Anthem

Medical Policy

Subject: Minimally Invasive Treatment of the Posterior Nasal Nerve to Treat Rhinitis
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Description/Scope

This document addresses the use of minimally invasive techniques to inactivate the posterior nasal nerve (PNN) and thereby decrease the symptoms of chronic rhinorrhea or nasal congestion. Currently there are two devices on the market, the ClariFix® device (Stryker, Plymouth, MN) which is a cryotherapy tool and the RhinAer™ Stylus (Aerin Medical, Austin, TX) device which is a radiofrequency tool. There are studies underway evaluating laser ablation of the PNN, but there is no FDA approved device at this time.

Note: For additional information regarding treatment of rhinitis, please see:

- MED.00091 Rhinophototherapy

Position Statement

Investigational and Not Medically Necessary:

Minimally invasive treatment of the posterior nasal nerve, such as cryotherapy or radiofrequency therapy, to decrease the symptoms of allergic or nonallergic rhinitis is considered **investigational and not medically necessary** in all cases.

Rationale

By reducing parasympathetic tone, secretions, and vasomotor activity, ablation of the PNN is proposed to improve symptoms of chronic rhinitis. PNN ablation can be completed using surgical dissection or with thermal ablation using cryotherapy, radiofrequency, or laser energy.

In 2023, Balai and colleagues assessed the effect of PNN treatment on the Total Nasal Symptom Score (TNSS) in a systematic review and meta-analysis. The review included 8 studies (n=463) that used minimally invasive techniques to treat chronic rhinitis: cryotherapy (6), radiofrequency therapy (1), or laser therapy (1). Six of these studies were non-randomized, unblinded, and uncontrolled studies for which the authors found a “serious” risk of bias for the reporting of the study’s subjective outcome measures. The analysis found limited evidence showing that cryotherapy or radiofrequency therapy of the PNN results in a higher response rate and greater TNSS improvement in the active treatment group compared to the sham treatment group. This conclusion was based on two randomized, controlled trials (RCTs). The authors note that the quality of current evidence is limited based primarily on a lack of a comparator group in most studies and the short-term follow-up periods.

Cryotherapy

The ClariFix device was cleared by FDA 510(k) on February 14, 2017 as a cryosurgical tool to treat adults with chronic rhinitis. The clearance was based on a study of 27 individuals and a review of related published literature regarding the use of cryosurgical ablation of tissue in the nasal passageways to treat rhinitis. While it is noted “there is paucity of studies concerning the vidian neurectomy by means of cryosurgery”, the FDA indicated that the safety profile and effectiveness results are comparable to the results published regarding cryosurgical ablation.

In an industry sponsored prospective single arm study by Chang and colleagues (2019), 98 adults with chronic, medically intractable rhinitis were treated with PNN cryoablation. Participation was limited to individuals with moderate or severe rhinorrhea symptoms, mild to severe symptoms of congestion and at least 4 out of 12 minimum total score on the Reflective TNSS (rTNSS). The primary clinical endpoint, the total rTNSS, was evaluated at baseline and at 30-, 90-, 180- and 270-days post-procedure. Following treatment, the total rTNSS scores were significantly improved over baseline at all post-procedure evaluations: baseline (6.1 ± 1.9), at 1 month (2.9 ± 1.9, $p<0.001$), 3 months (3.0 ± 2.3, $p<0.001$), 6 months (3.0 ± 2.1, $p<0.001$), and 9 months (3.0 ± 2.4, $p<0.001$). The authors defined the minimal clinically important difference (MCID) as a 30% reduction in baseline score. Following the procedure, 29 adverse events (AEs) related to the procedure or device were reported. The AEs included 2 instances of epistaxis, requiring office cautery or suction cautery in the operating room. The AEs also included 2 cases of new ostia (one uncinate process perforation and one maxillary sinus accessory os) and 1 case of nasal synechia. Other reported AEs were headache, eye dryness and sinus infections. The study reported a substantial drop-out rate. Four participants (4%) were lost to follow-up at or before the final 270-day follow-up and 3 participants were excluded due to ipratropium use during the post procedure period (total dropout rate 7%).

