Molina Clinical Policy
Radiofrequency Treatment of Nasal Airway Obstruction (e.g., VivAer System)
Policy No. 475

Last Approval: 10/08/2025
Next Review Due By: October 2026

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Nasal airway obstruction is characterized by reduced nasal patency and has a variety of etiologies, including nasal valve dysfunction, mucosal inflammation, nasal septal deviation, septal swell body hypertrophy, enlarged turbinate, and less commonly, nasal masses or polyps. Symptoms of nasal airway obstruction can have a significant impact on quality of life, with headaches, chronic congestion, snoring, and sleep disturbance that result in daytime sleepiness often being reported (Wang 2025). Treatment includes pharmacotherapy, over the counter devices such as external or internal nasal dilators, and surgical reconstruction (Bhattacharyya 2025). Over the counter devices and medications are aimed at symptom management and do not fix the underlying dysfunction, leading to patients being chronically dependent on these interventions. Nasal surgery and radiofrequency treatment intend to correct the underlying pathology.

Temperature controlled radiofrequency is a minimally invasive outpatient treatment for nasal airway obstruction. Local anesthetic is used to numb the nasal passages, after which a stylus is inserted and delivers low dose radiofrequency to induce the tightening and contraction of the nasal soft tissue and cartilage. This tissue remodeling is intended to widen the nasal passages and strengthen the nasal valve to prevent collapse upon inspiration (Hayes 2025). This treatment fills the gap between over-the-counter devices and medications, and invasive surgical nasal reconstruction. It is not appropriate for patients who have had nasal surgery within the past 3 months, patients with extreme nasal pathology or a history of extreme nasal injuries, or patients with comorbidities that may hinder the healing process (Aerin Medical 2023).

Regulatory Status

The VivAer stylus was approved by the FDA in April 2020 “for use in otorhinolaryngology surgery for the coagulation of soft tissue in the nasal airway, to treat nasal airway obstruction by shrinking submucosal tissue, including cartilage in the internal nasal valve area”. The VivAer system was approved via the 510(k)-approval pathway under the product code GEI and K200300 number.

COVERAGE POLICY

Temperature controlled radiofrequency treatment (e.g., VivAer System) for the treatment of nasal airway obstruction is considered **experimental, investigational, and unproven** due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

SUMMARY OF MEDICAL EVIDENCE

Randomized Controlled Trials

Silvers et al. (2021) conducted a prospective multicenter single blind randomized controlled trial to evaluate the efficacy of temperature-controlled radiofrequency (RF) treatment of nasal airway obstruction. Patients were randomly assigned 2:1 to either the treatment arm (n=77) or the sham procedure arm (n=40). The design was to examine the superiority of temperature-controlled RF and followed patients for three months before a crossover became available to eligible sham arm patients. Patients eligible for the trial were adult patients with a baseline Nasal Obstruction Symptom Evaluation (NOSE) scale score ≥55, nasal valve collapse or any other significant contributor to nasal obstruction, and dissatisfaction with medical management. The primary end point was a ≥20% improvement (decrease) in NOSE Scale score or ≥1 NOSE Scale severity category improvement from baseline. At the 3-month end point, the procedure arm had a 88.3% [95% CI, 79.2%-93.7%] responder rate compared to the sham arm of 42.5% [95% CI, 28.5%-57.8%]. The mean change in NOSE Scale score was significantly greater at 3 months in the treatment arm of −42.3 [95% CI, −47.6 to −37.1] compared to the sham arm of −16.8 [95% CI −26.3 to −7.2]; representing a 55.1% decrease in NOSE Scale score from baseline in the treatment arm vs a 21.3% decrease in the sham arm. No serious adverse events were recorded. Ultimately, 31 patients from the sham arm crossed over into active treatment after the 3-month endpoint of the original study and were followed through 36 months.

