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 to thereby decrease the symptoms of chronic rhinorrhea or nasal congestion. Currently there are two devices on the market, the Clarifix® device (Arrinex, Menlo Park, CA) which is a cryotherapy tool and the RhinAer™ Stylus (Aerin Medical, Austin, TX) device which is a radiofrequency tool.

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 area, 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

There are only a few articles published in the peer-reviewed literature addressing the use of either cryotherapy or radiofrequency techniques to reduce the secretory and vasoactive activity in the PNN area.

Cryotherapy

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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 congestions and at least 4 out of 12 minimum total score on the Reflective Total Nasal Symptom Score (rTNSS). The primary clinical endpoint, the total rTNSS, was evaluated at baseline and at 30, 90, 180 and 270 days postprocedure. Following treatment, the total rTNSS scores were significantly improved over baseline at all postprocedure 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 epitaxis, 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 drop out rate 7%). The prospective, single arm and open-label study design limited the value of this trial. Additional randomized trials with a control or sham treatment arm evaluating outcomes in the longer term 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 postprocedure 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).

Radiofrequency 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.

No published studies were identified that evaluated treatment of chronic rhinitis using radiofrequency energy to the PNN area.

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. 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 specific sensitivity triggers. Nonallergic rhinitis is thought to result from nociceptor and autonomic nerve dysregulation (Sur, 2018). Initial treatment consists of avoidance of known triggers and pharmacologic management (Liu, 2010).

There are surgical alternatives for individuals with intractable symptoms. The vidian verve 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).

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.

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.

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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 region, for example using cryotherapy, radiofrequency therapy or laser] 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 region , for example using cryotherapy, radiofrequency therapy or laser, the service is considered investigational and not medically necessary

ICD-10 Diagnosis	
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

References

Peer Reviewed Publications:

1. Calderón MA, Casale TB, Demoly P. Validation of patient-reported outcomes for clinical trials in allergic rhinitis: a systematic review. J Allergy Clin Immunol Pract. 2019; 7(5):1450-1461.
2. Chang MT, Song S, Hwang PH. Cryosurgical ablation for treatment of rhinitis: a prospective multicenter study. Laryngoscope. 2020; 130(8):1877-1884.
3. Hwang PH, Lin B, Weiss R, et al. Cryosurgical posterior nasal tissue ablation for the treatment of rhinitis. Int Forum Allergy Rhinol. 2017;7(10):952-956.
4. Kompelli AR, Janz TA, Rowan NR, et al. Cryotherapy for the treatment of chronic rhinitis: a qualitative systematic review. Am J Rhinol Allergy. 2018; 32(6):491-501.
5. Krespi YP, Wilson KA, Kizhner V. Laser ablation of posterior nasal nerves for rhinitis. Am J Otolaryngol. 2020;41(3):102396.

6. **Liu S, Wang H, Su W. Endoscopic vidian neurectomy: the value of preoperative computed tomographic guidance. Arch Otolaryngol Head Neck Surg. 2010; 136(6):595-602.**
7. **Sur DKC, Plesa ML. Chronic nonallergic rhinitis. Am Fam Physician. 2018; 98(3):171-176.**
8. **Yan CH, Hwang PH. Surgical management of nonallergic rhinitis. Otolaryngol Clin North Am. 2018; 51(5):945-955.**

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 July 23, 2019. Available at: https://clinicaltrials.gov/ct2/show/NCT03727347?term=NCT03727347&draw=2&rank=1. Accessed on June 16, 2020.**
2. **U.S. Food and Drug Administration (FDA). 510(k) Premarket Notification Database. Summary of Safety and Effectiveness. Rockville, MD: FDA. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Accessed on June 16, 2020.**
    - **ClariFix Device. K162608. February 14, 2017.**
    - **RHIN1 Stylus. K192471. December 20, 2019.**
3. **FDA. Allergic Rhinitis: Developing Drug Products for Treatment Guidance for Industry. September 2018. Available at: https://www.fda.gov/media/71158/download. Accessed on July 24, 2020.**

Websites for Additional Information

1. **American Academy of Allergy, Asthma & Immunology (AAAAI). Allergic and Nonallergic Rhinitis. Available at: https://www.aaaai.org/conditions-and-treatments/conditions-dictionary. Accessed on June 16, 2020.**
2. **American Academy of Otolaryngology- Head and Neck Surgery (AAO-HNS). Allergic Rhinitis (Nasal Allergies or Hay Fever). Available at: https://www.entnet.org/sites/default/files/uploads/PracticeManagement/Resources/_files/allergic-rhinitis-plain-language-summary.pdf. Accessed on June 16, 2020.**

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Clarifix

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RhinAer

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
New	08/13/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development.

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