction). The secondary outcomes included improvements in ESS scores (mean reduction from 10.3 to 4.5) and decreased medication use, with most participants reducing or discontinuing antihistamines, decongestants, and steroid sprays. No serious device- or procedure-related AEs occurred after 6 months. The authors concluded that TCRF treatment of the nasal valve is a safe, durable, effective, minimally invasive option for NAO that provides sustained symptom relief and improved sleep quality through 3 years post procedure. Limitations include the attrition at 3 years, single-arm design, uncontrolled medication use, and lack of objective airflow measures.

Han et al. (2024) conducted a systematic review and meta-analysis to compare surgical techniques with TCRF treatment of NVD. The meta-analysis included five prospective noncomparative studies (n = 318) that described TCRF treatment and 63 studies describing functional rhinoplasty procedures (primary or revision), with or without concomitant procedures, including SPL and turbinate treatment (n = 6,201). The mean age of the study populations ranged from 21.4 to 51.7 years, with 50.9% of the total study population being male. Of the 68 studies included in the meta-analysis, 54 (76.5%) were prospective, and 63 (92.6%) were single center. The authors reported that the treatment effect was equally durable for TCRF and each of the rhinoplasty procedures, as evidenced by the comparable effects in each group at each time point and when comparing the results temporally at 3, 6, and 12 months. Limitations of the meta-analysis include the lack of comparators, predominance of single-center designs, and heterogeneity of the types of procedures and medical conditions in the included studies. The authors concluded that TCRF treatment of the internal nasal valve for NVD was associated with sustained effects comparable to those of functional rhinoplasty of the nasal valve only, rhinoplasty without concomitant turbinate treatment, and all rhinoplasties. The Han et al. (2022) study, summarized below, is included in this meta-analysis.

In another systematic review and meta-analysis, Kang et al. (2024) evaluated the efficacy of TCRF treatment in alleviating nasal obstruction by rectifying nasal valve collapse. The review included eight prospective studies (three RCTs, two case series, one single-arm study, one open-label study, and one nonrandomized extended follow-up study), with a total population of 451 individuals, that evaluated the QOL and nasal obstruction scores before and after TCRF treatment. Individuals' demographic information could not be determined, as the data were not uniformly reported across the included studies. The authors reported that individuals who underwent TCRF treatment reported significantly enhanced QOL at 24 months post treatment compared with their pretreatment scores, as measured by the NOSE questionnaire during post procedure visits; additionally, the rates of clinically improved states and positive responses regarding QOL after treatment were 82% and 91%, respectively. Limitations of the study include the heterogeneity of the study designs; lack of demographic information; preponderance of short-term follow up (four studies reported out results to 3 months, and one study reported out to 24 months); lack of a control group undergoing sham surgery; small number of studies available and sample sizes in most of the studies; lack of diversity in the study populations; lack of a control for medication usage; and preponderance (six of the eight studies) that was either authored or funded by the manufacturer. The authors concluded that TCRF may help improve nasal obstruction symptoms and recommended further RCTs in larger cohorts to substantiate its efficacy in enhancing nasal function; they recommended further independent research on radiofrequency device treatment to address the potential impact of the confounders. This systematic review included the Silvers et al. (2021), Jacobowitz et al. (2022), and Han et al. (2022) studies, which are summarized below.

Silvers et al. (2024) published 2-year outcomes for their prospective, multicenter, participant-blinded, crossover RCT, included in this policy (Stolovitzky et al., 2021), to determine treatment effect durability and changes in medication/nasal dilator usage following TCRF treatment of NVD. All 108 participants who underwent active treatment (index active treatment participants and treated crossover participants) were added into a single analysis group for follow-up from 3 months through 2 years, with data from 85 participants (78.7%) available for the 2-year outcome study. The authors reported that the 2-year responder rate was 90.4%, and the NOSE score treatment effect showed a 54.7% improvement, with a 41.7-point decrease from a baseline score of 76.3; all components of the NOSE score had a significant and sustained improvement in mean score from 3 months through 2 years. The authors also reported that of the 57 participants who were using medications or nasal dilators at baseline, 45 (78.9%) either stopped use altogether (33.3%) or stopped or decreased (45.6%) use in one or more classes at 2 years. Limitations of this industry-sponsored study include the small sample size and lack of a comparison group that did not receive TCRF treatment. The authors concluded that TCRF treatment of NVD resulted in significant and sustained improvements in the symptoms of NAO at 2 years, with a substantial reduction in medication and nasal dilator use.

Casale et al. (2023) conducted a systematic review and meta-analysis to assess the efficacy of TCRF to treat nasal obstruction. There were four prospective studies, with 218 adults between the ages of 19 and 83 years included in the review and analysis, including the Silvers et al. (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; the authors also noted that two of the four studies were industry sponsored. The authors reported that the NOSE score was reduced at 3 months post operation (prior to treatment: 76.16 ±6.39; post treatment: 31.20 ±2.73; mean difference, 46.13; 95% CI, 43.27-48.99), with moderate heterogeneity. The authors concluded that radiofrequency treatment could be useful for treating nasal valve collapse and improving significant subjective breathing symptom scores; 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 a 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 2-year results on the use of TCRF for the treatment of NAO due to nasal valve collapse. This prospective, single-arm, multicenter cohort study included 122 adults with nasal valve collapse as a primary or significant contributor to their NAO and who had baseline NOSE Scale scores of ≥ 60. There were 101 participants who completed the 2-year follow-up, of whom 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 participants with a ≥ 20% improvement in NOSE Scale score or with at least one severity class improvement from baseline. The authors reported that the mean baseline NOSE Scale score in 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); 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, nasal valve collapse mechanism, septal deviation, and other anatomical contributors of NAO. Limitations of the study include 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 participants with both static and dynamic nasal valve collapse, septal deviation, turbinate enlargement, or prior nasal surgery.

