Rhinoplasty and Other Nasal Procedures (for Indiana Only)

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Related Policy

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Application

This Medical Policy only applies to the state of Indiana.

Coverage Rationale

For medical necessity clinical coverage criteria for rhinoplasty, refer to the Indiana Health Coverage Programs Provider Reference Module: Surgical Services.

Lysis of Intranasal Synechia is considered Reconstructive and medically necessary when:

- There is a documented Functional Impairment (e.g., obstruction, pain or bleeding) due to Intranasal Synechia (adhesions/scar bands); **and**
- The Functional Impairment will be eliminated by lysis of the Synechia.

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

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

- Prolonged, Persistent Obstructed nasal breathing due to internal and/or External Nasal Valve compromise; **and**
- Other causes of nasal obstruction (e.g., sinusitis, allergic rhinitis, vasomotor rhinitis, nasal polyposis, adenoid hypertrophy, and/or nasopharyngeal masses) have been adequately treated with maximal therapy and nasal obstruction persists; and
- Nasal septal deviation and turbinate hypertrophy either:
  - Are not present; or
  - Have been previously surgically treated; or
  - Are scheduled to be surgically treated at the same time as the nasal valve procedure/repair as part of the surgery plan; and
- Documented evidence of visible collapse of the alar (lower lateral) cartilage (External Nasal Valve) and/or lateral nasal wall (internal nasal valve) with deep inspiration; and
- Documented evidence of subjective and audible improvement in nasal airflow during modified Cottle maneuver; and

- Photos clearly document either dynamic collapse of the internal and/or External Nasal Valve or anatomic deformities narrowing the internal and/or External Nasal Valve as a main cause of an anatomic Mechanical Nasal Airway Obstruction and are consistent with the clinical exam; and
- The surgeon has clearly described:
  - Whether the nasal valve compromise is static or dynamic; and
  - Whether the nasal valve compromise involves internal nasal valve, External Nasal Valve, or both; and
  - A plainly stated and clear surgical plan including the need for a cartilage graft.

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

Radiofrequency treatment of nasal valves for the treatment of nasal airway obstruction (e.g., Vivaer ARC Stylus) is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy.

Rhinophyma excision is considered Reconstructive and medically necessary when all of the following criteria are present:
- One of the following:
  - Prolonged, Persistent Obstructed nasal breathing due to rhinophyma; or
  - Chronic infection or bleeding unresponsive to medical management due to rhinophyma; **and**
- Photos clearly document rhinophyma as the primary cause of an anatomic Mechanical Nasal Airway Obstruction or chronic infection and are consistent with the clinical exam; **and**
- The proposed procedure is designed to correct the anatomic Mechanical Nasal Airway Obstruction and relieve the Nasal Airway Obstruction by correcting the deformity or the proposed procedure is designed to address the chronic infection.

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

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

Click here to view the InterQual® criteria.

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

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

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

Posterior nasal nerve ablation (using radiofrequency or cryoablation) for the treatment of chronic rhinitis is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy.

Definitions

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

Congenital Anomaly: A physical developmental defect that is present at the time of birth, and that is identified within the first twelve months of birth (COC, 2018).

Cosmetic Procedures: Procedures or services that change or improve appearance without significantly improving Physiological Function (COC, 2018).

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

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

Intranasal Synechia: An adhesion of parts, typically the nasal side wall to the septum (AAO-HNS, 2015).

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

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

Reconstructive Surgery: Reconstructive Surgery is for congenital defects, developmental anomalies, trauma, infection, tumors, or disease. The primary goal of Reconstructive Surgery is to improve function, but it may also be performed to reshape abnormal structures of the body and to allow a person to have a more normal appearance. (IHCP, 2021)

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

Applicable Codes

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

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

CPT Code	Description
*30117	Excision or destruction (e.g., laser) of intranasal lesion; internal approach
*30120	Excision or surgical planing of skin of nose for rhinophyma
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
30460	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip only
30462	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip, septum, osteotomies
30465	Repair of nasal vestibular stenosis (e.g., spreader grafting, lateral nasal wall reconstruction)

CPT Code	Description
*30468	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)
*30469	Repair of nasal valve collapse with low energy, temperature-controlled (i.e., radiofrequency) subcutaneous/submucosal remodeling
*30560	Lysis intranasal synechia
*30999	Unlisted procedure, nose
*31237	Nasal/sinus endoscopy, surgical; with biopsy, polypectomy or debridement (separate procedure)
31242	Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve
31243	Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve
*L8699	Prosthetic implant, not otherwise specified

Note: Codes labeled with an asterisk (*) are not managed for medical necessity review for the state of Indiana at the time this policy became effective. Refer to the most up to date prior authorization list for Indiana at Prior Authorization and Notification: UnitedHealthcare Community Plan of Indiana.

