NO. 91506-R8

SEPTOPLASTY / RHINOPLASTY

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Instruction for use: This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion. Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

I. MEDICAL NECESSITY CRITERIA

A. Septoplasty/Rhinoplasty may be considered medically necessary when the criteria listed below are met.

1. **Septoplasty** is considered medically necessary when *any* of the following clinical criteria are met
   a. Septal deviation causing continuous nasal airway obstruction resulting in nasal breathing difficulty not responding to 4 to 6 weeks of appropriate medical therapy; ***or***
   b. Documented recurrent sinusitis felt to be due to a deviated septum not relieved by appropriate medical and antibiotic therapy; ***or***
   c. Recurrent epistaxis related to a septal deformity; ***or***
   d. Asymptomatic septal deformity that prevents access to other intranasal areas when such access is required to perform medically necessary surgical procedures (e.g., ethmoidectomy); ***or***
   e. When done in association with cleft palate repair.

2. **Rhinoplasty** is generally considered a cosmetic surgical procedure and is not a covered benefit. However, rhinoplasty may be considered medically necessary and a covered benefit when the Primary Care Physician and/or the consulting specialty physician documents that **ALL** of the following exist:
   a. To correct a nasal deformity secondary to congenital cleft lip and/or palate under age 18; ***or***

b. To correct chronic nasal airway obstruction due to trauma, disease, congenital defect, when all of the following criteria are met:
    i. Nasal airway obstruction is causing significant symptoms (e.g., chronic rhinosinusitis, difficulty breathing), ***and***
    ii. Photos demonstrate an external nasal deformity, ***and***
    iii. Obstructive symptoms persist despite conservative management for three months or greater, which includes, where appropriate, nasal steroids or immunotherapy; ***and***
    iv. Airway obstruction will not respond to septoplasty and turbinectomy alone, ***and***
    v. There is documentation of gross nasal obstruction on the same side as the septal deviation; ***and*** the rhinoplasty is an integral part of a coordinated surgical procedure, with a medically necessary septoplasty, to restore function.

For cases of trauma, treatment for the correction of an accidental injury must occur within a 24-month time frame from the date of injury. Exceptions to the 24-month time frame must be prior approved by the Medical Director, and may be approved by the Medical Director if documentation establishes sufficient medical justification for the delay(s).

Documentation of these criteria should include:

a. If there is an external nasal deformity, preoperative photographs showing the standard 4-way view - base of nose, anterior posterior (AP), and right and left lateral views; ***and***
b. Relevant history of accidental or surgical trauma, congenital defect, or disease (e.g., Wegener's granulomatosis, choanal atresia, nasal malignancy, abscess, septal infection with saddle deformity, or congenital deformity); ***and***
c. Documentation of duration and degree of symptoms related to nasal obstruction, such as chronic rhinosinusitis, mouth breathing, etc.; ***and***
d. Documentation of results of conservative management of symptoms.

3. The following procedures (not inclusive) are normally not covered. Coverage may be provided on an individual consideration basis by the Medical Director. This requires that documentation be provided substantiating that one or more of these procedures is required to correct a functional nasal airway obstruction:
    a. Alar tip cartilage repair
    b. Dorsal hump removal
    c. Shortening of the nasal septum
    d. Narrowing of the bony pyramid

e. Nasal tip reconstruction
f. Saddle nose deformity

4. Each of the following procedures and/or devices are considered experimental, investigational, and/or unproven:
   a. Repair of nasal valve collapse/vestibular lateral wall stenosis with absorbable nasal implant(s) (e.g., Latera®)
   b. Posterior nasal nerve ablation using a probe that either administers low-temperature radiofrequency energy (e.g., **RhinAer**®) or is cooled to freezing by nitrous oxide (e.g., **ClariFix**®). A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment for these indications. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

5. Repair of nasal valve collapse with low energy, temperature-controlled (i.e., radiofrequency) subcutaneous/submucosal remodeling (e.g., **VivAer**) is considered not medically necessary. This method/device is not superior to or any more beneficial than other standard treatments.

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
None identified.	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	None identified.
First Coast Service Options, Inc.	None identified.
National Government Services, Inc.	None identified.

Noridian Healthcare Solutions	None identified.
Novitas Solutions, Inc.	None identified.
Palmetto GBA	None identified.
WPS Insurance Corporation	None identified.

