Medical Coverage Policy | Cryoablation, Radiofrequency Ablation, and Laser Ablation for Treatment of Chronic Rhinitis

EFFECTIVE DATE: 11|01|2022
POLICY LAST REVIEWED: 03|05|2025

OVERVIEW

Chronic rhinitis is a common medical condition that encompasses allergic rhinitis, nonallergic rhinitis, and mixed rhinitis and can severely impact quality of life. The initial treatment for chronic rhinitis often involves medical management with pharmacotherapy that may include steroids, anticholinergics, nasal decongestants, and antihistamines. For individuals who do not attain improvement in chronic rhinitis symptoms after receiving adequate medical therapy (referred to as refractory chronic rhinitis), invasive surgical options to block posterior nasal nerve may be considered. Historically, vidian neurectomy which targets the vidian nerve was offered for refractory rhinitis. Although vidian neurectomy was shown to be effective in reducing symptoms like rhinorrhea, it is associated with side effects of cheek and palate numbness and dry eyes (in nearly 50% of cases, ranging between 35 to 72%). In an effort to improve on complications of vidian neurectomy such as xerophthalmia, interventions that specifically target the posterior nasal nerve branches of the vidian nerve have been developed. These interventions range from surgical ablation of the post-ganglionic posterior nasal nerve to minimally invasive options of cryotherapy, radiofrequency, or laser ablation of the nerve. These minimally invasive procedures can be performed under endoscopy. The efficacy of ablation of posterior nasal nerve is thought to result from the interruption of efferent parasympathetic stimulation of the nasal mucosa, which leads to reduction in submucosal gland secretions and blood flow.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

Cryoablation, radiofrequency ablation and laser ablation for chronic rhinitis (allergic or nonallergic) is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

Cryoablation, radiofrequency ablation and laser ablation for chronic rhinitis (allergic or nonallergic) is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable not covered/not medically necessary benefits/coverage.

BACKGROUND

Chronic rhinitis is a common medical condition that encompasses allergic rhinitis, nonallergic rhinitis, and mixed rhinitis and can severely impact quality of life. The initial treatment for chronic rhinitis often involves medical management with pharmacotherapy that may include steroids, anticholinergics, nasal decongestants, and antihistamines. Although medications are the mainstay treatment option, approximately 10% to 22% of the patients with chronic rhinitis still have persistent symptoms despite medical therapy and may require further interventions. For individuals who do not attain improvement in chronic rhinitis symptoms after receiving adequate medical therapy (referred to as refractory chronic rhinitis), invasive surgical options to block posterior nasal nerve may be considered. Historically, vidian neurectomy which targets the vidian nerve

was offered for refractory rhinitis. Although vidian neurectomy was shown to be effective in reducing symptoms like rhinorrhea, it is associated with side effects of cheek and palate numbness and dry eyes (in nearly 50% of cases, ranging between 35% to 72%). In an effort to improve on complications of vidian neurectomy such as xerophthalmia, interventions that specifically target the posterior nasal nerve branches of the vidian nerve have been developed. It is thought that such interventions would help to reduce the morbidity associated with vidian neurectomy. These interventions range from surgical ablation of the post-ganglionic posterior nasal nerve to minimally invasive options of cryotherapy, radiofrequency, or laser ablation of the nerve. These minimally invasive procedures can be performed under endoscopy. The efficacy of ablation of posterior nasal nerve is thought to result from the interruption of efferent parasympathetic stimulation of the nasal mucosa, which leads to reduction in submucosal gland secretions and blood flow.

To quantify the severity of chronic rhinitis and to assess treatment response, various outcome measures can be used, including radiologic scores, endoscopic grading, and patient-reported quality of life measures. The primary outcome measures relevant for the treatment of chronic rhinitis are patient-reported symptoms and quality of life. Examiner evaluation of the nasal and sinus appearance and polyp size may provide some information about treatment outcomes, but these evaluations are limited by the lack of universally accepted standards.

A consensus on the minimally clinically important difference (MCID) for some of these outcomes has not been established. The U.S. Food and Drug Administration (FDA) guidance on drugs for rhinitis recommends patient-reported total nasal symptom scores as the primary measure of efficacy. The FDA guidance on drugs for rhinitis does not specify a MCID for patient-reported symptom measures, but notes that a MCID should be prespecified in studies and the rationale explained. Adverse events must be assessed immediately (perioperative complications and postoperative pain) and over the longer term.

