Priority Health

MEDICAL POLICY
No. 91506-R7

SEPTOPLASTY / RHINOPLASTY

Effective Date: December 1, 2024	**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**
Date Of Origin: May 11, 2005	**Status: Current**

Summary of Changes

Clarifications:

- 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®) is considered experimental, investigational, or unproven.

I. POLICY/CRITERIA

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. MEDICAL NECESSITY REVIEW

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

- **Authorizations**
- **Procedures & services > Medical & surgical services > Rhinoplasty/septoplasty**

III. APPLICATION TO PRODUCTS

Coverage is subject to 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) and/or the Evidence of Coverage (EOC); 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 located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

IV. DESCRIPTION

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.

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.**

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.

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.

V. CODING INFORMATION

ICD-10 Codes that may apply:

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

S01.23xS	Puncture wound without foreign body of nose, sequela
S01.24xS	Puncture wound with foreign body of nose, sequela
S01.25xS	Open bite of nose, sequela
S02.2xxG	Fracture of nasal bones, subsequent encounter for fracture with delayed healing
S02.2xxK	Fracture of nasal bones, subsequent encounter for fracture with nonunion
S02.2xxS	Fracture of nasal bones, sequela
S08.811D	Complete traumatic amputation of nose, subsequent encounter
S08.811S	Complete traumatic amputation of nose, sequela
S08.812S	Partial traumatic amputation of nose, sequela
T33.02xS	Superficial frostbite of nose, sequela
T34.02xS	Frostbite with tissue necrosis of nose, sequela
T20.04xS	Burn of unspecified degree of nose (septum), sequela
T20.44xS	Corrosion of unspecified degree of nose (septum), 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)*

VI. REFERENCES

1. ARS [American Rhinologic Society] Position Statement: Posterior Nasal Nerve Ablation. American Rhinologic Society. January 2022.
2. Cigna. Medical Coverage Policy 0119. Rhinoplasty, Vestibular Stenosis Repair and Septoplasty.
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4. Hayes, Inc. Evolving Evidence Review. **Absorbable Nasal Implant (Latera, Stryker) for the Treatment of Nasal Valve Collapse**. Hayes, Inc. March 20, 2022.
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6. Hayes, Inc. Evolving Evidence Review. **RhinAer Procedure (Aerin Medical) for Treatment of Chronic Rhinitis.** January 13, 2022. Annual Review March 19, 2024.
7. Hayes, Inc. Evolving Evidence Review. **VivAer (Aerin Medical Inc.) for Nasal Airway Remodeling to Treat Nasal Obstruction.** Hayes, Inc. January 13, 2023.
8. Hayes, Inc. Medical Code Brief. **31242 – Category I**. Hayes, Inc. October 6, 2023.
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10. Kim DH, Lee HH, Kim SH, Hwang SH. **Effectiveness of using a bioabsorbable implant (Latera) to treat nasal valve collapse in patients with nasal obstruction: systemic review and meta-analysis**. *Int Forum Allergy Rhinol*. 2020;10(6):719-725. doi:10.1002/alr.22543
11. Position Statement: PNN [posterior nasal nerve] Ablation for the Treatment of Chronic Rhinitis. American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS). January 17, 2023. Approved February 2023.
12. Rhee JS, Weaver EM, Park SS, et al. **Clinical consensus statement: diagnosis and management of nasal valve compromise**. *Otolaryngol Head Neck Surg*. 2010;143(1):48-59. doi:10.1016/j.otohns.2010.04.019
13. Silvers SL, Rosenthal JN, McDuffie CM, Yen DM, Han JK. **Temperature-controlled radiofrequency device treatment of the nasal valve for nasal**

airway obstruction: a randomized controlled trial. *Int Forum Allergy Rhinol*. 2021;11(12):1676-1684. doi:10.1002/alr.22861

14. Wisconsin Physicians Service Insurance Corporation. Cosmetic and Reconstructive Surgery. Local Coverage Determination (LCD) L39051 (Billing and Coding: A58774).