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Subject: Surgical Ablation for Treatment of Chronic Rhinitis

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DESCRIPTION:

Cryoablation, radiofrequency, and laser ablation of the posterior nasal nerve (PNN) is proposed to improve symptoms of chronic rhinitis by blocking the PNN. These minimally invasive procedures can be performed under endoscopy.

Several devices have been approved by the U.S. Food and Drug Administration for ablation of the posterior nasal nerve (e.g., Clarifix, RhinAer, Neuromark™ System).

Summary and Analysis of Evidence

In an UpToDate article “Chronic nonallergic rhinitis” (Lieberman) “Chronic nonallergic rhinitis (NAR) is not a specific disease but rather a syndrome diagnosed by excluding other specific types of rhinitis. NAR is best defined by the chronic presence of one or more of the four following cardinal symptoms of rhinitis, in the absence of a specific etiology (such as an immunologic, infectious, pharmacologic, structural, hormonal, vasculitic, metabolic, or atrophic cause): sneezing, rhinorrhea, nasal congestion and postnasal drainage. Although there is no consensus about how long symptoms should be present to establish chronicity, some studies have utilized a minimum duration of over one year. The lack of clarity regarding the pathogenesis of this condition has led to an imprecise terminology and a number of synonyms used to refer to this entity. These include, idiopathic rhinitis, nonallergic, noninfectious rhinitis, intrinsic rhinitis and vasomotor rhinitis or nonallergic vasomotor rhinitis. Some experts use the term "nonallergic rhinitis" to refer more generally to any form of rhinitis that is noninfectious and nonallergic. Role of surgery — Several surgical approaches have been used in patients with severe chronic nonallergic rhinitis (NAR). These have been reported as uncontrolled case series. Such interventions may be helpful in patients with difficult symptoms that are refractory to multiple therapies

(e.g., corticosteroid nasal spray in combination with azelastine and/or decongestants and/or ipratropium nasal spray). Six to 12 months of medical management should be allowed before surgical options are considered. Studies of efficacy are lacking. A number of other surgical procedures have been tried in the past, including vidian nerve resection, electrocoagulation of anterior ethmoidal nerve, sphenopalatine ganglion block, and others]. None of these techniques have been shown to have long-term benefits, and the potential risks (e.g., persistent pain) have to be considered carefully since they may outweigh any possible benefits. However, this is an area of ongoing research, and future therapies may emerge. For example, temperature-controlled radiofrequency neurolysis has been successfully employed for ablation of the posterior nasal nerve area to produce a significant reduction in symptoms in a group of patients deemed refractory to medication treatment. Relief persisted for 52 weeks, and there were no significant side effects."

Gerka et al (2021) reported on a prospective single-arm trial of 24 adult patients at seven locations within a large health maintenance organization. Patients with chronic rhinitis that failed medical therapy were offered an in-office cryoablation of posterior nasal nerve (PNN). Patients completed the Total Nasal Symptom Score (TNSS) questionnaire consisting of 5 items reported based on the previous 12 hours and 2 weeks at the following time points: pre-treatment, 30 days, 90 days and 1-year post-treatment. Following cryoablation of the PNN, the TNSS 12-hour symptom score improved from 6.92 (±2.9) to 3.17 (±2.4, P < 0.001) at 30 days, 2.92 (±1.4, P < 0.001) at 90 days and 3.08 (±2.6, P < 0.001) at 1 year post treatment. Similar results were noted for the 2 weeks scores improving from 7.75 (±3.1) to 3.79 (±2.1, P < 0.001) at 30 days, 3.88 (±1.9, P < 0.001) at 90 days and 3.76 (±2.1, P < 0.001) at 1-year post-treatment. 64.7% of respondents stated the procedure decreased or eliminated nasal sprays. The authors note that their study has several limitations. Primary limitations of the study include small sample size and short follow up time. However, this independent non-sponsored evaluation is consistent with prior sponsored studies showing sustained benefit post-procedure for up to a 1 year. The rhinitis type subset analysis is limited by the relatively few pure allergic rhinitis patients. Future studies will be needed to demonstrate longer term improvement and sustained results without use of additional medications. The authors concluded that their independent evaluation of cryoablation of the PNN shows improvement in nasal symptoms over a 1-year period and is consistent with other published data.

Stolovitzky et al (2021) conducted a prospective, multicenter, single-blinded randomized controlled trial with a sham procedure control arm to determine the safety and efficacy of temperature-controlled radiofrequency (RF) neurolysis of the posterior nasal nerve (PNN) area for the treatment of chronic rhinitis. This trial was industry sponsored. Patients with 24-hour reflective Total Nasal Symptom Score (rTNSS) ≥6, including moderate to severe rhinorrhea and mild to severe congestion, were randomized 2:1 to active treatment of the posterior nasal nerve area with a temperature-controlled RF device or a sham procedure, with no RF energy delivery. The stylus was applied bilaterally to nonoverlapping areas of the posterior middle meatus and posterior inferior turbinate in each nostril in the region of the PNN. The primary endpoint was responder rate at 3 months, where a response was defined as ≥30% improvement (decrease) in rTNSS from baseline. Patients had a mean baseline rTNSS of 8.3 (95% CI, 7.9-8.7) and 8.2 (95% CI, 7.6-8.8) (*P* = .797) in the active treatment (n = 77) and sham control (n = 39) arms, respectively. At 3 months, responder rate was significantly higher in the active treatment arm: 67.5% (95% CI, 55.9%-77.8%) vs 41.0% (95% CI, 25.6%-57.9%) (*P* = .009). The active treatment arm had a significantly greater decrease in rTNSS (mean, -3.6 [95% CI, -4.2 to -3.0] vs -2.2 [95% CI, -3.2 to -1.3]) (*P* = .013). Three adverse events related to the device/procedure were reported, and all resolved. The

