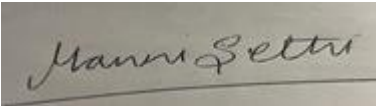


**Prior Authorization Review Panel
MCO Policy Submission**

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: Keystone First	Submission Date: 5/1/2024
Policy Number: ccp.1539	Effective Date: 3/2024 Revision Date: April 1, 2024
Policy Name: Radiofrequency ablation for nasal valve collapse	
Type of Submission – Check all that apply: <div style="margin-left: 20px;"><input checked="" type="checkbox"/> New Policy <input type="checkbox"/> Revised Policy* <input type="checkbox"/> Annual Review – No Revisions <input type="checkbox"/> Statewide PDL</div>	
*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: New Policy	
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: 4/2024

Next review date: 8/2025

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

Keystone First- CHIP has developed clinical policies to assist with making coverage determinations. Keystone First- CHIP's 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 Keystone First- CHIP, 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. Keystone First- CHIP's 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. Keystone First- CHIP's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First- CHIP will update its clinical policies as necessary. Keystone First- CHIP's clinical policies are not guarantees of payment.

Coverage policy

Radiofrequency ablation as a treatment to repair nasal valve collapse diets are 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 (Harris on Demand, 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 (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 tissues triggering 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

Radiofrequency ablation (e.g., Vivaer ARC Stylus, an FDA cleared device) can be considered an appropriate treatment for some patients with nasal obstruction related to nasal valve dysfunction or collapse. While conservative treatments are preferred initially (nasal dilators, steroids), the American Academy of Otolaryngology-Head and Neck Surgery suggests that radiofrequency ablation can be helpful to patients who have failed more conservative options and potentially prevent the need for more invasive open surgical repair (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 scores) from baseline to 12-24 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 1 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 87-98% from 3 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) evaluating 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 pre-treatment to 31.2 at three months post-treatment (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 (RF) turbinoplasty to microdebrider-assisted turbinoplasty (MAT) for inferior turbinate reduction. Meta-analysis found both procedures significantly improved subjective (visual analog scale score improved by 4.53 points for RF and 3.81 points for MAT) and objective nasal airflow metrics through a median follow-up of six months. There was no significant difference between RF and MAT on these outcomes. Minor complications occurred (Acevedo, 2015).

A 12-month follow-up of a randomized controlled trial evaluating temperature-controlled radiofrequency (TCRF) treatment in n=108 patients with nasal obstruction primarily due to nasal valve collapse. Patients treated with TCRF 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 ≥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 (TCRF) 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 ≥20% improvement on the NOSE score or ≥1 severity level improvement) was 88.3% in the TCRF group compared to 42.5% in the sham control group (p<0.001). The mean NOSE score improved by -42.3 points in the TCRF group versus only -16.8 points in the control group (p<0.001). This represents a 55.1% improvement for TCRF patients. There were no serious adverse events related to the TCRF device/procedure (Silvers, 2021).

References

On February 2, 2024, 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. *Otolaryngol Head Neck Surg.* 2015;153(6):951-956. Doi: 10.1177/0194599815607211.

American Academy of Otolaryngology-Head and Neck Surgery. Position statement: nasal valve repair. 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. *J Otolaryngol Head Neck Surg*. 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.

Harris On Demand. Nearly 1 in 4 Americans with nasal congestion experience symptoms almost every day 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>.

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.

Ng LS, Lo S, Hathiram BT, Khattar VS. Management of the internal nasal valve. *Otorhinolaryngology Clinics An International Journal*. 2013;5:21-23. 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