MEDICAL POLICY	**Rhinoplasty (All Lines of Business Except Medicare)**
Effective Date: 11/1/2022  11/1/2022 Medical Officer Date	Medical Policy Number: 166 Medical Policy Committee Approved Date: 11/09; 9/17; 3/18; 3/19; 6/19; 10/19; 11/2020; 10/2021; 10/2022

See Policy CPT CODES section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

All lines of business except Medicare (*unless otherwise directed by a Medicare medical policy. Note that investigational services are considered "**not medically necessary**" for Medicare members.)*

BENEFIT APPLICATION

Medicaid 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.

POLICY CRITERIA

Note: 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. **All** 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 and not covered** when criterion I. above is not been met.

III. Absorbable nasal implants are considered **investigational and not covered** for all indications, including but not limited to nasal valve collapse.

Link to Policy Summary

CPT CODES

All Lines of Business Except Medicare	
Prior Authorization Required	
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)
No Prior Authorization Required	
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)

DESCRIPTION

Rhinoplasty

Per the Centers for Medicare & Medicaid Local Coverage Determination (LCD): Plastic Surgery (L37020), rhinoplasty is defined as:[1]

> "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. It generally involves rearrangement or excision of the supporting bony and cartilaginous structures and incision or excision of the overlying skin of the nose."

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.[2]

REVIEW OF EVIDENCE

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 2022.

Systematic Reviews

- In 2022 Zhao and colleagues conducted a meta-analysis on the effects of functional rhinoplasty on nasal obstruction.[3] 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; I^2 = 83.6%; P = 0.00), 3-month follow-up (WMD = 48.40; 95% CI, 43.16–53.64; I^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; I^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; I^2 = 93.3%; P = 0.00), 6-month follow-up (WMD = 4.91; 95% CI, 4.04–5.78; I^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; I^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.[4]

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.[5] 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 (I^2 = 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.[6] 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 2022.

- In 2022 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.[7] 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 2017 (and updated 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.[2] 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.[8] 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. The

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 (AA0-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."[9]

POLICY 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 implant for the treatment of symptomatic nasal valve collapse. No evidence-based clinical guidelines recommend the use of an absorbable lateral nasal implant 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).

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 Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

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.

REGULATORY STATUS

Mental Health Parity Statement

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.

MEDICAL POLICY CROSS REFERENCES

- Cosmetic and Reconstructive Procedures (All Lines of Business Except Medicare)

REFERENCES

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13. Shuaib SW, Undavia S, Lin J, Johnson CM, Jr., Stupak HD. Can functional septorhinoplasty independently treat obstructive sleep apnea? *Plast Reconstr Surg.* 2015;135(6):1554-1565.