Medical Policy

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

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Policy Number: 843

BCBSA Reference Number: 7.01.168 (For Plan internal use only)
NCD/LCD: N/A

Related Policies

Balloon Ostial Dilation for Treatment of Chronic and Recurrent Acute Rhinosinusitis #582
Steroid-Eluting Sinus Stents and Implants #800

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

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 non-allergic) is considered **INVESTIGATIONAL**.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is **not** a covered service.
Commercial PPO and Indemnity	This is **not** a covered service.
Medicare HMO Blue℠	This is **not** a covered service.
Medicare PPO Blue℠	This is **not** a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following CPT codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
31242	Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve
31243	Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve

Description

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 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.

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.	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-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
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

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).[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.

Summary

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.

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 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.

Policy History

Date	Action
5/2024	Annual policy review. Policy updated with literature review through December 18, 2023; references added. Policy statements unchanged.
1/2024	Clarified coding information.
4/2023	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
7/2022	Annual policy review. New investigational indications described for radiofrequency ablation and laser ablation for chronic rhinitis. Title changed to Cryoablation, Radiofrequency Ablation, and Laser Ablation for Treatment. Effective 7/1/2022.
11/2021	New medical policy describing ongoing investigational indications. Cryoablation for Chronic Rhinitis was transferred from MP #400 Medical Technology Assessment Investigational (Non-Covered) Services List.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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