Molina Clinical Policy Posterior Nasal Nerve Ablation: MEDICARE

Last Approval: 02/12/2025 Next Review Due By: February 2026

Policy No. 465b



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OVERVIEW

Chronic rhinitis is a long-term condition characterized by inflammation and swelling of the nasal mucosa. It presents with symptoms such as nasal congestion, runny nose, postnasal drip, and frequent throat clearing or coughing that persist for more than four weeks. It can be classified into allergic rhinitis, caused by triggers like pollen or dust mites, and nonallergic rhinitis, which may result from irritants, infections, or hormonal factors (Lieberman 2023). While many patients respond to medical management, including intranasal corticosteroids and antihistamines, some individuals experience symptoms that are refractory to standard treatments. Advances in therapeutic approaches, such as cryoablation and radiofrequency ablation of the posterior nasal nerve, aim to address this unmet need, offering potential relief for patients with chronic, treatment-resistant rhinitis.

Posterior nasal nerve (PNN) ablation is a minimally invasive procedure used to treat chronic rhinitis, a condition characterized by persistent inflammation and swelling of the nasal mucosa. PNN ablation is a surgical technique that works by disrupting the nerve signals responsible for nasal hyperreactivity, providing relief from symptoms like congestion and rhinorrhea. The procedure is usually performed under local anesthesia and involves the use of cryotherapy or radiofrequency energy to deactivate the posterior nasal nerve. A probe is inserted into the nasal passage to deliver either low-temperature radiofrequency energy (via the RhinAer device) or freezing temperatures using nitrous oxide (via the ClariFix device) to ablate the nerve and reduce inflamed tissue (Hayes 2024). While it is considered a safe procedure, there is a lack of long-term evidence as to the side effects of this permanent procedure.

COVERAGE POLICY

Posterior nasal nerve ablation is considered **experimental**, **investigational**, **and unproven** due to insufficient clinical evidence and peer-reviewed medical literature establishing long-term safety, efficacy and effect on net health outcomes.

SUMMARY OF MEDICAL EVIDENCE

The existing evidence on posterior nasal nerve ablation for the treatment of chronic rhinitis, including cryoablation, radiofrequency (RF) ablation, and laser ablation, is limited and inconclusive, particularly regarding comparisons to other treatment options. Studies on cryoablation show some symptom improvement compared to sham procedures, but it is unclear whether participants had chronic rhinitis that was resistant to medical management, which is the intended target group for this treatment. Similar studies on radiofrequency and laser ablation report improvements in symptoms, but these studies often lack control groups and suffer from biases due to high dropout rates and unclear patient definitions. Overall, more rigorous, randomized controlled trials with clearly defined patient populations and comparisons to other treatments are needed to better understand the effectiveness and the long-term benefits and risks of these procedures for chronic rhinitis.

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Randomized Controlled Trials

Stolovitzky et al. (2021) conducted a multicenter, prospective, single-blinded, RCT to evaluate the safety and efficacy of temperature-controlled radiofrequency (TCRF) neurolysis of the posterior nasal nerve (PNN) for treating chronic rhinitis. The study involved 116 adults (mean age 57.5 years, 64.7% female) randomized into two groups: 77 participants received TCRF neurolysis of the PNN using RhinAer®, while 39 participants underwent a sham procedure. Participants had chronic rhinitis for at least six months, a total 24-hour reflective nasal symptom score (rTNSS) of ≥6, moderate-to-severe rhinorrhea, and mild-to-severe nasal congestion.

At three months, the primary endpoint was a responder rate defined as a ≥30% reduction in rTNSS from baseline. Baseline rTNSS scores averaged 8.3 in the active treatment group and 8.2 in the sham group. Results showed a significantly higher responder rate in the active treatment group (67.5%) compared to the sham group (41.0%), along with a greater reduction in rTNSS. The authors concluded that RF neurolysis was more effective than the sham procedure in reducing chronic rhinitis symptoms. The study had several limitations, including a design that did not standardize or reduce medication use, a short three-month follow-up period, lack of comparison to other treatments, and absence of investigator blinding.

