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MEDICAL POLICY – 7.01.168

Cryoablation, Radiofrequency Ablation, and Laser Ablation for Treatment of Chronic Rhinitis

BCBSA Ref. Policy:	7.01.168
Effective Date:	May 1, 2025
Last Revised:	Apr. 7, 2025
Replaces:	N/A

RELATED MEDICAL POLICIES:

7.01.134	Steroid-Eluting Sinus Stents
7.01.558	Rhinoplasty
7.01.559	Sinus Surgery in Adults

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Chronic rhinitis is a condition where the nasal passages become inflamed and lead to ongoing symptoms. These can include swelling inside the nose that makes breathing difficult, a stuffy or runny nose, itchiness, sneezing, and mucous in the throat. Chronic rhinitis can be caused by allergies, but this is not always the case. Standard treatment for this condition may include the use of drugs called decongestants or antihistamines, and sometimes allergy shots. Another type of treatment is called ablation therapy. Cryoablation uses extreme cold to freeze nerve endings near the back of the nose, radiofrequency ablation uses an electric current to heat up a small area of nerve tissue, and laser ablation uses intense light to heat and destroy nerve tissue. It is thought that this stops the nerve signals that contribute to symptoms. The use of ablation therapy to treat chronic rhinitis is unproven (investigational). More studies are needed to see if these procedures improve health outcomes.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Drug	Investigational
Cryoablation, radiofrequency ablation, and laser ablation for chronic rhinitis	**Cryoablation for chronic rhinitis (allergic or nonallergic) is considered investigational. (e.g., Clarifix device)** **Radiofrequency ablation for chronic rhinitis (allergic or nonallergic) is considered investigational. (e.g., RhinAer stylus)** **Laser ablation for chronic rhinitis (allergic or nonallergic) is considered investigational.**

Coding

Code	Description
CPT	
30117	Excision or destruction (e.g., laser), intranasal lesion; internal approach
31242	Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve (use to report: RhinAer)
31243	Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve (use to report: Clarifix)
HCPCS	

Related Information

N/A

Evidence Review

Description

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.

Background

Chronic rhinitis is a common medical condition that encompasses allergic rhinitis, nonallergic rhinitis, and mixed rhinitis and can severely impact quality of life.[1] 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.[2] 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.[3,4] 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%).[3] 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.[5] 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.[6]

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.

Frequently used outcome measures for treatments of chronic rhinitis in adults are shown in **Table 1**. A consensus on the minimally clinically important difference (MCID) for some of these outcomes has not been established. The US 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.

Table 1. Outcome Measures for Chronic Rhinitis Interventions

Outcome	Measures	Description	Minimal Clinically Important Difference	Timing
Symptoms	reflective Total Nasal Symptom Score (rTNSS)	Sum of 4 individual subject-assessed symptom scores for rhinorrhea, nasal congestion, nasal itching, and sneezing, each evaluated using a scale of 0 =	Not established; 30% change from baseline has been proposed	At least 6 months or longer

Outcome	Measures	Description	Minimal Clinically Important Difference	Timing
		none, 1 = mild, 2 = moderate, or 3 = severe. Maximum 12 points.		
	The Chronic Sinusitis Survey (CSS)	Measure of symptoms and medication usage over an 8-week recall period. Includes 3 questions regarding symptoms and 3 regarding medication usage, yielding a total score, symptom subscore, and medication subscore. Ranges from 0 to 100 in which a low CSS score represents greater symptoms and/or medication usage.	Not established	At least 6 months or longer
	Visual Analog Scale (VAS)	Patient-reported.	Not established	At least 6 months or longer
Disease-Specific Quality of Life	Sino-Nasal Outcome Test-20 (SNOT-20)	Patients complete 20 symptom questions on a categorical scale (0 [no bother] to 5 [worst symptoms can be]). Average rankings can be reported over all 20 symptoms, as well as by 4 subclassified symptom domains. The possible range of SNOT-20 scores is 0 to 5, with a higher score indicating a greater rhinosinusitis-related health burden. SNOT-22, a variation of the SNOT-20, includes 2 additional questions (on "nasal obstruction" and "loss of smell and taste").	SNOT-20: change in score of 0.8 or greater SNOT-22: change in score of 8.9 points	At least 6 months or longer
	Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ)	Measures the functional (physical, emotional, and social) problems associated with rhinitis.	Not established	At least 6 months or longer
	Visual analog scale (VAS)	Patient-reported.	Not established	At least 6 months or longer

Outcome	Measures	Description	Minimal Clinically Important Difference	Timing
Adverse events	Various; patient- and clinician reported	Potential procedure- and device-related adverse events include postoperative pain, epistaxis, and dry eyes.	Not applicable	Immediately post procedure to 6 months or longer

Summary of Evidence

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 the three studies enrolled individuals who were refractory to medical management. The definition of refractory varied from symptoms not adequately controlled with a minimum of four weeks of topical nasal steroid treatment or failure of medical therapy for a duration of at least three months. Although all three 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. Randomized controlled trials 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. Out of the two, one study 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 individual 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 individual 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 2**.