III. BACKGROUND

Nasal obstruction is one of the most common problems bringing a patient into a physician's office, and septal deviation is a frequent structural etiology. As a result, surgical correction of septal deviation is the third most common head and neck procedure in the United States and it generally is performed to improve quality of life. Presently, a variety of additional indications exists for septoplasty, from intractable epistaxis to harvesting cartilage for use in rhinoplasty

Rhinoplasty alters the aesthetic appearance and functional properties of the nose with surgical manipulation of the skin, underlying cartilage, and bone. A rhinoplasty is a surgical operation on the nose, which may be reconstructive, restorative or cosmetic in nature. It can reduce or increase the size of the nose, change the shape of the tip or the bridge, narrow or widen the span of the nostrils, or change the angle between the nose and the upper lip. It may also correct a birth defect or injury, or assist in relieving some breathing problems caused by obstruction.

Posterior nasal nerve ablation (e.g., RhinAer® and Clarifix®)

Posterior nasal nerve ablation involves the application of low-temperature radiofrequency energy or cryotherapy (extreme cold) to nasal mucosa overlying the posterior nasal nerve. This purportedly damages the posterior nasal nerve, resulting in disrupted transmission of the nerve signals that are thought to cause excess mucus production and congestion.

A probe is inserted intranasally that administers either low-temperature radiofrequency energy (**RhinAer®**) or is cooled to freezing by nitrous oxide (**Clarifix®**) to ablate the posterior nasal nerve. Both devices can be used to reduce and destroy inflamed soft tissue.

RhinAer

The RhinAer procedure is conducted using the Rhin1 Stylus by Aerin Medical. This device is regulated as a class II device under the Code of Federal Regulations (CFR) 21 CFR 878.4400 and was initially granted 510(k) clearance (K192471) on December 20, 2019, under product code GEI (electrosurgical cutting and coagulation device and accessories). The RHIN1 Stylus 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.

Hayes, Inc. released an Evolving Evidence Review of the RhinAer® procedure for treatment of chronic rhinitis January 13, 2022. The level of support for RhinAer® ranged

from no/unclear support (systematic reviews; clinical practice guidelines and position statements) to **minimal support (clinical studies)**. Hayes' most recent Annual Review suggests **likely** upgrades from no/unclear support to **minimal support in the form of systematic reviews and clinical practice guidelines and position statements.**

A prospective single-arm study of 129 patients with chronic rhinitis at 16 medical centers in the United States and Germany found that the mean 24-h reflective total nasal symptom score (rTNSS) improved from 7.8 (95% CI, 7.5-8.1) at baseline to 3.6 (95% CI, 3.2-4.0) at 3 months and continued to improve to 2.9 (95% CI, 2.5-3.3) at 6 months ($p < .001$ comparing follow-up to baseline and $p = .002$ comparing 3 and 6 months). This represented 53.8% improvement over baseline at 3 months and 62.8% improvement at 6 months. Rhinorrhea, congestion, sneezing, and itching subscores and postnasal drip and cough scores were all significantly improved over baseline at both timepoints. At 3 months, 76.2% (95% CI, 68.1%-82.8%) of patients achieved a minimal clinically important difference of ≥30% improvement in rTNSS over baseline and the percentage was higher at 6 months (83.5% [95% CI, 75.8%-89.0%]). At 3 months, 80.3% (95% CI, 72.6%-86.3%) reported a minimal clinically important difference of ≥0.4-point improvement in the mini rhinoconjunctivitis quality of life questionnaire score, and the percentage was higher at 6 months; 87.7% (95% CI, 80.7%-92.4%). There were no serious adverse events with a relationship to the device/procedure reported through 6 months. The authors concluded that neurolysis of the posterior nasal nerve was safe and resulted in a significant reduction in rhinitis symptom burden at 3 months that was sustained through 6 months. (Lee et al., 2022)

A systematic review and meta-analysis including 5 studies and a total of 284 participants evaluated pooled estimates for change in rTNSS from baseline at 3 months and responder rates (≥30% reduction in baseline rTNSS) at 3 and 6 months. Other outcomes, such as postnasal drip and cough scores, quality of life (QoL) measures, and adverse events were also included for qualitative review. The pooled change in rTNSS score at 3 months was -4.28 (95% CI, -5.10 to -3.46). The pooled responder rate at 3 months was 77.11% (95% CI, 68.21%-86.01%) and at 6 months 80.80% (95% CI, 70.85%-90.76%). Postnasal drip and cough scores and QoL also improved significantly at follow up. A total of 36 adverse events were reported in 21 (7.4%) patients. These findings suggest that temperature-controlled radiofrequency neurolysis of the PNN is effective at treating chronic rhinitis symptoms and that it has an overall favorable safety profile. (Yu et al., 2023)

Clarifix

Clarifix® (Arrinex Inc.) is regulated as a class II device under the Code of Federal Regulations (CFR) 21 CFR 878.4350 and was initially granted 510(k) clearance (K160669) on June 24, 2016, under product code GEH (unit, cryosurgical, accessories). The Clarifix® Device is intended to be used as a cryosurgical tool for the destruction of unwanted tissue during surgical procedures, including in adults with chronic rhinitis.

