# **Rhinoplasty and Other Nasal Surgeries**

**MEDICAL POLICY NUMBER: 166** 

Effective Date: 1/1/2024	COVERAGE CRITERIA	2
Last Review Date: 10/2023	POLICY CROSS REFERENCES	3
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**INSTRUCTIONS FOR USE:** Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

**SCOPE:** Providence Health Plan, Providence Health Assurance and Providence Plan Partners as applicable (referred to individually as "Company" and collectively as "Companies").

# PLAN PRODUCT AND BENEFIT APPLICATION

	Commercial	☐ Medicaid/OHP*	☐ Medicare**
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#### \*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

Notice to Medicaid Policy Readers: For comprehensive rules and guidelines pertaining to this policy, readers are advised to consult the Oregon Health Authority. It is essential to ensure full understanding and compliance with the state's regulations and directives. Please refer to OHA's prioritized list for the following coverage guidelines:

Rhinoplasty: Guideline Note 516, Lines 42, 119, 202, 246, 287, 466, 506, 525

#### \*\*Medicare Members

This <u>Company</u> policy may be applied to Medicare Plan members only when directed by a separate <u>Medicare</u> policy. Note that investigational services are considered "**not medically necessary**" for Medicare members.

### **COVERAGE CRITERIA**

<u>Note:</u> This medical policy does not address surgical treatments for rhinoplasty (with or without cleft palate repair) in patients 17 years of age or younger *OR* rhinoplasty in the case of acute nasal fracture/trauma, all of which may be considered medically necessary. "Acute" is defined as the emergent treatment of nasal fractures when the problem is diagnosed, and a treatment plan delineated within 72 hours of the fracture/trauma.

- I. Rhinoplasty for reconstructive purposes may be considered **medically necessary** when all of the following criteria (A.-C.) are met:
  - A. Patient has severe nasal airway obstruction and the procedure is essential to accomplish opening of the nasal airways; **and**
  - B. Patient has **one or more** of the following (1.-2.):
    - 1. Nasal deformity; and/or
    - 2. History of trauma; and
  - C. **Both** of the following (1.-2.) documentation is submitted:
    - 1. Complete otolaryngologist evaluation; and
    - 2. Documentation of the proposed surgical plan.

- II. Rhinoplasty is considered **cosmetic** when criterion I. above is not met.
- III. Absorbable nasal implants are considered **not medically necessary** for all indications, including but not limited to nasal valve collapse.
- IV. Radiofrequency energy to the nasal valve (e.g., Vivaer Nasal Airway Remodeling (Aerin Medical)) is considered **not medically necessary** for the treatment of all indications, including but not limited to nasal airway obstruction.

**Link to Evidence Summary** 

# **POLICY CROSS REFERENCES**

Cosmetic and Reconstructive Procedures, MP98

The full Company portfolio of current Medical Policies is available online and can be accessed here.

# **POLICY GUIDELINES**

#### **BACKGROUND**

#### Rhinoplasty

Rhinoplasty is a procedure performed on the external or internal structures of the nose, septum, or turbinate. This surgery may be performed to improve abnormal function, reconstruct congenital or acquired deformities, or to enhance appearance

### **Absorbable Nasal implant**

Intended as a minimally invasive alternative to surgery, absorbable nasal implants are intended to support upper and lower lateral cartilage in patients with nasal valve collapse as a primary factor for nasal airway obstruction.<sup>1</sup>

#### **Low-Dose Radiofrequency Energy to the Nasal Valve**

The VivAer procedure is a non-invasive, office-based procedure that uses low-dose radiofrequency energy to alter the soft tissue of the nose to improve nasal breathing.

# CLINICAL EVIDENCE AND LITERATURE REVIEW

#### **EVIDENCE REVIEW**

#### **Functional Rhinoplasty**

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of functional rhinoplasty. Below is a summary of the available evidence identified through September 2023.