authors concluded that this randomized controlled trial showed temperature-controlled neurolysis of the PNN area is free from significant adverse events and superior to a sham procedure in decreasing the symptom burden of chronic rhinitis. Longer-term follow-up is needed.

In an industry sponsored prospective, multicenter, patient-blinded randomized controlled trial (RCT) by Takashima and colleagues (2024), patients in the index active treatment arm were unblinded at 3 months and followed through 12 months. At 3 months, eligible patients from the sham-control arm of the study were invited to crossover to active treatment. Eligibility criteria included reflective total nasal symptom score ((rTNSS) ≥ 6, with moderate-severe rhinorrhea and mild-severe congestion. The temperature-controlled radiofrequency (TCRF) stylus was applied bilaterally to nonoverlapping areas in the region of the PNN. Patients in the index active treatment arm (n = 77) had a mean baseline rTNSS of 8.3 (95% confidence interval [CI], 7.9-8.7). At 12 months, the responder rate was 80.6% (n = 67) (95% CI, 69.1%-89.2%). At 12 months, the mean change in rTNSS was -4.8 (95% CI, -5.5 to -4.1; p < 0.001), a 57.8% improvement. The available initial rTNSS-based outcomes in the crossover active treatment arm (n = 27) were following the same course as the index treatment arm. No serious adverse events and 8 adverse events related to the device/procedure were reported in the trial to date. There were several limitations noted by the authors. The investigators were not blinded in the initial stages of the trial. Medication use was not controlled and could potentially have had some confounding effect on symptom relief, as measured by the rTNSS. The authors concluded that the results of this RCT after the primary endpoint and patient unblinding demonstrate that the treatment effect of TCRF neurolysis of the posterior nasal nerve (PNN) area is safe and effective in reducing the symptom burden of chronic rhinitis patients through 12 months post-procedure. To date, eligible patients in the index sham-control arm who elected to cross over to active treatment have continued to exhibit the same course of symptom improvement as the index active treatment arm. The combined active treatment group will be followed through 2 years in this trial to demonstrate the durability of this effect.

Lee and colleagues (2022) reported on an industry sponsored prospective single-arm study of 129 patients with chronic rhinitis at 16 medical centers in the United States and Germany to determine clinical outcomes and quality of life (QoL) following temperature-controlled radiofrequency (TCRF) neurolysis of the posterior nasal nerve (PNN) (RhinAer). The mean 24-h reflective total nasal symptom score (rTNSS) improved from 7.8 (95% CI, 7.5-8.1) at baseline to 3.6 (95% CI, 3.2-4.0) at 3 months and continued to improve to 2.9 (95% CI, 2.5-3.3) at 6 months ($p < .001$ comparing follow-up to baseline and $p = .002$ comparing 3 and 6 months). This represents 53.8% improvement over baseline at 3 months and 62.8% improvement at 6 months. Rhinorrhea, congestion, sneezing, and itching subscores and postnasal drip and cough scores were all significantly improved over baseline at both timepoints. At 3 months, 76.2% (95% CI, 68.1%-82.8%) of patients achieved a minimal clinically important difference of ≥30% improvement in rTNSS over baseline and the percentage was higher at 6 months (83.5% [95% CI, 75.8%-89.0%]). At 3 months, 80.3% (95% CI, 72.6%-86.3%) reported a minimal clinically important difference of ≥0.4-point improvement in the mini rhinoconjunctivitis quality of life questionnaire score, and the percentage was higher at 6 months; 87.7% (95% CI, 80.7%-92.4%). There were no serious adverse events with a relationship to the device/procedure reported through 6 months. There were several limitations noted by the authors. The lack of a control arm and limited follow-up to date. The authors

Concluded that TCRF neurolysis of the PNN was safe and resulted in a significant reduction in rhinitis symptom burden at 3 months that was sustained/improved through 6 months. The majority of patients reported a clinically relevant improvement in QoL at 3- and 6-months post-procedure.

POSITION STATEMENT:

Surgical ablation of the posterior nasal nerve by radiofrequency, cryoablation or laser ablation for treatment of chronic rhinitis and all other indications is considered **experimental or investigational**. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

BILLING/CODING INFORMATION:

CPT Coding:

31242	Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve (**investigational**)
31243	Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve (**investigational**)

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

No guideline specific definitions apply.

OTHER:

None applicable.

REFERENCES:

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3. American Rhinologic Society (ARS) Position Statement: Posterior Nasal Nerve Ablation, January 2022.
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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 05/22/25.

GUIDELINE UPDATE INFORMATION:

06/15/25	New Medical Coverage Guideline.