Hayes, Inc. release an Evolving Evidence Review of Clarifix® for treatment of chronic rhinitis March 7, 2022. The level of support for Clarifix® ranged from no/unclear support (systematic reviews; clinical practice guidelines and position statements) to **minimal support (clinical studies)**. Hayes' most recent Annual Review suggests **possible** upgrades from no/unclear support to **minimal support in the form of systematic reviews and clinical practice guidelines and position statements.**

Current guidance (ARS 2022; AAO-HNS, 2023) appears to confer at best minimal support for the use of posterior nasal ablation in patients with chronic rhinitis as the processes for developing the two position statements are not described.

In a 2023 systematic review and meta-analysis, a systematic search of Pubmed/Medline, Web of Science, and EBSCOhost was conducted from inception to May 2022. Peer-reviewed clinical trials reporting postcryotherapy reflective total nasal symptom score (rTNSS) at both 1- and 3-month intervals for patients with chronic rhinitis were included.The primary outcome measures included mean differences in rTNSS from baseline to both 1- and 3-month postoperative time points. Secondary measures included other questionnaires including the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ). There were 5 studies that met the criteria (247 individuals). The pooled rTNSS mean difference from baseline to 1 and 3 months postoperatively was found to be -3.48 points (95% CI: -3.73 to -3.23, I^2 = 0.13). and -3.50 (95% CI: -3.71 to -3.29, I^2 = 0.00), respectively. The mean difference from baseline to 3 months postoperatively regarding the RQLQ was found to be -1.53 (95% CI: -1.74 to -1.31, I^2 = 0.00). The most common adverse effects included facial or surgical site pain (40.4%), followed by headache (18.2%), oral numbness (11.1%), and sinusitis (4.0%). The authors concluded that cryoablation with Clarifix is an effective treatment modality for chronic rhinitis, however, higher-quality randomized controlled trials will need to be performed to affirm this. (Young et al., 2023)

Another systematic review published in 2023 consisted of 8 articles evaluating a total of 472 patients. The data showed a significant reduction in scores post-treatment across all studies based on validated outcome measures. In all studies, at all time intervals, there was a significant improvement in outcome scores from baseline. Minor adverse effects included post-procedural pain and discomfort, headache and palate numbness. No major adverse events were identified. Overall, the review highlighted an apparent benefit in using this intervention for chronic rhinitis that is refractory to medical management. (Desai et al., 2023)

Alanazi and colleagues (2024) conducted a systematic review and meta-analysis on the safety and efficacy of cryotherapy on chronic rhinitis consisting of 18 studies with 1,663 patients. All assessed outcomes showed improvement with cryotherapy from baseline status. Pooled MDs for Total Nasal Symptom Score (rTNSS), Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ), and Nasal Obstruction Symptom Evaluation (NOSE) scores were as follows: (- 3.58, 95% CI [- 3.80, - 3.37], $p < 0.001$), (- 1.48, 95% CI [- 1.68, - 1.27], $p < 0.001$), and (- 26.65, 95% CI [- 33.98, - 19.31], $p < 0.001$), respectively. Regarding nasal obstruction and rhinorrhea, cryotherapy showed

effectiveness in 61% and 52% of patients in the complete relief subgroup and 26% and 34% in the < 50%-relief subgroup, respectively. Significant improvement in measured outcomes was observed compared to baseline state and through all subsequent follow-up periods, demonstrating cryotherapy's efficacy. However, the authors note that more high-quality RCTs are needed for stronger evidence to be generalized.

VivAer

VivAer (Aerin Medical Inc.) is a device used in a noninvasive office-based procedure that is an alternative to invasive surgical intervention. VivAer is intended to modify the soft tissue of the nasal airway using low-dose nonablative radiofrequency (RF) energy. The RF energy can be used to remodel nasal cartilage and soft tissue throughout the nasal valve, including the septum, the inferior turbinate, and the nasal valve itself. However,

- There appear to be very few, if any, clinical studies which evaluated VivAer with another active treatment.
- There appear to be no systematic reviews evaluating the safety or efficacy of the VivAer procedure.
- There appear to be no professional society position statements or clinical practice guidelines specifically addressing VivAer or radiofrequency treatment of nasal airway obstruction.

