

Corporate Medical Policy

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

File Name: cryoablation_radiofrequency_ablation_and_laser_ablation_for_treatment_of_chronic_rhinitis
Origination: 10/2021
Last Review: 8/2024

Description of Procedure or Service

Chronic rhinitis is a common medical condition that encompasses allergic rhinitis, nonallergic rhinitis, and mixed rhinitis and can severely impact quality of life. Initially, 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 individuals 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%). 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.

Regulatory Status

In February 2019, the Clarifix® device (Stryker) was cleared for use in adults with chronic rhinitis through the 510(k) process (K190356). 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). 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 individuals with chronic rhinitis.

In October 2021, Neurent Medical's NEUROMARK® System received FDA clearance (K212666) via the 510(k) process as a second radiofrequency posterior nasal nerve ablation device.

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

Related Policies

Surgical Treatment of Sinus Disease
Balloon Ostial Dilatation (Balloon Sinuplasty)

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Cryoablation, radiofrequency ablation, and laser ablation for treatment of chronic rhinitis (allergic or nonallergic) is considered investigational for all applications. **BCBSNC does not provide coverage for investigational services or procedures.**

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Cryoablation, Radiofrequency Ablation, and Laser Ablation for Treatment of Chronic Rhinitis is covered

Not applicable.

When Cryoablation, Radiofrequency Ablation, and Laser Ablation for Treatment of Chronic Rhinitis is not covered

Cryoablation for chronic rhinitis (allergic or nonallergic) is considered investigational.

Radiofrequency ablation for chronic rhinitis (allergic or nonallergic) is considered investigational.

Laser ablation for chronic rhinitis (allergic and nonallergic) is considered investigational.

Policy Guidelines

For individuals with chronic rhinitis who receive cryoablation, the evidence includes a randomized controlled trial (RCT), 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 statistically 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. Out of the three, two 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

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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. Defining the appropriate patient population for posterior nasal nerve ablation would also necessitate more narrow inclusion criteria, whereas current diagnostic criteria for chronic rhinitis is too broad. A severity classification for chronic rhinitis would also be advised. 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 statistically 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. Randomized controlled trials 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. Randomized controlled trials 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 30999, 30117, 31242, 31243, 31299

Diagnoses: J30.0 – J31.0

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

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Scientific Background and Reference Sources

Food & Drug Administration. Clarifix 510(k) Premarket Notification. 2019 (K190356) <https://fda.report/PMN/K190356/19/K190356.pdf>. Accessed October 11, 2021.

Kompelli AR, Janz TA, Rowan NR, et al. Cryotherapy for the Treatment of Chronic Rhinitis: A Qualitative Systematic Review. *Am J Rhinol Allergy*. Nov 2018; 32(6): 491-501. PMID 30229670

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

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

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

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)*. Jan-Dec 2021; 12: 2152656720988565. PMID 33598336

Dykewicz MS, Wallace DV, Amrol DJ, et al. Rhinitis 2020: A practice parameter update. *J Allergy Clin Immunol*. Oct 2020; 146(4): 721-767. PMID 32707227

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.168, 9/9/2021

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.168, 2/10/2022

Specialty Matched Consultant Advisory Panel 8/2022

Food & Drug Administration. RhinAer (RHIN1 Stylus) 510(k) Premarket Notification. 2019 (K192471).

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. PMID34355872

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

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*. Jun 17 2022. PMID 35714267

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

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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

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

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

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Specialty Matched Consultant Advisory Panel 8/2023

Settipane RA, Charnock DR. Epidemiology of rhinitis: allergic and nonallergic. *Clin Allergy Immunol*. 2007; 19: 23-34. PMID 17153005

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

Halderman A, Sindwani R. Surgical management of vasomotor rhinitis: a systematic review. *Am J Rhinol Allergy*. 2015; 29(2): 128-34. PMID 25785754

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

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

Zubair A, Lasrado S. Vidian Neurectomy. [Updated 2023 May 14]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan.

Food & Drug Administration. Neuromark System Premarket Notification. 2021 (K212666). <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K212666>

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Policy Implementation/Update Information

10/19/21	New policy issued. Cryoablation for Chronic Rhinitis is considered investigational. Policy noticed 10/19/2021 for policy effective date 1/1/2022. (sk)
3/8/22	New indications for radiofrequency ablation and laser ablation for chronic rhinitis added and are considered investigational. Title changed to Cryoablation, Radiofrequency Ablation, and Laser Ablation for Treatment of Chronic Rhinitis. Notification given 3/22/2022 for policy effective date 5/31/2022. (sk)
2/7/23	Specialty Matched Consultant Advisory Panel review 8/19/2022. (sk)

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- 9/12/23 Description and Policy Guidelines sections updated. No change to policy intent. Added Related Policies. Updated References. Medical Director Review 8/2023. Specialty Matched Consultant Advisory Panel review 8/2023. (ldh)
 - 12/29/23 Added the following CPT codes to the Billing/Coding section: 31242, and 31243, effective 1/1/2024. Removed terminated HCPCS code C9771 from the Billing/Coding section. (ldh)
 - 9/18/24 Description and Policy Guidelines sections updated. No change to policy intent. Regulatory Status and References updated. Medical Director Review 8/2024. Specialty Matched Consultant Advisory Panel review 8/2024. (ldh)
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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.