### Systematic Reviews

- In 2022, Zhao and colleagues conducted a meta-analysis on the effects of functional rhinoplasty on nasal obstruction.<sup>2</sup> PubMed, EMBASE, and Cochrane Library databases were searched to identify studies evaluating nasal obstruction before and after functional rhinoplasty in patients with nasal valve problems. The authors noted that this has not yet been systematically reviewed on a large scale. A total of 57 cohorts from 43 studies (totaling 2024 patients) were included in the meta-analysis. Studies reviewed improved nasal ventilation after rhinoplasty was utilized to correct problems within the nasal valves. The Nasal Obstruction Symptom Evaluation (NOSE) scores indicated significant improvement in nasal obstruction at the 1-month follow-up (WMD = 38.12; 95% CI, 29.15–47.10;  $l^2$  = 83.6%; P = 0.00), 3-month follow-up (WMD = 48.40; 95% CI, 43.16–53.64;  $l^2$  = 69.1%; P = 0.00), 6-month follow-up (WMD = 44.35; 95% CI, 36.65– 52.04;  $I^2$  = 96.6%; P = 0.00), 12-month follow-up (WMD=43.07; 95% CI, 26.56– 59.58;  $I^2 = 97.9\%$ ; P = 0.00), and the last follow-up (WMD = 46.90; 95% CI, 43.92– 49.88;  $l^2 = 95.9\%$ ; P = 0.00) with respect to the preoperative baseline. The Visual Analogue Scale (VAS) scores indicated a similar trend at the 1-month follow-up (WMD = 4.68; 95% CI, 3.79– 5.57;  $I^2 = 86.8\%$ ; P = 0.00), 3-month follow-up (WMD = 4.46; 95% CI, 3.19– 5.74;  $l^2 = 93.3\%$ ; P = 0.00), 6-month follow-up (WMD = 4.91; 95% CI, 4.04–5.78;  $l^2 = 88\%$ ; P = 0.00) and last follow-up (WMD = 4.22; 95% CI, 3.12–5.32;  $I^2$  = 97.1%; P = 0.00). Nasal obstruction was obviously relieved through rhinomanometry (SMD=0.56; 95% CI, 0.27–0.84;  $l^2$  = 0.0%; P = 0.00) but not through peak nasal inspiratory flow (PNIF) (SMD=−1.51; 95% CI, −3.10 to 0.07;  $I^2 = 98.9\%$ ; P = 0.09). The authors concluded that functional rhinoplasty may have a positive effect on nasal obstruction caused by nasal valve problems but urged broader and well-designed studies were needed to shed more light on the relationships in this area.
- In 2019, Kandathil and colleagues conducted a systematic review and meta-analysis evaluating efficacy of repair of the lateral nasal wall in adult patients with nasal airway obstruction.<sup>3</sup> Independent investigators systematically searched the literature through July 2017, identified eligible studies, assessed study quality, and extracted data. Effect sizes were first calculated for each study and then pooled together using random effects synthesis. In total, 10 observational studies were included for review (8 prospective, 2 retrospective), assessing 324 participants (range: 6 to 79). Follow-up ranged from 3 months to 24 months. The pooled effect size supported the efficacy of functional rhinoplasty for the treatment of nasal airway obstruction caused by lateral nasal wall insufficiency the pooled effect size for functional rhinoplasty was -47.7 (95% CI, -53.4 to 42.1) points on the Nasal Obstruction Symptom Evaluation scale with high heterogeneity of 72%. Outcomes were similar at short- (-45.0 points [95% CI, -47.8 to -42.2 points]), mid- (-48.4 points [95% CI, -52.5 to -44.4 points]), and long-term (-49.0 points [95%

CI, -62.1 to -35.8 points]) follow-ups. Limitations included small sample sizes, study design, high heterogeneity ( $I^2 = 72\%$ ) and the lack of randomized or controlled trials.

- In 2017, Floyd and colleagues conducted a systematic review and meta-analysis of studies evaluating functional rhinoplasty outcomes with the Nasal Obstruction Symptom Evaluation (NOSE) score. Independent investigators systematically searched the literature through November 2015, identified eligible studies, assessed study quality, and extracted data. Study results were pooled with a random effects model; change in NOSE score after surgery was assessed with both the mean difference between baseline and postoperative results and the standardized mean difference. In total, 16 studies were included for review, assessing NOSE scores for 479 patients (range: 7 to 38). The studies' had a pooled mean preoperative NOSE score of 67.4 (95% CI, 61-73.9) based on random effects meta-analysis. The range of scores was 34.8 to 86.5 with very high heterogeneity (I² = 95). Substantial improvement in NOSE score was reported at 3-, 6-, and 12-month follow-up. Investigators concluded that nasal obstruction, as measured by the NOSE survey, improves substantially for at least 12 months after functional rhinoplasty. Limitations undermining results' validity included small sample sizes, high heterogeneity, the preponderance of case series included for review, inadequate follow-up, and a lack of randomized or controlled trials conducted to date.
- In 2008, Rhee and colleagues conducted a systematic review evaluating the safety and efficacy of functional rhinoplasty or nasal valve repair. Independent investigators systematically searched the literature through August 2007, identified eligible studies, assessed study quality, and extracted data. In total, 82 articles were included for review, 44 of which met inclusion criteria (42 case series, 2 cohort studies), evaluated 2,295 patients (range: 7 to 312) who had undergone some form of functional rhinoplasty. Follow-up ranged from 1 month to 13 years. Outcome measures of interest included subjective gross patient reports, non-validated questionnaires, validated patient-report measures and objective measurements (e.g. rhinomanometry, acoustic rhinometry, and nasal airflow studies). Limitations included heterogeneity of study design, quality, invention and outcome measures used, all of which prevented the pooling of data. Despite heterogeneity, all articles generally supported the efficacy of functional rhinoplasty techniques for the treatment of nasal obstruction. Efficacy ranged from 65% to 100%, with no study finding rhinoplasty ineffective as an intervention. Investigators concluded that there was substantial level 4 evidence (i.e. case series/case report) to support the efficacy of rhinoplasty techniques for treatment of nasal obstruction due to nasal valve collapse. Authors also called for additional studies using comparison cohorts and standardized objective outcome measures to further establish the efficacy of rhinoplasty.

