

## Clinical Policy: Repair of Nasal Valve Compromise

Reference Number: CP.MP.210

Date of Last Revision: 05/24

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### Description

Medical necessity guidelines for repair of nasal valve compromise.

### Policy/Criteria

- I. It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that repair of nasal valve compromise is **medically necessary** when meeting all of the following criteria:
  - A. Clinical findings of one or more of the following:
    1. Internal valve collapse or compromise of the upper lateral cartilage;
    2. External nasal valve compromise due to collapse of the lower lateral cartilage;
  - B. Complaints of obstructed breathing that resolve with the Cottle maneuver or lateralization of the upper lateral cartilage from inside the nose with an object (cotton swab, nasal speculum, outpatient nocturnal trial of external stents such as Breathe Right<sup>®</sup> nasal strips, or outpatient nocturnal trial of nasal dilators such as Max-Air Nose Cones<sup>®</sup> and Sinus Cones<sup>®</sup>);
  - C. Other causes of obstructed breathing have been ruled out, including all of the following:
    1. Sinusitis;
    2. Allergic rhinitis;
    3. Nonallergic rhinitis (i.e., vasomotor, gustatory and nonallergic rhinitis with eosinophilia syndrome);
    4. All of the following, unless addressed concurrently in a medically necessary procedure with repair of nasal valve compromise:
      - a. Nasal polyps;
      - b. Adenoid hypertrophy;
      - c. Nasopharyngeal masses;
      - d. Septal deviation;
      - e. Turbinate hypertrophy;
  - D. Symptoms persist despite conservative treatment including one or more of the following:
    1. Eight week trial of nasal steroids;
    2. Three months of immunotherapy;
    3. Multiple courses of antibiotics to treat infection;
    4. Allergy assessment and treatment.
- II. It is the policy of health plans affiliated with Centene Corporation that safety and efficacy have not been established for the following procedures for repair of nasal vestibular stenosis:
  - A. Radiofrequency ablation (VivAer<sup>®</sup>);
  - B. Absorbable implants (Latera<sup>®</sup>);
  - C. Nasal valve suspension surgery.

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#### Background

Nasal valve compromise (NVC), also known as nasal valve collapse, is a narrowing of the nasal passageway causing difficult, obstructed breathing. Reasons for NVC are often multifactorial and can be caused by structural weakness or collapse of the nasal valve due to injury or trauma, nasal surgery, chronic inflammation, congenital defects or the natural aging process. NVC may also present as a symptom of rhinitis, sinusitis, septal deviation or adenoid hypertrophy.<sup>1,2,3,4,5</sup>

Epidemiology information proposes that up to 13% of patients with chronic nasal obstruction have NVC, and it is primarily a unilateral condition in as many as 88% of patients.<sup>6</sup>

Symptoms of NVC include difficulty inhaling through the nose, sensation of congestion, stuffiness, fullness or blockage, nasal bleeding, and snoring. Symptoms may become exacerbated at different times of the day, seasonally, with exposure to different environmental stimuli and in the supine position.<sup>1</sup>

When diagnosing NVC there are several specific questions and tests a physician may use in addition to a thorough medical history and physical exam of the nose, nasal cavity, and nasopharynx.<sup>1,3</sup>

Important medical history questions include:<sup>1</sup>

- Location – Whether or not symptoms are unilateral or bilateral
- Time course – History of the nasal symptoms, including time of day and seasonal variation to rule out allergic processes
- Triggers – Allergic stimuli and airborne exposures
- Symptoms of rhinosinusitis – Facial pain or pressure, nasal congestion, dysosmia, headache, purulent nasal discharge
- Symptoms suggesting malignancy – Facial deformity, cranial nerve dysfunction, and unexplained epistaxis
- Intranasal drug use – Intranasal cocaine or overuse of topical nasal decongestant, such as oxymetazoline or phenylephrine
- Oral medications – Oral contraceptives, antithyroid medication, antihypertensive medication, antidepressants, and benzodiazepines
- Trauma – History of nasal trauma or previous nasal surgery, particularly rhinoplasty
- Medical history – Granulomatosis with polyangiitis, cystic fibrosis, sarcoidosis, and syphilis, and asthma

Specific tests indicated in cases of suspected NVC include:<sup>1,6</sup>

- NOSE score (Nasal Obstruction Symptom Evaluation)
- Cottle's maneuver – Widening the nasal valve angle by pulling laterally on the cheeks and assessing for improvement in nasal breathing
- Bachman's maneuver – Widening and stabilizing the nasal valve using instruments simulating the effect of a surgical procedure while assessing the subjective impact on nasal breathing
- Nasal decongestant instillation
- Rhinomanometry
- Acoustic rhinometry

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- Full assessment of facial nerves to detect denervation or paralysis
- Anterior rhinoscopy
- Nasal endoscopy
- Computed tomography (CT) scan of the nose and paranasal sinuses
- Peak nasal airflow