Ow and colleagues (2021) published additional post-procedure results (12-24 months) of the prospective single-arm study (Chang, 2019). Individuals were evaluated by office visit or phone regarding the change from baseline in the rTNSS. There were significantly improved total rTNSS scores at all timepoints between 12- and 24-month follow-ups. Participant satisfaction, as evaluated by the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) showed significant improvement at 18 and 24 months from baseline. There were no additional serious AEs reported during the follow-up period. This follow-up study is limited by the significant drop-off, while 91 individuals participated in the month follow-up, only 57 individuals completed the 24-month follow-up. The prospective, single arm and open-label study design limited the value of this trial. Randomized trials with a control or sham treatment arm evaluating outcomes are needed to evaluate the relative net health benefit of this treatment compared to standard treatment.

Hwang and colleagues (2017) reported on a series of 27 adults with rhinorrhea with or without nasal congestion symptoms despite medical therapy of more than 3 months, who were treated with the ClariFix device in an office setting. Participants included individuals with both allergic and nonallergic rhinitis. Individuals were evaluated using the TNSS and those with a minimum rhinorrhea and/or congestion subscore of 2 (moderate symptoms) were included. Treatment was completed in less than 20 minutes in all cases under topical or injected local anesthesia. TNSS mean scores decreased significantly at 7 days post-procedure compared to baseline (6.2 ± 0.5 versus 4.3 ± 0.4; $p<0.005$). At 90 days, the 27 individuals continued to report a decline in the TNSS mean score at 2.7 ± 0.4; $p<0.001$. While the TNSS scores continued to decline at 180 days (2.3 ± 0.5) and 365 days (1.9 ± 0.3), 6 individuals (22%) were lost to follow-up at 180 days and 12 individuals (44%) were lost to follow-up at 365 days. Individuals did report mild pain/discomfort, severe

ear blockage and severe nasal dryness, all of which had improved or resolved at the 30-day follow-up. A moderate nosebleed, reported 27 days post-procedure, was managed by electrocautery of the bleeding site. The findings of this study were limited by its small size and the high rate of subject attrition during follow-up. In addition, as medication use was not tracked during the study, other factors for possible improvement in symptoms may have confounded the results.

Cryotherapy had been used by others as a means to ablate posterior nasal tissue. Kompelli and associates (2018) published a qualitative systemic review regarding cryotherapy for the treatment of chronic rhinitis. Only one study (Hwang, 2017) used a cryosurgical device to treat the PNN area. While the authors note that cryotherapy appears to be safe and efficacious, the past evidence includes only low quality, heterogeneous and outdated studies. The current studies use symptom scoring measures (TNSS or rTNSS) as a measure of efficacy within the treated population. These survey instruments have not been validated across a wide range of populations, limiting their general usefulness (Calderón, 2019).

The 3-month results of a prospective, multicenter, 1:1 randomized, sham-controlled, patient-blinded trial assessed whether cryotherapy of the PNN area is more effective than sham treatment to control the symptoms of chronic rhinitis (Del Signore, 2022). Adults with moderate or severe chronic rhinitis with a minimum baseline total rTNSS score of at least 4 (with a minimum score of 2 for rhinorrhea and 1 for nasal congestion) were eligible for the study. Participants were randomized to receive either active cryotherapy (n=64) or sham (n=63) treatment. At 90 days, 47/64 (73.4%) of participants in the active treatment group compared to 23/63 (36.5%) of participants in the sham treatment group reported a ≥ 30% reduction of rTNSS from baseline. The mean rTNSS baseline to 90 days improved significantly more in the active treatment group compared to the sham treatment group (8.0 ± 1.6 to 4.3 ± 2.4 at 90 days compared to 8.1 ± 1.9 at baseline to 6.3 ± 2.5 at 90 days; respectively). Non-serious transient AEs were reported in 35 participants (32 active, 3 sham) and primarily consisted of headache and pain. Extended follow-up on participants is underway to further evaluate the durability of treatment.

In 2023, Young and colleagues published a systematic review and single arm meta-analysis assessing the efficacy of cryoablation of the PNN to manage the symptoms of chronic rhinitis. The meta-analysis included 5 studies (n=247) with outcomes reported at 1- and 3-months post-procedure. The authors note that cryoablation appeared to be effective in reducing chronic rhinitis symptoms. The pooled rTNSS mean difference from baseline to one month was –3.48 points (95% CI: –3.73 to –3.23) and from baseline to 3 months was –3.50 (95% CI: –3.71 to –3.29). The RQLQ demonstrated a -1.53-mean difference from baseline to 3 months across the 3 studies which reported this data. The meta-analysis is limited by the short-term follow-up period as well as the paucity of published material from RCTs.