Simmons and colleagues (2024) conducted a single-center retrospective chart review on 37 patients with a history of rhinoplasty or nasal valve repair who underwent VivAer RF treatment. Treatment outcomes were assessed using the Nasal Obstruction Symptom Evaluation (NOSE) scale. The primary outcome was defined as a decrease in NOSE score by at least one severity category or a 20 % reduction in total NOSE score. The study found a statistically significant average reduction in NOSE score of 22.4 points or 36.6 %. Among patients with a positive treatment response (21 patients or 56.8 %), the average NOSE score reduction was 34.7 points or 55.6 %. Repeat RF treatment in non-responders resulted in a 50 % response rate. No significant difference was observed in treatment outcomes based on the type of prior rhinoplasty or NVC. The authors concluded that further research, including randomized controlled trials, is needed to validate these promising results and expand the treatment options for this complex patient population.

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
American Rhinologic Society	ARS Position Statement: Posterior Nasal Nerve Ablation (2022)
American Academy of Otolaryngology	Position Statement: PNN Ablation for the Treatment of Chronic Rhinitis (2023)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Notice date
RhinAer® (Aerin Medical Inc.)	K221907	7/29/2022
VivAer (Aerin Medical Inc.)	K200300	04/13/2020
Clarifix® (Stryker Inc.)	K190356 K162608 K160669	2/26/2019 2/14/2017 6/24/2016

VI. CODING

ICD-10 Codes that may support medical necessity

C30.0	Malignant neoplasm of nasal cavity
C41.0	Malignant neoplasm of bones of skull and face
C44.300 – C44.399	Other and unspecified malignant neoplasm of skin of other and unspecified parts of face
C76.0	Malignant neoplasm of head, face and neck
D03.30	Melanoma in situ of unspecified part of face
D04.39	Carcinoma in situ of skin of other parts of face
D14.0	Benign neoplasm of middle ear, nasal cavity and accessory sinuses
D16.4	Benign neoplasm of bones of skull and face
D22.30 – D22.39	Melanocytic nevi of other part of face
D38.5	Neoplasm of uncertain behavior of other respiratory organs
D49.1	Neoplasm of unspecified behavior of respiratory system
J31.0	Chronic rhinitis
J32.0 – J32.9	Chronic sinusitis
J34.0 – J34.9	Other and unspecified disorders of nose and nasal sinuses
M95.0	Acquired deformity of nose
Q30.0 - Q30.9	Congenital malformations of nose
Q35.1 – Q35.9	Cleft palate
Q37.0 – 37.9	Cleft palate with cleft lip
Q67.0	Congenital facial asymmetry
Q67.1	Congenital compression facies
Q67.4	Other congenital deformities of skull, face and jaw
R04.0	Epistaxis
R06.00	Dyspnea, unspecified
R06.09	Other forms of dyspnea
R06.89	Other abnormalities of breathing
R09.81	Nasal congestion
S01.20xS	Unspecified open wound of nose, sequela
S01.21xS	Laceration without foreign body of nose, sequela

S01.22xS	Laceration with foreign body of nose, sequela

CPT/HCPCS Codes

30520	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft

Prior Authorization Required:

(Codes 30400-30410, 30430-30462 not covered for certain individual plans)

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

Not Covered

30468	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s) *(Covered for Medicaid and Medicare)*
30469	Repair of nasal valve collapse with low energy, temperature-controlled (ie, radiofrequency) subcutaneous/submucosal remodeling [Includes VivAer® (Aerin Medical Inc.)] *(Covered for Medicaid and Medicare)*
31242	Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve [includes RhinAer® (Aerin Medical Inc.)] *(Covered for Medicaid and Medicare)*
31243	Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve [includes ClariFix® (Stryker)] *(Covered for Medicaid and Medicare)*

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN**: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IX. REFERENCES

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VivAer

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Past review dates: 5/05, 12/05, 2/06, 2/07, 7/07, 2/08, 2/09, 2/10, 2/11, 2/12, 2/13, 2/14, 2/15, 2/16, 2/17, 2/18, 2/19, 2/20, 2/21, 5/21, 5/22, 5/23, 5/24, 11/24