Corporate Medical Policy

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

File Name: cryoablation_radiofrequency_ablation_and_laser_ablation_for_treatment_of_chronic_rhinitis
Origination: 10/2021
Last Review: 8/2023

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 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.

Regulatory Status

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). 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.

Related Policies
Surgical Treatment of Sinus Disease
Balloon Ostial Dilation (Balloon Sinuplasty)

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

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

Cryoablation, radiofrequency ablation, and laser ablation for treatment of chronic rhinitis (allergic or nonallergic) is considered investigational for all applications. **BCBSNC does not provide coverage for investigational services or procedures.**

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Cryoablation, Radiofrequency Ablation, and Laser Ablation for Treatment of Chronic Rhinitis is covered

Not applicable.

When Cryoablation, Radiofrequency Ablation, and Laser Ablation for Treatment of Chronic Rhinitis is not covered

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.

Policy Guidelines

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 one year. Sustained improvement for up to two years was observed in one study, however only 62 of 98 patients 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 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 three 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 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 nonrandomized study. 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.

Evidence on laser ablation for chronic rhinitis is limited to a single small nonrandomized study with three months followup. 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 30999, 30117, 31299, C9771

Diagnoses: J30.0 – J31.0

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Food & Drug Administration. Clarifix 510(k) Premarket Notification. 2019 (K190356) https://fda.report/PMN/K190356/19/K190356.pdf. Accessed October 11, 2021.

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Specialty Matched Consultant Advisory Panel 8/2022

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Medical Director Review 8/2023

Specialty Matched Consultant Advisory Panel 8/2023

Policy Implementation/Update Information

10/19/21 New policy issued. Cryoablation for Chronic Rhinitis is considered investigational. Policy noticed 10/19/2021 for policy effective date 1/1/2022. (sk)

3/8/22 New indications for radiofrequency ablation and laser ablation for chronic rhinitis added and are considered investigational. Title changed to Cryoablation, Radiofrequency Ablation, and Laser Ablation for Treatment of Chronic Rhinitis. Notification given 3/22/2022 for policy effective date 5/31/2022. (sk)

2/7/23 Specialty Matched Consultant Advisory Panel review 8/19/2022. (sk)

9/12/23 Description and Policy Guidelines sections updated. No change to policy intent. Added Related Policies. Updated References. Medical Director Review 8/2023. Specialty Matched Consultant Advisory Panel review 8/2023. (ldh)