#### **Absorbable Nasal Implant**

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of absorbable nasal implants. Below is a summary of the available evidence identified through September 2023.

In 2023, Hayes completed an evolving evidence review stating that there was minimal support
from clinical studies and systematic reviews for the use of absorbable nasal implant for the
treatment of nasal valve collapse.<sup>6</sup> There were no clinical practice guideline or position
statement documents found that specifically addressed the use of absorbable nasal implants for
nasal valve collapse. Hayes stated that Clinical evidence suggests absorbable nasal implants are

technically feasible to implant and are associated with reductions in nasal airway obstruction symptoms and pain; however, evidence is of generally very poor quality and there is a paucity of studies with control groups to inform whether absorbable nasal implants have clinical performance that is better, worse, or similar to competing technologies, such as nonabsorbable nasal implants. Additionally, many patients received adjunctive treatment with the nasal implants, which confounds interpretation of results. There is no applicable Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) for absorbable nasal implants for NVC; payers generally consider them experimental or investigational and therefore noncovered.

- In 2022, ECRI conducted a clinical evidence review assessing the safety and efficacy of the Latera Absorbable Nasal Implant for Supporting Nasal Upper and Lower Lateral Cartilage.¹ Evidence from one randomized controlled trial (RCT) and four pre-post studies synthesized in meta-analysis shows that Latera is safe and improves breathing in patients with nasal wall collapse at one-year follow-up. However, how well Latera works longer term (>1 year) and how it compares with rhinoplasty is unclear because studies provide too few data. Consistent evidence synthesized in meta-analysis supports low-confidence conclusions; however, pooled findings are at risk of bias because all but one study included parallel control groups, the sole RCT was not blinded, and studies reported subjective measures (e.g., NOSE scores, pain). Also, findings may not be generalized to all patients because some patients underwent Latera treatment in addition to turbinectomy and septoplasty. Sham-controlled, double-blind RCTs with uniform treatment protocols are needed to support stronger conclusions Evidence bar was evidence was somewhat favorable.
- In 2020 Kim and colleagues completed a systematic review and meta-analysis on the effectiveness of using a bioabsorbable implant to treat nasal valve collapse. PubMed, SCOPUS, EMBASE, Web of Science, and the Cochrane Data were independently reviewed by two researchers. Five studies (totaling 396 patients) were included in the review. The authors found that bioabsorbable nasal implants significantly reduced endoscopic lateral wall motion compared to pretreatment values and also improved quality of life (QOL) at 12 months postoperatively. Most adverse effects following the nasal implant, such as skin or mucosal reaction, infection, or implant retrieval, were reported with a 5% incidence rate. All adverse outcomes were resolved without significant sequelae. Compared with sham surgery, bioabsorbable nasal implants significantly improved disease-specific QOL.

#### Low-Dose Radiofrequency Energy to the Nasal Valve

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of radiofrequency energy to the nasal valve for the treatment of nasal obstruction (i.e. VivAer Stylus). Below is a summary of the available evidence identified through September 2023.