Description of Services

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

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

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

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

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

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

Clinical Evidence

Lysis of Intranasal Synechia

A prospective, multi-institutional cohort study was completed by Henriquez et al. (2013) to evaluate the impact of synechiae formation on quality-of-life (QOL) outcomes after endoscopic sinus surgery (ESS) in patients with chronic rhinosinusitis. Rhinosinusitis Disability Index (RSDI) and Chronic Sinusitis Survey (CSS) scores were measured in adult patients before and after undergoing ESS for CRS. Differences in QOL were evaluated between those who developed sinonasal synechiae and those who did not, controlling for demographic factors, medical comorbidities, and measures of disease severity at baseline. The study included a total of 286 patients who underwent ESS between July 2004 and May 2012, with 55 (19.2%) developing

synechiae in the follow-up period. Patients developing synechiae reported significantly less improvement on the RSDI total scores (13.5 vs. 21.4, p = 0.008), RSDI physical sub-scores (5.3 vs. 8.3, p = 0.007), RSDI emotional sub-scores (2.9 vs. 5.8, p = 0.008), CSS total scores (14.5 vs. 21.2, p = 0.093) and CSS symptom sub-scores (19.9 vs. 30.3, p = 0.069) compared to those who did not develop synechiae postoperatively. These differences persisted even after controlling for baseline differences in disease severity. The authors concluded that synechiae of the sinonasal cavity commonly occurs following ESS, particularly in those undergoing revision surgeries. Although both groups improved, the degree of QOL improvement was less in those who formed postoperative synechiae after surgery compared to those who did not. Limitations included a lack of site specific synechiae information. Furthermore, the staging system used in the study did not discriminate synechiae by location, nor did it define the difference between mild and severe.

Rhinophyma Excision

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

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

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

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

small sample size, the lack of a control group that did not crossover/receive TCRF and the short length of follow up of 12 months. The authors concluded that patients who receive active TCRF device treatment of the nasal valve demonstrated that the treatment was safe and that the effect was durable through 12 months post-procedure. However, the study design did not allow comparison to the sham procedure beyond 3 months and loss-to-follow-up may have introduced biases.

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

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

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

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

Clinical Practice Guidelines

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

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

Nasal Septal Swell Body (NSB) Reduction

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

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

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

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

Haight et al. conducted a prospective non-randomized study of 28 patients who underwent inferior turbinate reduction alone and 28 patients who underwent inferior turbinate reduction in conjunction with NST reduction. Both cryosurgery and cautery were utilized. At 10 to 16 weeks postoperatively, there were no differences in patient symptoms or rhinometry between the two patient groups. Catalano et al. conducted a prospective study of NST RFA in 60 patients who had a history of a failed prior septoplasty and turbinate reduction. There were statistically significant reductions in nasal obstruction symptom evaluation (NOSE) scores: 41.6 at pre-treatment, 17 at month 3, and 21 at month 6. There were also statistically significant improvements in endoscopic middle turbinate visualization. There were three minor infections, one small, asymptomatic septal perforation, and five patients who required multiple treatments. Kim et al. (described in detail below) retrospectively reviewed nasal obstruction scores in 8 patients who underwent NST coblation. Utilizing a visual analog scale, an average pre-treatment score of 7.63 was reduced to 3.88 (month 3) 4.16 (month 6), and 4.63 (month 12). There were no complications reported. Yu et al. (described in detail below) conducted a prospective randomized controlled study of 51 patients. Of those patients, 25 underwent a microdebrider submucous turbinate reduction alone and 26 underwent a concurrent NST reduction. At 3 months postoperatively, there were multiple statistically significant advantages in the NST group, including larger nasal obstruction score improvements (2.02 versus 1.43) and pronounced improvement in total nasal volume on rhinometry (0.83 mL versus 0.36 mL). Olfaction, rhinorrhea, and sneezing were similar between both treatment groups. There were no complications found related to NST reduction. The authors concluded that evaluating the NST as a treatment target is encouraging, as 3 of the 4 treatment studies found significant benefits to surgical intervention. There was no benefit with NST cautery or cryosurgery. NST RFA, coblation, and submucosa reduction were safe and effective. However, the studies included in the review have some limitations. Haight et al. was non-randomized and included multiple treatment modalities. Yu et al. was the only prospective randomized controlled trial. Kim et al. was retrospective and included only a small sample size. Study follow-up in these studies was rarely longer than 3 to 6 months, limiting conclusions about long-term results. Future prospective studies evaluating NST treatment as an isolated and adjunct treatment are needed.