Han et al. (2025) reported the 36-month long term follow up results of the Silver et al. (2021) trial. Of the 108 patients that received active treatment at the end of the original trial (77 in the original RF treatment arm plus 31 crossover patients), 52 remained for the 36-month analysis due to patients either withdrawing from the study, being lost to follow up, or becoming ineligible for analysis due to needing further nasal surgery. The analysis of the 52 remaining patients revealed a responder rate of 87%, consistent with earlier findings due to a NOSE Scale score improvement from baseline at all follow-up timepoints and sustained through 3 years. The adjusted mean NOSE Scale score of 27.1 (95% CI, 20.4-33.8) compared to baseline of 76.9 (95% CI, 74.4 to 79.6); mean difference, -49.5 (95% CI, −56.6 to −42.4; P < .001), which represents a 64.6% improvement in the NOSE score from baseline at 3 years. No adverse events were recorded. The authors concluded that the temperature-controlled RF treatment of nasal obstruction was both safe and effective with sustained results. There are several limitations to this trial including patients being unrestricted in their nasal medication usage as an enrollment criterion throughout the study, some industry sponsored conflicts of interest among researchers, lack of blinding among the analysts, small sample size, and a lack of clinically objective measurements analyzed for nasal airflow, such as rhinomanometry, acoustic rhinometry, and peak nasal inspiratory flow.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Yao et al. (2023) conducted a single arm prospective study to evaluate the safety and efficacy of temperature-controlled RF treatment of nasal airway obstruction due to nasal valve collapse. A total of 122 received treatment, with 91 patients retained for two-year follow-up. Inclusion criteria comprised of adult patients with a baseline NOSE Scale score of ≥ 60 and a positive response to temporary nasal valve dilation. Primary endpoint was percentage of patient responders, defined as patients with ≥20% improvement in NOSE Scale score or ≥1 severity class improvement from baseline, to the procedure. The mean baseline NOSE Scale score was 80.3 (95% CI, 78.1–82.6), which significantly improved over baseline at all timepoints from 3 months onwards with an adjusted mean change at two years of −45.8 [(95% CI, −53.5 to −38.1), p < .001]. This represents a 57.0% improvement from baseline in NOSE Scale score. Ultimately, 90.1% (95% CI, 82.3%–94.7%) of the patients were sustained responders at the two-year endpoint. Twelve of the 122 participants underwent additional nasal procedures and were not included in the analysis. No serious adverse events were reported. The limitations of this study included lack of a control arm and thus randomization, small sample size, and patient reporting bias due to lack of blinding.

Pritikin et al. (2023) conducted a prospective open label single arm study on 69 patients to evaluate the safety and efficacy of temperature-controlled RF treatment of the septal swell body (SSB) to treat nasal airway obstruction. Inclusion criteria were adult patients with the presence of septal swell body hypertrophy limiting visualization of the middle turbinate by more than 50% (prior to application of a decongestant), and a NOSE Scale score of ≥ 55. The primary endpoint was an improvement (decrease) in NOSE Scale scores from baseline to 3 months post procedure. A subset of study patients underwent computed tomography (CT) imaging to evaluate posttreatment changes in SSB

size. The primary objective was ≥1 NOSE Scale severity category improvement or an improvement in NOSE Scale score of ≥20% from baseline to 3 months post procedure. Safety data was recorded, along with a subset of study patients undergoing CT imaging to evaluate post procedure changes in septal swell body size. The primary objective analysis revealed a 27.9 versus 73.5, respectively (mean change −45.3 [SD 21.4]; 95% CI: −50.4 to −40.1; $p < 0.0001$) in post procedure vs baseline NOSE Scale score, representing a 61.0% decrease in NOSE Scale scores from baseline to 3 months. CT evaluation of 37 patients revealed a 15.2%, 29.4%, and 14.0% reduction in the anterior, middle, and posterior septal swell body measurements, respectively. No serious adverse events were recorded. Pritikin (2024) reported the 12-month post procedure results. The analysis revealed sustained improvement of NOSE Scale score with a 65.4% decrease at 12 months (mean change -48.1, 95% CI -53.7 to -42.5); $p < 0.001$). This analysis was done on 62 of the original patients, as 7 patients were lost to follow up. The study is ongoing, as the intended long term follow up is 36 months post-procedure.

Jacobowitz et al. (2019) conducted a prospective nonrandomized multicenter case series on 50 patients to evaluate the safety and efficacy of in office temperature-controlled RF treatment of nasal valve obstruction. Efficacy was assessed via the NOSE Scale score change from baseline at 26 weeks. Safety was assessed via event reporting, clinical inspection for complications, and VAS score for pain. Efficacy analysis revealed the mean NOSE Scale score declined from 80 to 37, 27, and 25 at 4, 12, and 26 weeks, respectively. Safety analysis revealed no serious adverse events occurred, with minor adverse events (e.g., nasal congestion, swelling, headache) subsiding by 26 weeks post procedure. Jacobowitz et al. (2022) reported on 29 patients from the original study who agreed to follow up through 48 months. The NOSE Scale scores at various timepoints were as follows: 81.0 (±9.9) at baseline to 21.6 (±18.6) after 6 months (73.3% change), 25.6 (±21.1) after 12 months (68.3% change), 29.3 (±26.6) after 18 months (63.8% change), 22.5 (±20.9) after 24 months (72.2% change), 32.3 (±21.4) after 36 months (60.1% change), and 25.7 (±19.1) after 48 months (68.3% change) ($p < 0.001$ for all comparisons). This data revealed that efficacy was maintained through 48 months post procedure.

National/Specialty Organizations

The **American Academy of Otolaryngology-Head and Neck Surgery** published *Position Statement: Nasal Valve Repair* (2023) which states "The treatment of nasal valve dysfunction may involve techniques that include cartilage grafting and open surgical repair, suture suspension techniques, and implants or radiofrequency treatment aimed at stabilizing the nasal valve."

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
30469	Repair of nasal valve collapse with low energy, temperature-controlled (i.e., radiofrequency) subcutaneous/submucosal remodeling

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/08/2025 New policy. IRO Peer Review on September 24, 2025, by a practicing physician board-certified in Otolaryngology.

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

This policy contains prior authorization requirements.