Yen and colleagues (2020) evaluated cryoablation of the PNN at the inferior and middle meatus in 30 individuals with moderate to severe rhinorrhea and mild to severe nasal congestion for at least 3 months. The majority of previous studies were limited to applying cryoablation to the PNN at the middle meatus. While the participants reported significant symptom improvement at 3 months, the study was limited by the limited number of participants and follow-up and no control arm. This is representative of the body of evidence for this technology; larger studies with long-term follow-up are needed to better assess the safety and efficacy of this therapy.

Desai and associates (2023) evaluated the efficacy and safety profile of intranasal cryotherapy to treat chronic rhinitis. The final analysis consisted of 8 studies with 472 participants. The studies demonstrated a significant improvement in the mean outcomes scores from baseline to the primary endpoint. The documented AEs were minor, no major AEs were reported. There were a number of limitations noted by the authors. The analysis included 1 RCT and 7 uncontrolled studies. Five of the uncontrolled studies were industry sponsored. Published study results were limited to mean values and variances, individual participant data was not available. The initial data shows clinically meaningful sustained reductions in nasal symptoms, however further studies are needed. Citing the paucity of studies regarding this relatively new technology, the authors concluded that further studies, including RCTs are needed to further analyze the efficacy of cryotherapy.

Radiofrequency (RF) Energy

On December 20, 2019, the RhinAer stylus received FDA clearance as a tool for use in the destruction of soft tissue in the nasal airway, including in posterior nasal nerve regions to treat chronic rhinitis. The procedure requires only local anesthesia and can be performed in the office. It uses low-power RF energy to disrupt PNN activity with the intent to improve chronic rhinitis symptoms.

Stolovitzky and associates (2021) published an evaluation of the safety and efficacy of RF neurolysis of the PNN in the treatment of moderate to severe chronic rhinitis. Individuals were randomized to receive active treatment of the PNN area with a RF device (n=77) or with a sham device (n=39). The primary endpoint was the responder rate (at least a 30% improvement in rTNSS score from baseline) at 3 months. A significantly higher responder rate was reported in the active treatment arm compared to the sham arm (67.5% (95% CI, 55.9%-77.8%) versus 41.0% (95% CI, 25.6%-57.9%) at 3 months. The rTNSS significantly improved over baseline (8.3; (95% CI: 7.9-8.7) at 3 months with an adjusted mean change of –3.6 (95% CI: –4.2 to –3.0). No serious AEs were reported. The study did not limit the use of prescribed medications but did track medication use. At 3-month follow-up 7 individuals (9.1%) in the active treatment arm and 5 individuals (12.8%) in the sham treatment group increased their use of medications during the follow-up. Individuals who increased their medication use were assigned to non-responder status, regardless of rTNSS scores.

At 3 months, participants were unblinded and individuals in the sham arm could cross-over to the treatment arm (n=27). Clinical outcomes at 12 months following active treatment and 6-month outcomes in the crossover arm were reported (Takashima, 2023). At 12 months post-procedure, the responder rate in the active group (n=67) was maintained (80.6% (95% CI: 69.1%-89.2%). The rTNSS remained significantly improved over baseline (8.3; 95% CI: 7.9-8.7) at 12 months with an adjusted mean change of –4.8 (95% CI: –5.5 to –4.1). The clinical course following treatment in the crossover group was similar to the active treatment group. The responder rates at 3 and 6 months were 75.0% (95% CI, 53.3%- 90.2%) and 64.0% (95% CI, 42.5%-82.0%); respectively. There were no serious device or procedure related AEs reported within either of the treatment groups. The authors anticipate follow-up through 2 years to assess durability of response.

Ehmer and associates (2022b) reported on the results of a prospective, single-arm multicenter study which followed individuals with chronic rhinitis with a baseline of rTNSS of 6 or greater who underwent RF treatment to the PNN area (n=50). Participants were evaluated at 2, 4-, 12-, 26- and 52-weeks post-procedure and 47 participants completed the study. The primary efficacy point was the change in rTNSS score from baseline through 12 weeks. The mean rTNSS score of 47 participants improved from 8.5 at baseline to 3.4 at 12 weeks. At 12 months, the mean rTNSS score was reported to be 3.6. A clinically significant change (MCID) defined as an improvement of greater than 1 point was achieved in 93.9% of participants at 12 weeks and in 100% of participants at 52 weeks. There were no serious AEs reported. This early study contained some limitations, including a lack of blinding and a lack of control group.