Regulatory Status

In February 2019, the Clarifix ™ device (Stryker) was cleared for use in adults with chronic rhinitis through the 510(k) process (K190356).2, Clearance was based on substantial equivalence to the predicate device, ClariFix (K162608). The only modification to the subject device was an update to the indications for use to include adults with chronic rhinitis.

In December 2019, the RhinAer™ stylus (Aerin Medical) was cleared by the FDA through the 510(k) process as a tool to treat chronic rhinitis (K192471).3, Clearance was based on equivalence in design and intended use of a predicate device, the InSeca ARC Stylus (K162810). The RhinAer stylus includes modification of the InSecaARC stylus shaft components and flexibility. Asper the FDA 510K summary, the RhinAer is indicated for use in otorhinolaryngology surgery for the destruction of soft tissue inthe nasal airway, including in posterior nasal nerve regions in patients with chronic rhinitis.

There are currently no laser ablation devices with FDA clearance for treatment of chronic rhinitis.

For individuals with chronic rhinitis who receive cryoablation, the evidence includes a randomized controlled trial (RCT) and nonrandomized studies. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. One RCT that compared cryoablation using the ClariFix device with a sham procedure showed a statistical significant difference in response rate in favor of cryoablation group compared to the sham group. However, it is unclear if the trial enrolled individuals with chronic rhinitis who were refractory to medical management. This limitation precludes meaningful interpretation of these results as the intended use of ClariFix device is for individuals with chronic rhinitis who are refractory to medical management. Three single-arm prospective studies evaluated efficacy and safety of cryoablation for patients with chronic rhinitis. Two (of 3) studies enrolled individuals who were refractory to medical management. The definition of refractory varied from symptoms not adequately controlled with a minimum of 4 weeks of topical nasal steroid treatment or failure of medical therapy for a duration of at least 3 months. Although all 3 single arm studies reported improvement in symptom control, the major limitation is lack of a comparator group and open-label nature of the study design, which likely introduces biases. Additionally, loss to follow-up was high. RCTs with a clearly defined refractory patient population directly comparing cryoablation with

sham surgery or other surgical interventions are needed to confirm the efficacy of cryoablation for treatment of chronic rhinitis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with chronic rhinitis refractory to medical management who receive radiofrequency ablation, the evidence includes an RCT and nonrandomized studies. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. One RCT that compared radiofrequency using the RhinAer device with a sham procedure showed a statistical significant difference in response rate in favor of radiofrequency ablation group compared to the sham group. However, it is unclear if the trial enrolled individuals with chronic rhinitis who were refractory to medical management. This limitation precludes meaningful interpretation of these results as the intended use of RhinAer device is for individuals with chronic rhinitis who are refractory to medical management. Two single-arm prospective studies evaluated efficacy and safety of radiofrequency ablation for patients with chronic rhinitis. One (of 2) studies enrolled individuals who were refractory to medical management. Although both single arm studies reported improvement in symptom control, the major limitation is lack of a comparator group and open-label nature of the study design, which likely introduces biases. RCTs with a clearly defined refractory patient population directly comparing radiofrequency with sham surgery or other surgical interventions are needed to confirm the efficacy of radiofrequency ablation for treatment of chronic rhinitis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with allergic or nonallergic chronic rhinitis who receive laser ablation, the evidence includes one nonrandomized study. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Although the single-arm prospective study reported improvement in symptom control, the major limitation is lack of a comparator group and open-label nature of the study design, which likely introduces biases. In addition, the authors did not define how study participants were classified as refractory to medical management. RCTs with a clearly defined refractory patient population directly comparing laser ablation with sham surgery or other surgical interventions are needed to confirm the efficacy of radiofrequency ablation for treatment of chronic rhinitis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

The following code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products when filed with the ICD-10-CM codes, below:

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

ICD-10-CM

J30.0 Vasomotor rhinitis
J30.1 Allergic rhinitis due to pollen
J30.2 Other seasonal allergic rhinitis
J30.5 Allergic rhinitis due to food
J30.81 Allergic rhinitis due to animal (cat) (dog) hair and dander
J30.89 Other allergic rhinitis
J30.9 Allergic rhinitis, unspecified
J31.0 Chronic rhinitis

HCPCS/CPT codes have not been assigned to all of the services addressed in this policy. Therefore, the following procedure code(s) should be used:

30999 Unlisted procedure, nose
31299 Unlisted procedure, accessory sinuses

RELATED POLICIES

None

PUBLISHED

Provider Update, May 2025
Provider Update, December 2024
Provider Update, June 2023
Provider Update, September 2022