ECRI published a Clinical Evidence Assessment (2021; updated 2024) on the VivAer nasal airway remodeling stylus, with a full-text review of eight studies, consisting of two systematic reviews, one RCT, and five pre-post studies (including the Silvers et al., 2021, Pritikin et al., 2023, Yao et al., 2023, and Jacobowitz et al., 2022, studies that are summarized in this policy); the total population was 521 individuals who had been treated with the device. ECRI had a favorable outlook that the device works well for reshaping the nasal airway and improving nasal breathing at the 3-month and up to 24-month follow-up and determined that the effects reported in the studies were clinically significant and consistent. However, ECRI noted that the studies they reviewed provided very low-quality evidence and that they were not able to make conclusions about the device's comparative effectiveness. ECRI recommended that additional studies providing head-to-head comparisons or comparison studies with appropriately matched individuals, which account for individuals' prognoses and report on individual-oriented outcomes with longer-term follow-up (more than 2 years), are needed to determine how well the device works compared with other NAO treatments (such as functional rhinoplasty or nasal implants).

In an Evolving Evidence Review, Hayes (2021; updated 2025) reviewed four full-text clinical studies and determined that there is 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, nonrandomized, pretest-posttest studies with small populations of 20 to 50 individuals. One was found to be of very poor quality, and two were found to be of poor quality, while the RCT (Silvers et al., 2021, study below) was found to be fair quality and showed clinical benefit over sham at up to 3 months post procedure. No systematic reviews or clinical practice guidelines were identified to include in the review. The 2024 updated review identified two additional published clinical studies and three published systematic reviews, including the Casale et al. (2023), Han et al. (2024), Kang et al. (2024), Silvers et al. (2024), and Yao et al. (2023) studies that are summarized in this policy. The 2025 updated review added one very poor-quality study (Simmons et al., 2024), indicating a category drop from severe to moderate in nasal symptoms after VivAer treatment. However, 43.2% of individuals did not meet the positive response threshold, while 69% had to undergo additional rhinoplasty or Latera placement due to unresponsiveness to treatment. After reviewing the study abstracts, Hayes determined that new evidence regarding efficacy and safety has become available but that there is no new evidence with longer-term follow-up since the original 2023 report. Hayes concluded that there is no change to their current minimal level of support for the use of the VivAer radiofrequency procedure for remodeling the nasal valve area when collapse of the nasal valve is associated with chronic nasal obstructive symptoms.

Han et al. (2022) completed a 12-month follow-up study in a cohort from the Silvers et al. (2021) study (below) to determine if active treatment of the nasal valve with TCRF was safe and had sustained improvements in symptoms of NAO through 12 months. In the initial Silvers et al. study, 108 participants 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 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 AEs. The use of medications, nasal strips, and cones was 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 include medication use that was not defined by the protocol and that could potentially have had some confounding effect on symptom relief; the small sample size; the lack of a control group that did not cross over/receive TCRF; and the short length of follow-up of 12 months. The authors concluded that participants who received 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 with the sham procedure beyond 3 months, and loss to follow-up may have introduced biases.

An RCT was completed by Silvers et al. (2021) to evaluate the safety and efficacy of a TCRF device for the treatment of the nasal valve for NAO. The objective of the trial was to compare active device treatment against a sham procedure (control). The study included a total of 117 participants assigned to two separate groups: bilateral TCRF treatment of the nasal valve (n = 77) or a sham procedure (n = 40) in which no radiofrequency energy was applied. The device was applied to the mucosa over the lower lateral cartilage on the lateral nasal wall. The primary end point was the responder rate at 3 months, defined as a ≥ 20% reduction in NOSE Scale score or one or more reductions in clinical severity category. At baseline, participants had a mean NOSE Scale score of 76.7 (95% CI, 73.8-79.5) and 78.8 (95% CI, 74.2-83.3) (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 AEs at least possibly related to the device and/or procedure were reported, including vasovagal reaction, headache, and nasal bleeding with mucus, which all resolved. The authors concluded that TCRF treatment of the nasal valve is safe and effective in reducing symptoms of NAO in short-term follow-up. Limitations include 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; ear, nose, and throat (ENT); and manual surgical]. This is a broad product code category that includes a variety of devices used in ENT 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. However, all manufacturers are 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 January 6, 2026)

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 January 6, 2026)

Intranasal septal splint devices are classified by the FDA as Class I devices under product code LYA. This category includes over 40 devices, including but not limited to the Alar Nasal Valve Stent, Spiway Endonasal Access Guide, Novashield Injectable Nasal Packing and Stent, and 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 January 6, 2026)

The Latera Absorbable Nasal Implant (Stryker) received 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, 2024.

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 January 6, 2026)

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 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 January 6, 2026)

The 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.
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Policy History/Revision Information

Date	Summary of Changes
04/01/2026	**Definitions** • Updated definition of "External Nasal Valve" **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information

Date	Summary of Changes
	• Archived previous policy version MP.019.33

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, check the member specific benefit plan document and any applicable federal or state mandates. 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.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

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