



Louisiana

Ablation and Surgical Treatment of Chronic Rhinitis

Policy # 00723

Original Effective Date: 05/01/2021

Current Effective Date: 11/01/2024

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**.*

Based on review of available data, the Company considers vidian neurectomy (regardless of approach) in the management of chronic sinusitis, recurrent acute sinusitis, allergic rhinitis, and all other forms of chronic rhinitis to be **investigational**.*

Background/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. 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

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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.

The nerve of the pterygoid canal, also known as the vidian nerve, supplies parasympathetic fibers to the nasal mucosa, palate, and lacrimal gland through the pterygopalatine ganglion. A vidian neurectomy diminishes autonomic supply to the nasal cavity and reduces nasal secretions. Open approaches to the pterygopalatine fossa, like transantral and transpalatal exposures, were associated with significant morbidity, including ophthalmoplegia, orbital complications, and palatal fistulae. In 1991 Kamel and Zaher introduced endoscopic transnasal vidian neurectomy in cadaveric models. This innovation paved the way for modern surgical techniques, offering a more precise and less morbid approach.

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. Adverse events must be assessed immediately (perioperative complications and postoperative pain) and over the longer term.

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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	SNOT-20: change in score of 0.8 or greater	At least 6 months or longer

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		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-22: change in score of 8.9 points	
	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
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

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In February 2019, the ClariFix™‡ 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. As per the FDA 510K

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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 patients with chronic rhinitis.

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

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

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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.

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. Out of the 3, 2 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. 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

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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 2, 1 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.

For individuals with allergic or nonallergic chronic rhinitis who receive vidian nerve resection (vidian neurectomy) the evidence is limited to case series. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Clinical studies have reported improved nasal symptom outcomes with vidian neurectomy compared to medical management or alternative surgical procedures like turbinoplasty or septoplasty. It has also been reported that endoscopic vidian neurectomy is more likely to cause dry eyes and palatal numbness. Despite the growing interest in vidian neurectomy, there remains limited evidence concerning its long-term results and potential complications. Further research is needed to comprehensively understand the procedure's efficacy and safety in the context of long-term outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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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.

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.

- 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".

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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. 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. 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."

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.

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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)	116	Apr 2024
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	36	Dec 2023

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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First published: 16 September 2023
<https://doi.org/10.1002/alr.23259>

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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 |

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- 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.
- 10/03/2024 Medical Policy Committee review
- 10/08/2024 Medical Policy Implementation Committee approval. Title changed from “Cryoablation, Radiofrequency Ablation, and Laser Ablation for Treatment of Chronic Rhinitis” to “Ablation and Surgical Treatment of Chronic Rhinitis”. Added an investigational statement for vidian neurectomy (regardless of approach) in the management of chronic sinusitis, recurrent acute sinusitis, and allergic rhinitis, and all other forms of chronic rhinitis.

Next Scheduled Review Date: 10/2025

Coding

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Ablation and Surgical Treatment of Chronic Rhinitis

Policy # 00723

Original Effective Date: 05/01/2021

Current Effective Date: 11/01/2024

attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	30117, 30999, 31242, 31243, 31299 Add code effective 11/01/2024: 64771 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 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

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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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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