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

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

Absorbable Nasal Cartilage Support Implants

According to the manufacturer's website, the Latera implant is used to support upper and lower lateral cartilage in the nose, reinforcing the nasal wall like traditional cartilage and polymer grafts. Supporting the cartilage in this manner may reduce nasal airway obstruction symptoms and help patients breathe better. The Latera implant supports the upper and lower lateral

cartilage by anchoring above the maxilla to provide cantilever support. Through a minimally invasive procedure, the nasal implant is inserted through a small incision made inside a patient's nose. (Stryker, 2019).

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

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

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

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

In a follow-up of a cross-over trial by Stolovitzky et al. (2019), using a case series design, Bikhazi, et al. (2021) followed 40 of the sham participants who subsequently had absorbable nasal implants placed along with the initial 71 participants in the treatment group for up to 24 months post placement. At each follow-up visit at 3, 6, 12, 18, and 24 months, post-implant assessment was completed that included collection of patient-reported outcome measures using the nasal obstructive symptom evaluation (NOSE), nasal obstruction visual analog scale (VAS), and the Epworth Sleepiness Scale (ESS) tools and adverse event monitoring. The authors reported that at all follow-ups from 3 months through 24 months, 70.0% or more participants reported

improvement to mild or moderate NOSE scores, mean VAS score reduction was 29.7 points or greater and statistically significant and that the mean baseline ESS value for the whole participant cohort was within the normal range for the ESS, so while the changes in scores were statistically significant ($p < 0.001$), the clinical impact was unclear. The authors noted 34 device/procedure-related adverse events in 26 participants that were mild to moderate in severity and that resolved without clinical sequelae or were ongoing but stable at study completion. Study limitations the authors reported included the lack of long-term follow-up of the control arm, significant loss of study participants to follow-up at 18 months (74 participants) and 24 months (70 participants), a lack of an objective assessment tool for nasal valve collapse and an uneven distribution of participants of varying race or ethnicity. The authors concluded that use of an absorbable nasal implant is a safe and effective treatment option for dynamic nasal valve collapse in patients with severe to extreme nasal obstruction and that the procedure provides symptom improvement through 24 months following placement.

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

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

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

data observed at 12-month, 18-month, and 24-month follow-up. This is a single-blinded study in which all patients were blinded but physicians were aware of the assignment, which may have introduced risk of bias. Additionally, 8 participants in the implant group (11%) were excluded after randomization due to protocol deviation and implant retrieval and the data are analyzed per protocol rather than using intent-to-treat, which could have introduced biases in the findings.

Stolovitzky et al. (2018, included in Kim [2020] systematic review above) reported 6-month outcomes from a prospective, multicenter, single-blinded (blinded assessor) case series for treatment of nasal valve collapse due to lateral wall insufficiency. One hundred and one patients with severe-to-extreme class of Nasal Obstruction Symptom Evaluation (NOSE) scores were enrolled at 14 U.S. clinics. Some participants appear to overlap with these of Sidle, et al (2020) discussed above. Patients were treated with a bioabsorbable implant designed to support lateral wall, with or without concurrent septoplasty and/or turbinate reduction procedure(s). NOSE scores and visual analog scale (VAS) were measured at baseline and month 1, 3, and 6 postoperatively. The Lateral Wall Insufficiency (LWI) score was determined by independent physicians observing the lateral wall motion video. Forty-three patients were treated with implants alone, whereas 58 had adjunctive procedures. Seventeen patients reported 19 AEs, all of which resolved with no clinical sequelae. Patients showed significant reduction in NOSE scores at 1, 3, and 6 months postoperatively (79.5 ±13.5 preoperatively, 34.6 ±25.0 at 1 month, 32.0 ±28.4 at 3 months, and 30.6 ±25.8 at 6 months postoperatively; $p < 0.01$ for all). They also showed significant reduction in VAS scores postoperatively (71.9 ±18.8 preoperatively, 32.7 ±27.1 at 1 month, 30.1 ±28.3 at 3 months, and 30.7 ±29.6 at 6 months postoperatively; $p < 0.01$ for all). These results were similar in patients treated with the implant alone compared to those treated with the implant and adjunctive procedures. Consistent with patient-reported outcomes, postoperative LWI scores were demonstrably lower (1.83 ±0.10 and 1.30 ±0.11 pre- and postoperatively; $p < 0.01$). The authors concluded that stabilization of the lateral nasal wall with a bioabsorbable implant improves patients' nasal obstructive symptoms over 6 months. Longer-term outcomes are needed to validate the efficacy of a bioabsorbable implant for the treatment of nasal valve collapse. This study was also limited by lack of comparison group that did not receive the studied implant.

