



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

Policy # 00723

Original Effective Date: 05/01/2021

Current Effective Date: 03/11/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Nasal Swell Body Ablation Reduction in the Treatment of Nasal Obstruction is addressed separately in medical policy 00724.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers intranasal ablation (e.g., cryoablation using Clarifix^{®†}, radiofrequency using RhinAer^{®†}, or laser ablation) of the posterior nasal nerves and/or sphenopalatine ganglion for the treatment of chronic allergic and non-allergic rhinitis to be **investigational**.*

Background/Overview

Medical management is the standard of care for chronic rhinitis. Surgical options have been investigated for patients with chronic rhinitis refractory to multiple medical therapies. Ablation therapy is proposed as an alternative to medical management for patients 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

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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	Not established	At least 6 months or longer



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		subscore, and medication subscore. Ranges from 0 to 100 in which a low CSS score represents greater symptoms and/or medication usage.		
	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
	VAS	Patient-reported.	Not established	At least 6 months or longer



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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
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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In February 2019, the ClariFix^{TM‡} device (Stryker) was cleared for use in adults with chronic rhinitis by the FDA 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.

In December 2019, the RhinAer^{TM‡} 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^{TM‡} (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.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Description

Ablation therapy is proposed as an alternative to medical management for patients with chronic rhinitis symptoms. Ablation therapy includes cryoablation (also known as cryosurgical ablation, cryosurgery, or cryotherapy), radiofrequency ablation, and laser ablation. Ablation therapy is

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thought to correct the imbalance of autonomic input to the nasal mucosa, thereby reducing nasal antigen responses and vascular hyperreactivity.

Summary of Evidence

For individuals with chronic rhinitis who receive cryoablation, the evidence includes a 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 patients reported improvements from baseline in patient-reported symptom scores up to 1 year. Sustained improvement for up to 2 years was observed in 1 study, however only 62 of 98 patients enrolled in the longer-term follow-up phase. In the largest study, there were 2 serious procedure-related adverse events (2.0%), and 77.8% of patients 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 3 months. Randomized controlled trials with a clearly defined patient 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 1 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 2 nonrandomized 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 2 years and in symptom-related quality of life up to 6 months. Randomized controlled trials with a clearly defined patient 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.

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Evidence on laser ablation for chronic rhinitis is limited to a single small nonrandomized study with 3 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 patient 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.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' 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.

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.

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. Specific guidance on usage of these techniques was not issued.

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U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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 Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
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.

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- Food & Drug Administration. Clarifix 510(k) Premarket Notification. 2019 (K190356) <https://fda.report/PMN/K190356/19/K190356.pdf>.
- Food & Drug Administration. RhinAer (RHIN1 Stylus) 510(k) Premarket Notification. 2019 (K192471).
- 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
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16. American Rhinologic Society. Posterior Nasal Nerve Ablation ARS Position Statement. January 2022.

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02/04/2021 Medical Policy Committee review

02/10/2021 Medical Policy Implementation Committee approval. New policy.

07/01/2021 Medical Policy Committee review

07/14/2021 Medical Policy Implementation Committee approval. Title changed from “Cryotherapy for the Treatment of Chronic Rhinitis” to “Ablation Therapy for the Treatment of Chronic Rhinitis for the Treatment of Chronic Rhinitis”. Changed “cryotherapy” to “intranasal ablation of the posterior nasal nerves and/or sphenopalatine ganglion” in the investigational statement for the treatment of allergic and non-allergic rhinitis. Added the RhinAer device as an example in the investigational statement.

02/03/2022 Medical Policy Committee review

02/09/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

02/02/2023 Medical Policy Committee review

02/08/2023 Medical Policy Implementation Committee approval. Title changed from “Ablation Therapy for the Treatment of Chronic Rhinitis” to “Cryoablation, Radiofrequency Ablation, and Laser Ablation for Treatment of Chronic Rhinitis”. Revised investigational statement by adding examples “(e.g., cryoablation using Clarifix^{®‡}, radiofrequency using RhinAer^{®‡}, or laser ablation)” for intranasal ablation and adding “chronic” to describe allergic and non-allergic rhinitis.

08/02/2023 Coding update

12/12/2023 Coding update

02/01/2024 Medical Policy Committee review

02/14/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 02/2025

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT^{®‡}), copyright 2023

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Code Type	Code
CPT	30117, 30999, 31242, 31243, 31299 Delete code effective 09/01/2023: 0442T
HCPCS	Delete code effective 01/01/2024: C9771
ICD-10 Diagnosis	J30.0-J30.9, J31.0-J31.2, R09.81, R09.82

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and

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whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

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