Takashima et al. (2023) reported 12-month outcomes for the randomized controlled trial conducted by Stolovitzky et al. (2021). At the three-month primary endpoint, the sham control group was unblinded. Of the 39 participants in the sham group, 27 met the eligibility criteria and agreed to transition to active treatment. Participants who did not meet the criteria, declined to continue, or underwent additional nasal procedures during follow-up were exited from the trial. The active treatment group showed a sustained responder rate of 80.6% at 12 months, with a 57.8% improvement in rTNSS. Postnasal drip and cough scores also improved throughout the study period. The crossover group demonstrated similar baseline characteristics and treatment outcomes to the active group. Study limitations included uncontrolled medication use, the absence of a sustained control group, and inclusion of patients with both allergic and nonallergic rhinitis. Despite these limitations, the authors concluded that temperature-controlled RF neurolysis of the PNN area is a safe and effective treatment for chronic rhinitis, with symptom relief lasting through 12 months.

Takashima et al. (2024) reported 2-year outcomes for the randomized controlled trial conducted by Stolovitzky et al. (2021). The study combined patients from the active treatment arm and those who crossed over from the control arm after the primary 3-month endpoint. At baseline, the mean reflective total nasal symptom score (rTNSS) was 8.2, which improved by 64.6% to a mean change of -5.3 at two years (p < 0.001). The responder rate, defined as a ≥30% improvement in rTNSS, was 87.3%. All components of the rTNSS—rhinorrhea, congestion, sneezing, and nasal itching—showed significant improvements, with rhinorrhea and congestion improving the most. Postnasal drip and cough also improved significantly. At two years, 81% of participants reported meaningful quality-of-life improvements, and nearly half of those using chronic rhinitis medications at baseline reduced or stopped their medication use. No serious device- or procedure-related adverse events were reported. Adjusting for patients who left the trial or underwent additional nasal procedures, the imputed two-year responder rate was 79.4%. The study concluded that TCRF ablation of the PNN is a safe, effective, and durable treatment for chronic rhinitis, with the added benefit of reducing medication reliance.

Systematic Reviews and Meta-Analyses

Kang et al. (2023) conducted a systematic review and meta-analysis of 12 studies, including the Chang et al. (2019) and Ow et al. (2021) studies, to evaluate the effectiveness of cryotherapy and radiofrequency ablation (RFA) in managing allergic and nonallergic rhinitis. The analysis included 12 studies with a total of 788 patients, five of which utilized RFA devices for refractory rhinitis, and seven employed cryotherapy devices. Primary outcomes were measured using the Total Nasal Symptom Score (TNSS) and the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ). A "good response" to treatment was defined as a ≥30% reduction in the total TNSS, while a "clinical response" was considered an improvement of at least one point from baseline. Cryotherapy and RFA both significantly reduced TNSS at 1, 3, 6, and 12 months, though RFA showed a higher clinical response rate at three months (91.9% vs. 81.8%; P=0.005). Chang et al. (2019) reported that cryotherapy significantly improved rTNSS at all time points (P < 0.001), with notable reductions in rhinorrhea, congestion, sneezing, and nasal itchiness, as well as improved RQLQ scores at three months (P < 0.001). Additionally, 35.2% of participants discontinued intranasal medications, though limitations such as lack of a control group were noted. Ow et al. (2021) extended these findings, demonstrating sustained improvements in TNSS and RQLQ at 18 and 24 months, with over 80% achieving meaningful clinical improvement in symptoms and quality of life. Adverse events across studies were generally mild and transient, with one participant experiencing serious complications. Overall, the meta-analysis concluded that cryotherapy and RFA are effective

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treatments for chronic rhinitis, with RFA offering slightly greater efficacy for nonallergic rhinitis symptoms, while cryotherapy provided sustained benefits up to 24 months.