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

Clinical Practice Guidelines

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

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

Posterior Nasal Nerve Ablation

A 2022 Evolving Evidence Review (Hayes 2022a) addressed the use of ClariFix (Arrinex, Inc.) for improving the symptoms of chronic rhinitis. The review of full-text clinical studies, including one good-quality randomized controlled trial (RCT) and two poor-quality single-arm studies, showed minimal support for the use of ClariFix to treat chronic rhinitis. One systematic review

including a study utilizing ClariFix was identified, but no conclusions or findings specific to ClariFix were reported. There are no current clinical/society guidelines addressing ClariFix or cryoablation in general for nasal rhinitis. Therefore, Hayes concluded that the existing evidence suggest minimal or unclear support for the utilization of ClariFix at this time.

In a recent Evolving Evidence Review (Hayes 2022b), use of the RhinAer procedure (Aerin Medical) for treatment of chronic rhinitis was reviewed. One poor quality and one fair quality study both reported that most individuals showed clinically significant relief of nasal symptoms post-treatment with RhinAer. One of these studies compared individual improvements to sham; the RhinAer group displayed improvement when compared with sham, but no studies compared RhinAer with other treatments. No relevant systematic reviews or guidelines were found. The Hayes Review notes that several clinical trials are currently underway, but at this time, evidence does not permit conclusions regarding whether outcomes of the RhinAer procedure are better, worse, or the same as any other treatment.

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

Ehmer et al. (2022, included in the 2022b Hayes Evolving Evidence Review) conducted a prospective, single-arm multicenter study with follow-up through 52 weeks. The study aimed to determine the outcomes of patients diagnosed with chronic refractory rhinitis and treated with temperature-controlled radiofrequency (RF) neurolysis of the posterior nasal nerve (PNN) area in a minimally invasive procedure. To be eligible for the study, participants had to have had chronic rhinitis symptoms for at least six months without adequate response to at least four weeks of treatment with intranasal steroids. Additionally, participants had to have an overall 12-hour reflective rTNSS greater than or equal to 6 with sub-scores 2 to 3 for rhinorrhea, 1 to 3 for nasal congestion, and 0 to 3 for each nasal itching and sneezing. The temperature-controlled radiofrequency energy was delivered via the nasal cavity mucosa overlying the PNN region with a novel single-use, disposable, handheld device. The study resulted in 50 individuals being treated, with 47 completing the study at 52 weeks. The average rTNSS improved from 8.5 at baseline to 3.6 at 52 weeks, showing a 57.6% improvement. Similarly, improvements were noted for rTNSS sub-scores for rhinorrhea, nasal congestion, itching, sneezing, postnasal drip, and chronic cough scores. Treatment was effective regardless of rhinitis classification according to the subgroup analysis. Adverse events (AEs) were recorded in 16 individuals, with eight events considered possibly device or procedure related. Although the study resulted in significant improvements in symptoms of chronic rhinitis after temperature-controlled RF neurolysis of the PNN area, limitations to the study exist. Limiting factors include lack of control or blinding and possible placebo effects contributing to the reported outcomes. More extensive, controlled studies are necessary to demonstrate the device's efficacy.

Ow et al. (2021, included in the 2022a Hayes Evolving Evidence Review) conducted a prospective single-arm multicenter study to assess the long-term safety and effectiveness of the PNN cryoablation as a treatment for chronic rhinitis. Change from baseline in the rTNSS, physician assessment of improvement using the Clinical Global Impression Improvement (CG-I), Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ), and the incidence of treatment-related adverse events were the studies endpoints. Of the 100 participants enrolled at six US investigational sites, in the first 12 months, ninety-one participants completed the study, and sixty-two participants consented to the long-term follow-up, with 57 completing the 24month follow-up. The total rTNSS showed significant improvements with the median change from baseline of -3.0 or -4.0. The minimum clinically importance difference (MCID) was achieved by greater than 80% of participants on the rTNSS at all follow-ups. RQLQ

