LifeWise
Health Plan of Washington

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, 2023
Last Revised:	Jan. 1, 2024
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.

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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	
30999	Unlisted procedure, nose
30117	Excision or destruction (eg, laser), intranasal lesion; internal approach
31242	Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve (new code effective 1/1/2024)
31243	Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve (new code effective 1/1/2024)
31299	Unlisted procedure, accessory sinuses
HCPCS	
C9771	Nasal/sinus endoscopy, cryoablation nasal tissue(s) and/or nerve(s), unilateral or bilateral (code termed effective 1/1/2024)

Related Information

N/A

Evidence Review

Description

Ablation therapy is proposed as an alternative to medical management for individuals with chronic rhinitis symptoms. Ablation therapy includes cryoablation (also known as cryosurgical ablation, cryosurgery, or cryotherapy), radiofrequency ablation, and laser ablation. Ablation therapy is thought to correct the imbalance of autonomic input to the nasal mucosa thereby reducing nasal antigen responses and vascular hyperreactivity.

Background

Medical management is the standard of care for chronic rhinitis. Surgical options have been investigated for individuals with chronic rhinitis refractory to multiple medical therapies. Ablation therapy is proposed as an alternative to medical management for individuals with chronic rhinitis symptoms. Ablation therapy includes cryoablation (also known as cryosurgical ablation, cryosurgery, or cryotherapy), radiofrequency ablation, and laser ablation. Ablation therapy is thought to correct the imbalance of autonomic input to the nasal mucosa thereby reducing nasal antigen responses and vascular hyperreactivity.

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 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.

Six months of follow-up is considered necessary to demonstrate efficacy. Adverse events can be assessed immediately (perioperative complications and postoperative pain) or 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 = none, 1 = mild, 2 = moderate, or 3 = severe. Maximum 12 points.	Not established; 30% change from baseline has been proposed	At least 6 months or longer
	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-20: change in score of 0.8 or greater SNOT-22: change in score of 8.9 points	At least 6 months or longer

Outcome	Measures	Description	Minimal Clinically Important Difference	Timing
		SNOT-22, a variation of the SNOT-20, includes 2 additional questions (on "nasal obstruction" and "loss of smell and taste").		
	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
	VAS	Patient-reported.	Not established	At least 6 months or longer
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 an randomized controlled trial (RCT), nonrandomized studies, and a systematic review of nonrandomized trials. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Three single-arm, open-label studies enrolling a total of 149 individuals reported improvements from baseline in individual-reported symptom scores up to one year. Sustained improvement for up to two years was observed in one study, however only 62 of 98 individuals enrolled in the longer-term follow-up phase. In the largest study, there were two serious procedure-related adverse events (2.0%), and 77.8% of individuals who responded to a post-procedure questionnaire reported some degree of pain or discomfort. Study limitations, including lack of a control group and high loss to follow-up, preclude drawing conclusions from this body of evidence. The RCT used a sham control group, and follow-up was limited to three months. Randomized controlled trials with a clearly defined individual population directly comparing cryoablation with medical management and with follow-up for active and control groups ≥6 months are needed to confirm the efficacy of cryoablation for treatment of chronic rhinitis. A systematic review of 15 nonrandomized studies reported improvements with cryoablation; however, only one study used an approved device and validated outcome measuring, limiting conclusions from this systematic review. The evidence is

insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with chronic rhinitis who receive radiofrequency ablation, the evidence includes an RCT and two nonrandomizeds studies. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Results from the RCT suggest that radiofrequency ablation is more effective than sham ablation in improving short-term reflective Total Nasal Symptom Score (rTNSS) scores. Results from nonrandomized, uncontrolled studies also found radiofrequency ablation associated with improvements in rTNSS scores at time points up to two years and in symptom-related quality of life up to six months. Randomized controlled trials with a clearly defined individual population directly comparing radiofrequency ablation with medical management and with follow-up for active and control groups ≥6 months 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.

Evidence on laser ablation for chronic rhinitis is limited to a single small nonrandomized study with three months follow-up. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Although laser ablation reduced rTNSS scores, additional studies are needed to determine the efficacy and safety of laser ablation for treatment of chronic rhinitis. Randomized controlled trials with a clearly defined individual population directly comparing laser ablation with medical management and with follow-up for active and control groups ≥6 months are needed to confirm the efficacy of laser 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			

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT04154605[a]	ClariFix Rhinitis Randomized Controlled Trial	133	Jul 2022
NCT04533438[a]	The RhinAer Procedure for Treatment of CHronic RhInitis - A Prospective, MulticeNter Randomized ConTrolled TRial Comparing RhinAer to Sham Control (RHINTRAC)	120	Apr 2023

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 U.S. professional society, an international society with U.S. 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.

No clinical practice guidelines on cryoablation, radiofrequency ablation, or laser ablation for chronic rhinitis were identified through clinical consultation or literature searches conducted through December 7, 2022.

American Academy of Allergy, Asthma, and Immunology

A 2020 practice parameter update on rhinitis from the American Academy of Allergy, Asthma, and Immunology did not address ablation techniques, including cryoablation, radiofrequency ablation, or laser ablation..[15]

American Rhinologic Society

A position statement issued by the American Rhinologic Society stated that posterior nasal nerve ablation, including cryoablation and radiofrequency ablation, should be considered as an

effective option in treating chronic rhinitis and improving patient quality of life.[16] Specific guidance on usage of these techniques was not issued.

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).[1] 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).[2] 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.

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

References

1. Food & Drug Administration. Clarifix 510(k) Premarket Notification. 2019 (K190356) **https://fda.report/PMN/K190356/**. Accessed March 24, 2023.
2. Food & Drug Administration. RhinAer (RHIN1 Stylus) 510(k) Premarket Notification. 2019 (K192471).
3. 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
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14. Krespi YP, Wilson KA, Kizhner V. Laser ablation of posterior nasal nerves for rhinitis. Am J Otolaryngol. 2020; 41(3): 102396. PMID 31948695
15. 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
16. American Rhinologic Society. Posterior Nasal Nerve Ablation ARS Position Statement. January 2022.

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.

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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.

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