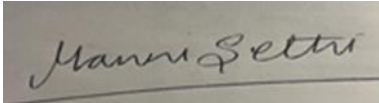


Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: AmeriHealth Caritas Pennsylvania & Keystone First		Submission Date: 5/1/2025	
Policy Number: CCP.1539		Effective Date: 3/1/2024 Revision Date: 4/2025	
Policy Name: Radiofrequency ablation for nasal valve collapse			
Type of Submission:		Type of Policy:	
☐ New Policy		☒ Prior Authorization Policy	
☒ Revised Policy*		☐ Base Policy	
☐ Annual Review- no revisions		☒ Experimental/Investigational Policy	
		☐ Statewide PDL	
		☐ Other:	
*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below:			
Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM		Signature of Authorized Individual: 	

Radiofrequency ablation for nasal valve collapse

Clinical Policy ID: CCP.1539

Recent review date: 4/2025

Next review date: 8/2026

Policy contains: Nasal blockage, nasal valve collapse; nasal obstruction; radiofrequency ablation; temperature-controlled radiofrequency devices.

AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas Pennsylvania on a case by case basis when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Pennsylvania clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Pennsylvania clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania clinical policies are not guarantees of payment.

Coverage policy

Radiofrequency ablation as a treatment to repair nasal valve collapse is investigational/not clinically proven, and therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

No alternative covered services were identified during the writing of this policy.

Background

Nasal obstruction, also known as nasal congestion or blockage, is a common condition that affects many people in the United States. It can be caused by various factors, including anatomical issues like septal deviation, inferior turbinate hypertrophy, nasal valve collapse, and conditions like allergies and viral infections (Clark, 2018). A study involving patients with sinonasal complaints (n = 1,906) found that the prevalence of nasal valve collapse was 67%, septal deviation was 76%, and inferior turbinate hypertrophy was 72% (Clark, 2018). Another study found that nearly one in four Americans with nasal congestion experience symptoms almost every day (Optinose, 2021).

Nasal obstruction can significantly impact a person's quality of life, leading to symptoms such as difficulty breathing, persistent nasal congestion, and disrupted sleep patterns (García-Chabur, 2023). It can also be associated with sleep-disordered breathing, including conditions like sleep apnea. Treatment options for nasal obstruction range from home remedies and medications to surgical interventions, depending on the severity and cause of the obstruction (García-Chabur, 2023).

Common surgical approaches, known as rhinoplasty techniques, aim to address nasal valve compromise (Ng, 2013). These involve placing grafts or splints to widen and open the cross-sectional nasal valve area to improve airflow dynamics. Functional rhinoplasty approaches attempt to decrease nasal airway resistance and improve nasal breathing capacity by structurally modifying the nasal valve region (Shia Ng, 2013).

Temperature-controlled radiofrequency devices offer an alternative treatment option for nasal obstruction, particularly for conditions like nasal valve collapse (Silvers, 2021). The treatment works by delivering controlled energy to the nasal valve area, which heats the tissue in a controlled manner. This process aims to cause tissue remodeling and tightening, thereby reducing the symptoms of nasal obstruction (Silvers, 2021).

Radiofrequency ablation is viewed as a minimally invasive approach to heat the nasal submucosa while protecting the overlying mucous layers (Neiderman, 2023). The controlled damage elicits healing responses such as fibrosis and volume reduction capable of remodeling the tissues triggering the obstructive symptoms (Neiderman, 2023). Compared to more invasive interventions, radiofrequency ablation offers simpler and less disruptive correction of obstructed airways through its outpatient application under local anesthesia (Neiderman, 2023).

Findings

The American Academy of Otolaryngology—Head and Neck Surgery issued a position statement that listed radiofrequency treatment as one of several potential office-based treatments that can be used to stabilize the nasal valve, along with implants. However, it goes on to say that for patients requiring anatomic widening and definitive stabilization, surgical treatment is needed to optimize outcomes (American Academy of Otolaryngology—Head and Neck Surgery, 2023).

In a systematic review and meta-analysis, data across eight studies ($n = 451$) was analyzed to evaluate the efficacy of temperature-controlled radiofrequency treatment for nasal valve collapse causing nasal obstruction. The studies showed statistically significant improvement in disease-specific quality of life scores (measured by NOSE Scale scores) from baseline to 12 to 24 months post-radiofrequency treatment. The mean difference in NOSE scores ranged from 41.75 points at one month to 56.35 points at 24 months across the studies ($P = 0.0107$). The NOSE score is a standardized scoring system used to quantify patients' subjective symptoms related to nasal obstruction and its impact on disease-specific quality of life. Additionally, the rates of clinically improved status after treatment ranged from 78% at one month to 86% at 24 months ($P = 0.3661$). Responder rates (defined as $\geq 20\%$ decrease in NOSE score or ≥ 1 severity level improvement) ranged from 87% to 98% from three to 24 months. The sham control group showed less improvement in scores and responder rates. This evidence supports coverage for radiofrequency ablation under appropriate indications. Additional randomized controlled trials are still warranted to confirm treatment efficacy (Kang, 2024).