Surgical intervention is the primary treatment for NVC and typically consists of insertion of cartilage grafts to support the existing cartilage in the lateral nasal wall or alar rim.<sup>7,8,9</sup> There is also consensus that, although a separate entity, correction of a deviated septum or hypertrophied turbinate can sometimes correct NVC.<sup>7</sup>

#### *VivAer*<sup>®</sup>

The Aerin<sup>™</sup> VivAer<sup>®</sup> procedure is a non-invasive, office-based procedure that employs low-dose radiofrequency (RF) energy to modify soft tissues of the nose with the intent of improving airflow for patients with nasal valve collapse (NVC). The Aerin<sup>™</sup> System automatically adjusts the power output to maintain target temperature for therapeutic benefit while sparing surrounding tissue, including mucosa. The RF energy allows tissue to be repositioned laterally and creates a coagulation lesion. As the lesion heals, the tissue retracts and stiffens to lessen the degree of obstruction, decrease the airflow resistance, and improve the inhaled flow of air through the nose. The device consists of a console and two styluses, one for nasal airway obstruction and one for chronic rhinitis.<sup>6,10</sup>

According to the Hayes Evolving Evidence Review, a review of full-text clinical studies suggests 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. VivAer is a novel treatment for nasal airway obstruction that allows delivery of energy to multiple intranasal surfaces (as opposed to only the turbinate) during a treatment session. VivAer can also be used following nasal surgeries, which are a common cause of nasal valve dysfunction. Four clinical studies (one fair quality, two poor quality, one very poor quality) suggest that nasal airway remodeling with VivAer is safe and may result in clinically and statistically significant improvements in patient-reported nasal symptoms due to nasal airway obstruction up to four years posttreatment. It is unclear whether VivAer significantly improves objective measures of nasal patency and airflow, and no studies compared VivAer to active treatment.

Although there are several ongoing clinical studies of VivAer, most are single-arm and the one comparative study uses a sham control. Additional well-designed comparative studies are needed to determine the effectiveness, safety, and durability of effect of VivAer and how VivAer compares to other active treatments for nasal airway obstruction associated with nasal valve dysfunction. A review of full-text systematic reviews suggests no support for using VivAer for the management of nasal obstruction related to NVC, as there were no systematic reviews identified. Additionally, a full-text review of clinical practice guidelines and position statements suggests no support for using VivAer for the management of nasal obstruction related to NVC due to no guidelines being identified.<sup>6</sup>

#### *Latera*<sup>®</sup>

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Latera<sup>®</sup> is an absorbable nasal implant used to support the upper and lower cartilage inside the lateral wall of the nose. It is placed under general anesthesia with a 16-gauge cannula via an endonasal access point. Over the course of approximately 12 months following placement, the implant is enveloped by fibrous tissue that helps to maintain stability and positioning. Within approximately 18 months, the implant will have been absorbed and replaced with fibrous collagen matrix that provides continued support. The system consists of the Latera Absorbable Nasal Implant and delivery device as well as an implant positioning guide intended to serve as an external visual planning aid prior to implant placement. The Implant is composed of a PLLA-PDLA copolymer.<sup>11,12</sup>

Per Hayes' Evolving Evidence Review, clinical evidence suggests absorbable nasal implants are technically feasible to implant and are associated with reductions in nasal airway obstruction 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 non-absorbable nasal implants. A review of clinical studies suggests minimal support for using absorbable nasal implants for NVC due to poor quality studies that had limited follow up or provided adjunctive treatment with the absorbable nasal implant.<sup>11</sup>

#### Coding Implications

This clinical policy references Current Procedural Terminology (CPT<sup>®</sup>). CPT<sup>®</sup> is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2023, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

#### CPT Codes That Support Coverage Criteria

CPT <sup>®*</sup> Codes	Description
30465	Repair of nasal vestibular stenosis (e.g., spreader grafting, lateral nasal wall reconstruction)

#### CPT Codes That Do Not Support Coverage Criteria

CPT <sup>®*</sup> Codes	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

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed.	04/21	05/21

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Reviews, Revisions, and Approvals	Revision Date	Approval Date
Annual Review. Updated Criteria I.B. to include nasal dilators such as Max-Air Nose Cones® and Sinus Cones®. Background updated with no impact on criteria. References reviewed and updated. Changed “Last Review Date” in policy header to “Date of Last Revision,” and “Date” in the revision log header to “Revision Date.”	05/22	05/22
Annual review completed. Updated Criteria I.C.3. to include nonallergic rhinitis with examples. Background updated with no impact to clinical criteria. Dashes removed from ranges. CPT Code 30469 added to Codes That Do Not Support Coverage table. ICD-10 diagnosis code table removed. References reviewed and updated. External specialist reviewed.	05/23	05/23
Annual review. Background updated with no impact to criteria. References reviewed and updated.	05/24	05/24

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**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note: For Medicaid members/enrollees**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note: For Medicare members/enrollees**, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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