BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

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

Policy #: 744
Latest Review Date: February 2022
Category: Surgery

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **cryoablation for chronic rhinitis (allergic or nonallergic)** as a **non-covered benefit** and as **investigational**.

Blue Advantage will treat **radiofrequency ablation for chronic rhinitis (allergic or nonallergic)** as a **non-covered benefit** and as **investigational**.

Blue Advantage will treat **laser ablation for chronic rhinitis (allergic and nonallergic)** as a **non-covered benefit** and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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.

Medical management is the standard of care for chronic rhinitis. Surgical options such as vidian nerve resection have been investigated for patients with chronic rhinitis refractory to multiple medical therapies, and cryoablation is proposed as a less invasive alternative. Vidian neurectomy has not been widely adopted however, due to the need for general anesthesia, risk of serious adverse events (e.g., dry eyes in up to 25% of patients), and uncertainty about the procedure's long-term benefits.

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

		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-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
	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

KEY POINTS:

This evidence review was created in September 2019 with a search of the PubMed database. The most recent literature update was performed through December 30, 2021.

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 directly comparing cryoablation with standard medical management and with longer follow-up are needed. 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 a nonrandomized study. 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 a 1-year, nonrandomized, uncontrolled study also found radiofrequency ablation associated with improvements in rTNSS scores at timepoints up to 1 year. Randomized controlled trials directly comparing radiofrequency ablation with medical management and with longer follow-up 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 nonrandomized study with 3 months followup. Although laser ablation reduced rTNSS scores, additional studies are needed to determine the efficacy and safety 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.

Practice Guidelines and Position Statements

No clinical practice guidelines on cryoablation, radiofrequency ablation, or laser ablation for chronic rhinitis were identified through clinical consultation or literature searches conducted through January 5, 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.

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

KEY WORDS:
Cryoablation, Cryosurgical ablation, cryosurgery, Chronic Rhinitis, ClariFix® (Arrinex), RhinAer® stylus, Radiofrequency ablation, Laser ablation

APPROVED BY GOVERNING BODIES:
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.

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).3, 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.

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:
CPT Codes:

30999	Unlisted procedure, nose
30117	Excision or destruction (eg, laser), intranasal lesion; internal approach
31299	Unlisted procedure, accessory sinuses

HCPCS codes:

C9771	Nasal/sinus endoscopy, cryoablation nasal tissue(s) and/or nerve(s), unilateral or bilateral

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POLICY HISTORY:

Adopted for Blue Advantage, September 2021
Medical Policy Group, September 2021
Medical Policy Group, February 2022

services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.