• In 2023, Hayes published an evidence review assessing the clinical utility of VivAer for the treatment of nasal obstruction. A review of full-text clinical studies suggests minimal support for using the VivAer radiofrequency (RF) procedure for remodeling the nasal valve area when collapse of the nasal valve is associated with chronic nasal obstructive symptoms. Four clinical studies were identified, 3 of which were rated poor or very poor quality. Only 1 study compared VivAer with sham. No studies evaluated VivAer with another active treatment. Results were

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consistent across studies in direction and significance (both clinical and statistical) for patient-reported outcomes. The rate of clinical response exceeded 85%, and all studies reported improvements in symptom scores. VivAer also appeared to improve nasal patency and may improve quality of life (QOL), especially as a result of improved sleep. The duration of effect was reported to last up to 4 years in 1 study. However, the follow-up duration of the sham-controlled part of the randomized controlled trial (RCT) was only 3 months. Only 1 study reported objective measures of nasal patency and airflow. Authors concluded that it was unclear whether VivAer significantly improves objective measures of nasal patency and airflow, and that additional well-designed comparative studies were needed to assess the effectiveness, safety, and durability of effect of VivAer and determine how VivAer compares to other active treatments for nasal obstruction.

• In 2022, ECRI conducted an evidence review assessing the clinical utility of Vivaer for treating nasal airway obstruction. Evidence from one RCT and four pre-post studies reported consistent, clinically significant effects at three-month follow-up. Only 1 study reported longer follow-up (48-month follow-up on 29 of 50 patients), and high attrition confounds interpretation of results. Authors' confidence in the conclusions is low because these studies are at high risk of bias from two or more of the following: small size, lack of parallel controls, lack of randomization, lack of blinding, and high patient attrition at longest follow-up. Also, follow-up of at least two years would be useful to assess risks of recurrence and need for retreatment after airway remodelling. Despite claiming that evidence supporting the use of Vivaer was "somewhat favorable," authors stated that larger, multicenter RCTs were needed, comparing Vivaer with standard surgical tools and other devices and treatments for nasal valve collapse (e.g., functional rhinoplasty, nasal implant), reporting longer-term outcomes.

#### **CLINICAL PRACTICE GUIDELINES**

No relevant clinical practice guidelines were identified addressing the use of functional rhinoplasty for the treatment of nasal obstruction.

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

In 2018, the AAO-HNS published a position statement regarding the use of absorbable nasal implants:

"The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) acknowledges the benefit of use of absorbable nasal implants for treatment of nasal valve collapse, based on currently available data. The Academy believes this implant technology may be of significant benefit to select patients." <sup>10</sup>

#### **EVIDENCE SUMMARY**

Data from systematic reviews of case series indicate that rhinoplasty is a safe and effective treatment of nasal obstruction. Despite limitations arising from studies' small sample sizes, case series design and high heterogeneity, meta-analyses suggest that rhinoplasty significantly improves patients' Nasal Obstruction Symptom Evaluation (NOSE) score, an important patient-reported outcome. While

randomized and controlled trials with larger patient cohorts are necessary to further establish validity, especially of objective outcomes measures, long-term data from low-quality studies sufficiently demonstrates the procedure's efficacy.

Evidence is insufficient to support the use of an absorbable lateral nasal implants for the treatment of symptomatic nasal valve collapse and low-dose radiofrequency energy for the treatment of nasal obstruction. No evidence-based clinical guidelines recommend the use of these services and studies to date are limited by a lack of long-term follow-up, large sample sizes, and lack of reporting on key patient-oriented outcomes (e.g. retreatment rates, quality of life).

### **BILLING GUIDELINES AND CODING**

CODES*			
CPT	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	
	30468	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)	
	30469	Repair of nasal valve collapse with low energy, temperature-controlled (ie, radiofrequency) subcutaneous/submucosal remodeling	

#### \*Coding Notes:

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this
  policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for
  medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential
  utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code
  is submitted for non-covered services addressed in this policy then it will be denied as not covered. If an unlisted
  code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, prior
  authorization is recommended.
- See the non-covered and prior authorization lists on the Company <u>Medical Policy</u>, <u>Reimbursement Policy</u>, <u>Pharmacy Policy and Provider Information website for additional information</u>.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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- 10. American Academy of Otolaryngology- Head and Neck Surgery (AAO-HNS). AAO-HNS Statement on Absorable Nasal Implants. <a href="https://www.entnet.org/wp-content/uploads/2021/04/Nasal-Implant-Letter-and-Statement-2018.pdf">https://www.entnet.org/wp-content/uploads/2021/04/Nasal-Implant-Letter-and-Statement-2018.pdf</a>. Published 2018. Accessed 9/12/2023.

# **POLICY REVISION HISTORY**

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
6/2023	Interim update. Changed denial from investigational to not medically necessary
1/2024	Annual update. Added criterion addressing low-dose radiofrequency to the nasal valve.