BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.168 Cryoablation, Radiofrequency Ablation, and Laser Ablation for Treatment of Chronic Rhinitis

Effective Policy Date: July 1, 2022

Original Policy Date: January 2022

Related Policies:

7.01.105 - Balloon Ostial Dilation for Treatment of Chronic and Recurrent Acute Rhinosinusitis

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

Description

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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.

OBJECTIVE

The objective of this evidence review is to determine if the use of cryoablation, radiofrequency ablation, and laser ablation improves the net health outcome in individuals with chronic rhinitis.

POLICY STATEMENT

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

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

In February 2019, the Clarifix ™ device (Stryker) was cleared for use in adults with chronic rhinitis through the 510(k) process (K190356).[2,] 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.

RATIONALE

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 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 small nonrandomized study with 3 months follow-up. 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.

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 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.[13,]

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.

REFERENCES

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2021	New policy	Policy created with literature review through August 3, 2021. Cryoablation for chronic rhinitis is considered investigational.
June 2022	Replace policy	Policy updated with literature review through December 30, 2021. 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