A systematic review of four studies (n = 218) evaluated temperature-controlled radiofrequency treatment for nasal valve collapse causing nasal obstruction. The meta-analysis found a significant improvement in the mean NOSE score from 76.16 pretreatment to 31.2 at three months posttreatment (mean difference of 46.13 points, $P < 0.05$). In the one randomized, sham-controlled trial, the temperature-controlled radiofrequency treatment group improved significantly more than sham control on the NOSE score at three months (34.4 vs 62.0, $P < 0.05$). Minor adverse events like nasal congestion and pain occurred in a small number of patients and resolved (Casale, 2023). Silvers (2021) was analyzed in the Casale study.

A systematic review of 26 studies (n = 1,476) patients comparing radiofrequency turbinoplasty to microdebrider-assisted turbinoplasty for inferior turbinate reduction. Meta-analysis found both procedures significantly improved subjective (visual analog scale score improved by 4.53 points for radiofrequency turbinoplasty and 3.81 points for microdebrider-assisted turbinoplasty) and objective nasal airflow metrics through a median follow-up of six months. There was no significant difference between radiofrequency turbinoplasty and microdebrider-assisted turbinoplasty on these outcomes. Minor complications occurred (Acevedo, 2015).

A 12-month follow-up of a randomized, controlled trial evaluated temperature-controlled radiofrequency treatment in n=108 patients with nasal obstruction primarily due to nasal valve collapse. Patients treated with temperature-controlled radiofrequency showed a significant improvement in nasal obstruction symptoms compared to sham control at three months in the initial trial. In this longer-term follow-up study, the responder rate (defined as $\geq 20\%$ improvement on the NOSE score or ≥ 1 severity level improvement) was 89.8% at 12 months. The mean NOSE score improved by -44.9 points from baseline (58.8% improvement). There were no device-related serious adverse events (Han, 2022).

A second randomized, controlled trial (n = 117) compared temperature-controlled radiofrequency treatment of the nasal valve versus sham control in patients with nasal obstruction primarily due to nasal valve collapse. At three months, the responder rate (defined as $\geq 20\%$ improvement on the NOSE score or ≥ 1 severity level improvement) was 88.3% in the temperature-controlled radiofrequency group compared to 42.5% in the sham-control group ($P < 0.001$). The mean NOSE score improved by -42.3 points in the temperature-controlled radiofrequency group versus only -16.8 points in the control group ($P < 0.001$). This represents a 55.1% improvement for temperature-controlled radiofrequency patients. There were no serious adverse events related to the temperature-controlled radiofrequency device/procedure (Silvers, 2021).

In 2025, no new relevant literature was found. No policy changes were made.

References

On March 5, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “nasal valve collapse” and “radio frequency ablation”, “nasal blockage and “radio frequency ablation,” and “temperature-controlled radiofrequency devices.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

Acevedo JL, Camacho M, Brietzke SE. Radiofrequency ablation turbinoplasty versus microdebrider-assisted turbinoplasty: a systematic review and meta-analysis. *Otolaryngology—Head and Neck Surgery*. 2015;153(6):951–956. Doi: 10.1177/0194599815607211.

American Academy of Otolaryngology-Head and Neck Surgery. Position statement: nasal valve repair. March 22, 2023; <https://www.entnet.org/resource/position-statement-nasal-valve-repair/>.

Casale M, Moffa A, Giorgi L, et al. Could the use of a new novel bipolar radiofrequency device (Aerin) improve nasal valve collapse? A systematic review and meta-analysis. *Journal of Otolaryngology—Head & Neck Surgery*. 2023;52(1):42. Doi: 10.1186/s40463-023-00644-7.

Neiderman, NNC, Caspi I, Eisenberg N, et al. Quality of life after radio frequency ablation turbinate reduction (RFATR) among patients with rhinitis medicamentosa & withdrawal from decongestant topical spray abuse. *American Journal of Otolaryngology*. 2023;44(4):103842. Doi: 10.1016/j.amjoto.2023.103842.

Clark DW, Del Signore AG, Raithatha R, Senior BA. Nasal airway obstruction: prevalence and anatomic contributors. *Ear Nose Throat J*. 2018;97(6):173–176. Doi: 10.1177/014556131809700615.

Han JK, Silvers SL, Rosenthal JN, McDuffie CM, Yen DM. Outcomes 12 Months After Temperature-Controlled Radiofrequency Device Treatment of the Nasal Valve for Patients With Nasal Airway Obstruction. *JAMA Otolaryngology—Head & Neck Surgery*. 2022;148(10):940–946. Doi: 10.1001/jamaoto.2022.2293.

Kang YJ, Kim DH, Stybayeva G, Hwang SH. Effectiveness of Radiofrequency Device Treatment for Nasal Valve Collapse in Patients With Nasal Obstruction. *Otolaryngology—Head and Neck Surgery*. 2024;170(1):34–44. Doi: 10.1002/ohn.522.

Optinose. Nearly 1 in 4 Americans with nasal congestion experience symptoms almost every day [Press release] April 27, 2021; <https://www.prnewswire.com/news-releases/new-harris-survey-reveals-chronic-nasal-congestion-is-surprisingly-widespread-nearly-1-in-4-americans-with-nasal-congestion-experience-symptoms-almost-every-day-301277257.html>.

Shia Ng L, Lo S. Management of the internal nasal valve. *An International Journal of Otorhinolaryngology Clinics*. 2013;5(1):43–45. Doi:10.5005/jp-journals-10003-1109.

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. *International Forum of Allergy & Rhinology*. 2021;11(12):1676–1684. Doi: 10.1002/alr.22861.

Policy updates

2/2024: initial review date and clinical policy effective date: 3/2024

4/2025: Policy references updated.