A total of 34 individuals completed a 24-month post-procedure clinical outcomes evaluation (Ehmer, 2022a). Participants completed a rTNSS questionnaire and scored postnasal drip and chronic cough symptoms on a 6-point scale (with 0 being no problem). At 24 months, the mean rTNSS remained significantly improved over baseline (–5.5 (95% CI:–6.4 to–4.6), $p < 0.001$; 65.5% improvement). A total of 97.1% (95% CI: 85.1%-99.5%) maintained a 1 point or greater improvement from baseline. While fewer individuals reported

using oral medications and nasal breathing strips to manage symptoms at 24 months compared to baseline, the difference was not significant.

A prospective single-arm study reported on the 6-month outcomes of individuals who underwent radiofrequency neurolysis of the PNN to treat chronic rhinitis (Lee, 2022). Adults with moderate to severe chronic rhinitis, as evidenced by a rTNSS score of ≥ 6 were included (n=126). Treatment targeted tissue in the posterior middle meatus and superior portion of the posterior inferior turbinate. The adjusted mean rTNSS at baseline was 7.8. At 3 months post-procedure, there was a 53.8% improvement in rTNSS from baseline (mean change −4.2 (95% CI: −4.6 to −3.7). At 6 months post-procedure, there was a 62.8% improvement in rTNSS from baseline (mean change −4.9 (95% CI: −5.5 to −4.3). Participant symptom improvement were also reflected in the responder rate, patient Quality of Life (QOL) and RQLQ. Continued follow-up of participants is anticipated to provide additional long-term data.

The current published studies are industry-sponsored with 12 months or less follow-up. Further studies with long-term follow-up are needed.

Laser Ablation

Krespi and colleagues (2020) conducted a small prospective study to evaluate the effectiveness of an endoscopic diode laser as a tool for PNN ablation. Individuals with chronic medically intractable rhinitis (n=32) underwent endoscopic laser ablation in an office or ambulatory surgical center. Individuals were followed for 90 days following treatment. Symptom severity and treatment outcomes were measured using the TNSS. The procedure was successfully performed in 31 of the participants. TNSS scores were significantly reduced after 90 days (mean ± Standard Deviation (SD): 6.0 ± 0.7 prior to ablation, 2.3 ± 0.4 at 90 days, $p<0.001$). The authors reported no laser safety events or other post procedure complications. The value of this study is limited by multiple factors, including small size, no control arm, follow-up limited to 90 days, non-standardized concomitant use of medications, and the publication only of summarized data in the study.

Currently, there are no laser devices which are FDA approved for ablation in the nasal area in the treatment of rhinitis. Adequately powered randomized controlled studies are needed to evaluate net health benefits from the use of laser ablation for the treatment of chronic rhinitis.

Background/Overview

Chronic rhinitis can be categorized as allergic, nonallergic and mixed subtypes. Chronic nonallergic rhinitis includes several subtypes of rhinitis which are not associated with an allergic or infectious etiology. Approximately 60 million people in the United States, about 1 in 5 individuals, are afflicted with chronic rhinitis (Kompelli, 2018; Krespi, 2020). Nonallergic chronic rhinitis affects 20 to 30 million individuals in the United States and represents approximately 25% of rhinitis cases (Sur, 2018). Similar symptoms are present in all subtypes: nasal obstruction, postnasal drip, itching, redness, clear rhinorrhea, and watery eyes. However, the underlying pathophysiology of allergic and nonallergic rhinitis differs. Allergic rhinitis is caused by exposure to specific sensitivity triggers which results in the secretion of multiple proinflammatory mediators, manifesting as nasal obstruction and rhinorrhea (Gerka, 2021). Nonallergic rhinitis is thought to result from nociceptor and autonomic nerve dysregulation (Gerka, 2021; Sur, 2018). Initial treatment consists of avoidance of known triggers and pharmacologic management (Liu, 2010). Approximately 10% to 22% of individuals with rhinitis are refractory to medical management (Balai, 2023).