scores showed a significant improvement in quality of life, with over 77% of participants achieving the MCID for the total RQLQ score. The CGI-I resulted in greater than or equal 83% of participants experiencing improvement at all visits except the 12-month follow-up (61.9%). AEs were reported in 23 participants, with one participant experiencing epistaxis and retained pledget. Although the study included a relatively large population of participants followed through 24 months after treatment using multiple validated assessments to evaluate various outcomes, the single-arm design without a concurrent control arm and the loss of nearly 30% of individuals after 12 months creates significant limitations. After the study, no significant differences were seen in rTNSS outcomes between allergic and nonallergic rhinitis participants. Furthermore, between the observed and imputed rTNSS results, there was a -1 difference in the change from baseline and a 3% difference in the percent of participants who achieved MCID.

Stolovitzky et al. (2021, included in the 2022b Hayes Evolving Evidence Review) headed a multicenter, prospective, single-blinded, randomized control trial in which the control arm underwent a sham procedure to determine the safety and efficacy of temperature-controlled RF neurolysis of the PNN for the treatment of chronic rhinitis. In the setting of 16 otolaryngology centers, individuals with an rTNSS greater than or equal to 6 were randomized 2:1 to active treatment of the PNN area with a temperature-controlled RF or sham procedure without the delivery of RF energy. At three months, the primary endpoint responder rate showed a response greater than or equal to a 30% improvement (decrease) in rTNSS from baseline. The active treatment group showed results of average baseline rTNSS of 8.3, and the results of the sham control were 8.2. At three months in the active treatment arm, the responder rate was significantly higher, resulting in 67.5% vs. 41.0%. Additionally, the active treatment arm showed a significantly greater decrease in rTNSS than that sham arm. The authors concluded that the results of the RCT demonstrated that RF neurolysis is superior to sham control in reducing the overall symptom burden experienced by individuals with chronic rhinitis. However, the trial was pragmatic in its design as it did not demonstrate a reduction in medication use with active treatment and did not dictate medication use. Additional limitations include the short three-month follow-up, lack of comparison to other treatments, and no investigator blinding during the study. Longer-term follow-up is necessary to report on the durability of treatment effects.

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

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

U.S. Food and Drug Administration (FDA)

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

The FDA classifies devices used for rhinoplasty and other sinus surgeries under product code LRC (instrument, ENT, manual surgical). This is a broad product code category that includes a variety of devices used in ear, nose, and throat surgeries (e.g., knives, hooks, injection systems, dilation devices). Additionally, this product code is 510(k)-exempt. Although manufacturers may voluntarily submit product information via the 510(k) process, it is not a requirement. All manufacturers are, however, required to register their establishment and submit a "Device Listing" form; these records can be viewed in the Registration and Device Listing Database (search by product code, device, or manufacturer name). Refer to the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed December 19, 2022)

The VivAer® Stylus received 510K 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 December 14, 2022)

Intranasal septal splint devices are classified by the FDA as class 1 devices under product code LYA. This category includes over 40 devices including, but not limited to, Alar Nasal Valve Stent, Spiway Endonasal Access Guide, Novashield Injectable Nasal Packing and Stent and the Macropore Ent Reconstruction Film. The FDA has exempted almost all class I devices (except for reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the Federal Registers of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with 21 CFR 874.9. Refer to the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed December 19, 2022)

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

For additional information, 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 December 19, 2022)

The ClariFix Device is a cryosurgical tool intended to be used for the destruction of unwanted tissue during surgical procedures, including in adults with chronic rhinitis. It received U.S. Food and Drug Administration (FDA) clearance as a Class II device through the 510(k) premarket notification pathway on February 14, 2017. Refer to the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K190356.
(Accessed December 19, 2022)

U.S. Food and Drug Administration (FDA) cleared The RhinAer Stylus as a Class II device through the 510(k) premarket notification pathway on July 29, 2022. This device is indicated for use in otorhinolaryngology (ENT) surgery for the destruction of soft tissue in the nasal airway, including in posterior nasal nerve regions in patients with chronic rhinitis. Refer to the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K221907.
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Policy History/Revision Information

Date	Summary of Changes
05/01/2024	**Related Policies** • Removed reference link to the Medical Policy titled *Orthognathic (Jaw) Surgery (for Indiana Only)* (retired May. 1, 2024)
01/01/2024	**Applicable Codes** • Updated list of applicable CPT codes to reflect annual edits; added 31242 and 31243 **Supporting Information** • Archived previous policy version CS107IN.05

Instructions for Use

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

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