Table 2. Summary of Key Unpublished Trial

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04154605[a]	ClariFix Rhinitis Randomized Controlled Trial	133	Jul 2022 (unknown status)

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT04533438[a]	The RhinAer Procedure for Treatment of CHronic RhInitis - A Prospective, MulticeNter Randomized ConTrolled TRial Comparing RhinAer to Sham Control (RHINTRAC)	116	Apr 2025
Unpublished			
NCT05648565	Effects of Radiofrequency Ablation of Posterior Nasal Nerves on Inflammatory Cytokines, Peak Nasal Inspiratory Flow, and Nasal Blood Flow in Patients with Chronic Rhinitis	17	Feb 2024

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Allergy, Asthma, and Immunology

The 2023 International Consensus Statement on Allergy and Rhinology stated the following for cryotherapy/radiofrequency ablation of posterior nasal nerve. [21]

- Aggregate grade of evidence: C (Level 3: 2 studies, level 4: 4 studies, level 5: 5 studies)
- Benefit: Improvement in rhinorrhea.
- Harm: Risk of complications (e.g., epistaxis, temporary facial pain and swelling, headaches), limited long-term results.
- Cost: Surgical/procedural costs, cost of device, potential time off from work.

- Benefits-harm assessment: Potential benefit must be balanced with low risk of harm, especially considering limited long-term results.
- Value judgments: Patients may experience an improvement in symptoms.
- Policy level: Option.
- Intervention: Cryoablation and radiofrequency ablation of the posterior nasal nerve may be considered in allergic rhinitis patients that have failed medical management, particularly for rhinorrhea.

Grade of evidence "C" implies that body of evidence consisted of observational studies (case control and cohort design). Policy level "Option" implies "either that the evidence quality that exists is suspect or that well-designed, well conducted studies have demonstrated little clear advantage to one approach versus another. Options offer clinicians flexibility in their decision-making regarding appropriate practice, although they may set boundaries on alternatives. Patient preference should have a substantial role in influencing clinical decision-making, particularly when policies are expressed as options." As per the consensus statement, "because the current evidence is primarily based on industry-sponsored studies with limited long-term data, these office-based interventions remain an option for properly selected patients".

American Academy of Otolaryngology

In January 2023, the American Academy of Otolaryngology issued a position statement on peripheral nerve ablation for the treatment of chronic rhinitis.[22] The position statement was not based on a systematic review or strength of evidence rating. According to the position statement, " Based on these safety and efficacy data, the American Academy of Otolaryngology endorses the use of posterior nasal nerve ablation for the treatment of medically-refractory chronic rhinitis. We do not consider these treatments to be experimental."

American Rhinologic Society

In January 2022, the American Rhinologic Society issued a position paper on posterior nasal nerve ablation.[23] The position statement was not based on a systematic review or strength of evidence rating. According to the position statement, "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."

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In February 2019, the Clarifix device (Stryker) was cleared for use in adults with chronic rhinitis through the 510(k) process (K190356).[7] 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. As per the FDA 510K summary, the ClariFix device is intended to be used as a cryosurgical tool for the destruction of unwanted tissue during surgical procedures, including in 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).[8] 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 InSeca ARC stylus shaft components and flexibility. As per the FDA 510K summary, the RhinAer is indicated for use in otorhinolaryngology surgery for the destruction of soft tissue in the 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.

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/**]. Last accessed March 17, 2025.

7. Food & Drug Administration. Clarifix 510(k) Premarket Notification. 2019 (K190356). **https://www.accessdata.fda.gov/cdrh_docs/pdf19/K190356.pdf**. Accessed March 17, 2025

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. 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. Jul 2024; 14(7): 1182-1194. PMID 38266636

17. 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

18. 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

19. 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

20. Krespi YP, Wilson KA, Kizhner V. Laser ablation of posterior nasal nerves for rhinitis. Am J Otolaryngol. 2020; 41(3): 102396. PMID 31948695

21. 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

22. American Academy of Otolaryngology. Position Statement: PNN ablation for the treatment of chronic rhinitis. January 2023. Accessed December 18, 2024.

23. American Rhinologic Society. Posterior Nasal Nerve Ablation ARS Position Statement. January 2022. Accessed December 18, 2024.

History

Date	Comments
12/01/21	New policy, approved November 9, 2021. Policy created with literature review through August 3, 2021. Cryoablation for chronic rhinitis is considered investigational.
05/01/22	Annual Review, approved April 12, 2022. Policy updated with literature review through December 30, 2021. Added radiofrequency ablation and laser ablation for chronic rhinitis are considered investigational. Title changed to Cryoablation, Radiofrequency Ablation, and Laser Ablation for Treatment of Chronic Rhinitis.
05/01/23	Annual Review, approved April 10, 2023. Policy updated with literature review through December 7, 2022; references added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
01/01/24	Coding update. Added new CPT codes 31242 and 31243 and added term date to HCPCS code C9771.
06/01/24	Annual Review, approved May 13, 2024. Policy updated with literature review through December 18, 2023; references added. Policy was extensively edited to improve clarity that included changing the comparator from "medical management" to "other surgical procedures". Policy statements unchanged.
05/01/25	Annual Review, approved April 7, 2025. Policy updated with literature review through December 18, 2024; references added. Policy statements unchanged. Removed UNL codes 30999 and 31299 since CPT codes for RhinAer and Clarifix have now been established.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.