There are surgical alternatives for individuals with intractable symptoms. The vidian nerve is responsible for the majority of the parasympathetic innervation to the secretory nasal mucosa via the preganglionic parasympathetic fibers of the greater petrosal nerve, which synapses at the pterygopalatine ganglion. This results in postganglionic innervation to the nasal mucosa via the PNN. Vidian neurectomy has been reported as effective in treating rhinitis, although persistent dry eye symptoms have also been reported as a possible complication. PNN resection, which targets postganglionic parasympathetic fibers that are anatomically distal to the lacrimal innervation branch point, has also been effective to treat both allergic and nonallergic rhinitis while sparing lacrimal innervation (Hwang, 2017).

The PNN can be accessed at the middle and inferior meatus. Minimally invasive treatment using cryotherapy involves consecutive bilateral application of cold to the mucosa in the region of the PNN under endoscopic visualization. It can be performed under local anesthesia. Cryotherapy reduces parasympathetic tone and both secretory and vasoactive activity in the PNN area. The procedure may require periodic repeat sessions to maintain clinical benefit. Minimally invasive treatment may also use radiofrequency energy to disrupt the PNN activation process by destroying tissue in the PNN area while preserving surrounding tissue. There is no literature regarding whether repeat sessions might be required. Repeat sessions at some point may be required as peripheral regeneration takes place at a rate of 1-6 inches/month (Ehmer, 2022a).

Definitions

Allergic rhinitis: A group of symptoms affecting the nose, which occur when someone breathes in something they are allergic to, such as dust, dander, insect venom, or pollen. These symptoms include chronic sneezing, congestion or runny nose.

Nonallergic rhinitis: The symptoms are similar to those of allergic rhinitis, however, the immune system is not involved. Formerly known as vasomotor rhinitis, no vascular basis for this condition has been established.

Reflective Total Nasal Symptom Score (RTNSS): An evaluation of the TNSS after a predefined period of time (such as one month). RTNSS is used to assess the degree of overall effectiveness after the predefined time period. This is in contrast to instantaneous TNSS, in which TNSS is evaluated at a specific time in therapy (such as immediately preceding the next dose of a medication).

Total Nasal Symptom Score (TNSS): A symptom severity scoring system, consisting of four individual subject-assessed symptom scores for rhinorrhea, nasal congestion, nasal itching, and sneezing, each evaluated using a scale of 0 = none, 1 = mild, 2 = moderate, or 3 = severe. The four individual scores are then added together for maximum 12-point score which is based on the individuals perceived symptom severity over the preceding 12 hours.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

30999	Unlisted procedure, nose [when specified as minimally invasive treatment of the posterior nasal nerve using laser]
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 Note: if code 30117 [Excision or destruction (eg, laser), intranasal lesion, internal approach] is used to describe minimally invasive treatment of the posterior nasal nerve, for example using cryotherapy, radiofrequency therapy or laser, the service is considered investigational and not medically necessary

ICD-10 Diagnosis

	All diagnoses, including but not limited to the following:
J30.0-J30.9	Vasomotor and allergic rhinitis
J31.0-J31.2	Chronic rhinitis, nasopharyngitis and pharyngitis
R09.81	Nasal congestion
R09.82	Postnasal drip

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Government Agency, Medical Society, and Other Authoritative Publications:

1. Aerin Medical. Clinical evaluation of low power radiofrequency energy applied to the posterior nasal nerve area for symptomatic relief of chronic rhinitis. NLM Identifier: NCT03727347. Last updated June 16, 2021. Available at: https://clinicaltrials.gov/ct2/show/NCT03727347?term=NCT03727347&draw=2&rank=1. Accessed on June 2, 2023.
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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
	04/01/2024	Updated Coding section to add note.
	12/28/2023	Updated Coding section with 01/01/2024 CPT and HCPCS changes; added 31242, 31243 and removed C9771 deleted as of 01/01/2024, also removed note related to use of code 30117 no longer applicable.
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Description, Rationale, Background and References sections.
Reviewed	08/11/2022	MPTAC review. Updated Rationale and References sections.
Revised	08/12/2021	MPTAC review. Removed “area” from the term “posterior nasal nerve area”. Updated Description, Rationale, Background and References sections.
	12/16/2020	Updated Coding section with 01/01/2021 HCPCS changes; added C9771.
New	08/13/2020	MPTAC review. Initial document development.