REFERENCES

1. Settipane RA, Charnock DR. Epidemiology of rhinitis: allergic and nonallergic. Clin Allergy Immunol. 2007; 19: 23-34. PMID 17153005
2. Lieberman P, Kaliner MA, Wheeler WJ. Open-label evaluation of azelastine nasal spray in patients with seasonal allergic rhinitis and nonallergic vasomotor rhinitis. Curr Med Res Opin. Apr 2005; 21(4): 611-8. PMID 15899111
3. Halderman A, Sindwani R. Surgical management of vasomotor rhinitis: a systematic review. Am J Rhinol Allergy. 2015; 29(2): 128-34. PMID 25785754
4. Marshak T, Yun WK, Hazout C, et al. A systematic review of the evidence base for vidian neurectomy in managing rhinitis. J Laryngol Otol. Jul 2016; 130 Suppl 4: S7-S28. PMID 27488341
5. Senanayake P, Wong E, McBride K, et al. Efficacy of Vidian Neurectomy and Posterior Nasal Neurectomy in the Management of Nonallergic Rhinitis: A Systematic Review. Am J Rhinol Allergy. Nov 2022; 36(6): 849-871. PMID 35695191
6. Zubair A, Lasrado S. Vidian Neurectomy. [Updated 2023 May 14]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK563142/]
7. Food & Drug Administration. Clarifix 510(k) Premarket Notification. 2019 (K190356). https://www.accessdata.fda.gov/cdrh_docs/pdf19/K190356.pdf. Accessed December 18, 2024.
8. Food & Drug Administration. RhinAer (RHIN1 Stylus) 510(k) Premarket Notification. 2019 (K192471). Accessed December 17, 2024.
9. Del Signore AG, Greene JB, Russell JL, et al. Cryotherapy for treatment of chronic rhinitis: 3-month outcomes of a randomized, sham-controlled trial. Int Forum Allergy Rhinol. Jan 2022; 12(1): 51-61. PMID 34355872
10. Hwang PH, Lin B, Weiss R, et al. Cryosurgical posterior nasal tissue ablation for the treatment of rhinitis. Int Forum Allergy Rhinol. Oct 2017; 7(10): 952-956. PMID 28799727
11. Chang MT, Song S, Hwang PH. Cryosurgical ablation for treatment of rhinitis: A prospective multicenter study. Laryngoscope. Aug 2020; 130(8): 1877-1884. PMID 31566744
12. Ow RA, O'Malley EM, Han JK, et al. Cryosurgical Ablation for Treatment of Rhinitis: Two-Year Results of a Prospective Multicenter Study. Laryngoscope. Sep 2021; 131(9): 1952-1957. PMID 33616224
13. Gerka Stuyt JA, Luk L, Keschner D, et al. Evaluation of In-Office Cryoablation of Posterior Nasal Nerves for the Treatment of Rhinitis. Allergy Rhinol (Providence). 2021; 12: 2152656720988565. PMID 33598336
14. 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; 5(3): 2473974X211041124. PMID 34527852
15. 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. Feb 2023; 13(2): 107-115. PMID 35714267
16. Lee JT, Abbas GM, Charous DD, et al. Clinical and Quality of Life Outcomes Following Temperature-Controlled Radiofrequency Neurolysis of the Posterior Nasal Nerve (RhinAer) for Treatment of Chronic Rhinitis. Am J Rhinol Allergy. Nov 2022; 36(6): 747-754. PMID 35818709
17. Ehmer D, McDuffie CM, Scurry WC, et al. Temperature-Controlled Radiofrequency Neurolysis for the Treatment of Rhinitis. Am J Rhinol Allergy. Jan 2022; 36(1): 149-156. PMID 34382444
18. Ehmer D, McDuffie CM, McIntyre JB, et al. Long-term Outcomes Following Temperature-Controlled Radiofrequency Neurolysis for the Treatment of Chronic Rhinitis. Allergy Rhinol (Providence). 2022; 13: 21526575221096045. PMID 35663498
19. Krespi YP, Wilson KA, Kizhner V. Laser ablation of posterior nasal nerves for rhinitis. Am J Otolaryngol. 2020; 41(3): 102396. PMID 31948695

20. Wise SK, Damask C, Roland LT, et al. International consensus statement on allergy and rhinology: Allergic rhinitis - 2023. Int Forum Allergy Rhinol. Apr 2023; 13(4): 293-859. PMID 36878860
21. American Academy of Otolaryngology. Position Statement: PNN ablation for the treatment of chronic rhinitis. January 2023. Accessed December 18, 2024.
22. American Rhinologic Society. Posterior Nasal Nerve Ablation ARS Position Statement. January 2022. Accessed December 18, 2024.