National and Specialty Organizations

The American Academy of Otolaryngology (AAO) released a position statement on peripheral nerve ablation for chronic rhinitis in January 2023. The statement endorsed PNN ablation for medically refractory chronic rhinitis. According to the statement, "Based on these safety and efficacy data, we endorse the use of posterior nasal nerve ablation for the treatment of medically refractory chronic rhinitis. We do not consider these treatments to be experimental." (AAO 2023).

The American Rhinologic Society (ARS) issued a position paper on posterior nasal nerve ablation. The position statement affirms the procedures effectiveness, stating, "The American Rhinologic Society supports the use of posterior nasal nerve ablation for the treatment of chronic rhinitis, including both allergic and non-allergic subtypes. This procedure should not be considered experimental but should be considered as an effective option in treating chronic rhinitis and improving patient quality of life in those suffering from rhinorrhea and nasal congestion based on the following data" (ARS 2022).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
31242	Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve
31243	Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve
30999	Unlisted procedure, nose [when specified as posterior nasal nerve ablation]

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APPROVAL HISTORY

02/12/2025 New policy. IRO Peer Review on January 14, 2025, by practicing physician board-certified in Otolaryngology.

REFERENCES

- American Academy of Otolaryngology (AAO). Position statement: PNN ablation for the treatment of chronic rhinitis. Published January 17, 1. 2023. Accessed January 7, 2025. https://www.entnet.org/resource/position-statement-posterior-nasal-nerve.
- 2. American Rhinologic Society (ARS). ARS position statement: Posterior nasal nerve ablation. Published January 2022. Accessed January 7, 2025. https://www.american-rhinologic.org/position-statements.
- 3. Chang MT, Song S, Hwang PH. Cryosurgical ablation for treatment of rhinitis: A prospective multicenter study. Laryngoscope. 2020 Aug;130(8):1877-1884. doi: 10.1002/lary.28301. Epub 2019 Sep 30. PMID: 31566744; PMCID: PMC7384004.
- 4. Hayes. ClariFix (Arrinex Inc.) for treatment of chronic rhinitis. Published March 7, 2022. Updated March 15, 2024. Accessed January 7, 2025. https://evidence.hayesinc.com/.
- Kang YJ, Stybayeva G, et al. Comparative Effectiveness of Cryotherapy and Radiofrequency Ablation for Chronic Rhinitis: A Systematic Review and Meta-analysis. Clin Exp Otorhinolaryngol. 2023 Nov;16(4):369-379. doi: 10.21053/ceo.2023.01214. Epub 2023 Oct 23. PMID: 37871904;
- Lieberman P. Chronic nonallergic rhinitis. Updated October 22, 2023. Accessed January 8, 2025. http://www.uptodate.com. 6
- Ow RA, O'Malley EM, Han JK, et al. Cryosurgical Ablation for Treatment of Rhinitis: Two-Year Results of a Prospective Multicenter Study. Laryngoscope. 2021 Sep;131(9):1952-1957. doi: 10.1002/lary.29453. Epub 2021 Feb 22. PMID: 33616224; PMCID: PMC8451775.
- Stolovitzky JP, Ow RA, Silvers SL, et al. Effect of Radiofrequency Neurolysis on the Symptoms of Chronic Rhinitis: A Randomized Controlled Trial. OTO Open. 2021 Sep 10;5(3):2473974X211041124. doi: 10.1177/2473974X211041124. PMID: 34527852; PMCID: PMC8436321.
- Takashima M, Stolovitzky JP, Ow RA, et al. Temperature-controlled radiofrequency ablation for the treatment of chronic rhinitis: Two-year outcomes from a prospective multicenter trial. Int Forum Allergy Rhinol. 2024 Jul;14(7):1182-1194. doi: 10.1002/alr.23315. Epub 2024 Jan 24. PMID: 38266636.

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10. Takashima M, Stolovitzky JP, Ow RA, et al. Temperature-controlled radiofrequency neurolysis for treatment of chronic rhinitis: 12-month outcomes after treatment in a randomized controlled trial. Int Forum Allergy Rhinol. 2023 Feb;13(2):107-115. doi: 10.1002/alr.23047. Epub 2022 Jul 5. PMID: 35714267; PMCID: PMC10083967.