Ablation for the Treatment of Chronic Rhinitis

Effective: January 1, 2024

Next Review: October 2024
Last Review: December 2023

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

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 POLICY CRITERIA

Cryoablation, radiofrequency ablation, and/or laser ablation for chronic rhinitis (allergic or nonallergic) are considered **investigational**.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Rhinoplasty, Surgery, Policy No. 12.28
2. Balloon Ostial Dilation for Treatment of Sinusitis, Surgery, Policy No. 153
3. Surgeries for Snoring, Obstructive Sleep Apnea Syndrome, and Upper Airway Resistance Syndrome, Surgery, Policy No. 166

4. Implantable Sinus Devices for Postoperative Use Following Endoscopic Sinus Surgery and for Recurrent Sinonasal Polyposis, Surgery, Policy No. 198
5. Absorbable Nasal Implant for Treatment of Nasal Valve Collapse, Surgery, Policy No. 209

BACKGROUND

Cryosurgical ablation (known as cryosurgery) is proposed as an alternative to medical management for patients with chronic rhinitis symptoms. The procedure involves ablation of tissue in the posterior nasal nerve region, using nitrous oxide to freeze the nasal tissue and cause nerve damage. The procedure 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.[1]

REGULATORY STATUS

In February 2019, the Clarifix® device 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.

EVIDENCE SUMMARY

CRYOABLATION

SYSTEMATIC REVIEWS

Desai (2023) published a systematic review of eight studies including 472 patients receiving cryoablation for the treatment of chronic rhinitis.[3] The results of the review indicated a significant reduction in post-treatment scores in all eight included studies. This review included a single RCT and seven additional non-randomized, non-comparative studies, several of which had small sample sizes of 30 or less.

Kompelli (2018) conducted a systematic review of cryoablation for chronic rhinitis, identifying 15 nonrandomized studies enrolling a total of 1266 patients.[4] Across all of the studies, 63% to 95.7% of patients noted improvement in overall symptoms, and no serious adverse events were reported. The authors concluded that although the procedure appeared to be safe and efficacious, methodological weaknesses and heterogeneity limited the strength of conclusions that could be drawn from this body of evidence. In addition to their uncontrolled design, most studies were outdated, published between 1977 and 1997. Only one study, reported by Hwang (2017) used an FDA-cleared device and a validated outcome measure.[5] This study is discussed in detail, along with other recent nonrandomized studies, in the following section.

RANDOMIZED CONTROLLED TRIALS

Stolovitsky (2021) conducted an RCT comparing radiofrequency ablation using the RhinAer device with sham treatment.[6] The trial enrolled 117 adults (age, 18 to 85 years; mean age, 57

years) with chronic rhinitis. Use of medication to treat chronic rhinitis was allowed in both groups. Based on an intention to treat analysis that accounted for all randomized participants, after 3-months follow-up, the proportion of participants with a ≥30% improvement in rTNSS score was higher in the active radiofrequency ablation group (66.7%; 95% CI, 55.1% to 76.9%) than in the sham group (41.0%; 95% CI, 25.6% to 57.9%; p=.01). A similar number of participants in the active (9.1% [7/77]) and sham (12.8% [5/39]) groups increased their medication use during the study (Table 12). The study was unblinded at 3 months, and individuals in the control group were allowed to crossover to the active intervention group.

Takashima (2022) reported 12-month follow-up for patients (n=77) initially randomized to the active intervention group. Study results for the active intervention group at 6- and 12-months are reported in Table 12. Treatment response and mean change from baseline remained stable through 12 months in the active intervention group, while concomitant medication use increased. The study is ongoing, with planned 3-year follow-up.

NONRANDOMIZED STUDIES

Three recent single arm, nonrandomized studies including 149 patients, reported in four publications, have evaluated cryoablation for patients with chronic rhinitis. The largest study (N = 98) was reported by Chang (2020)[7], with 2-year follow-up data on a subset of patients (n = 62) reported by Ow (2021)[8]. Scores on the rTNSS improved significantly over baseline at one month, three months, six months, and nine months, and improvements were sustained for up to two years among those patients who enrolled in the follow-up study. Smaller single-arm studies reported by Hwang (2017)[5] and Gerka Stuyt (2021)[9] also reported improvements in symptoms from baseline. Chang (2020) reported two serious procedure-related adverse events: severe epistaxis occurring on posttreatment day 19 due to a pledget inadvertently left in the nasal cavity from the day of treatment, and one case of mild epistaxis occurring on post-treatment day 36 which resolved with in-office cautery. Of 72 patients completing a telephone questionnaire about procedure-related discomfort, 56 (77.8%) experienced some degree of pain or discomfort. Seventeen patents reported severe headache, five reported severe nasal pain, and two reported severe sinus pain.[7] No serious adverse events were reported in the other studies.

Key limitations of these studies include no comparison groups, nonrandomization, and small sample size. A major limitation was their uncontrolled, open-label design. Additionally, loss to follow-up was high and MCID were not pre-specified for important outcome measures. Randomized controlled trials are needed to confirm improvements in symptom scores observed in nonrandomized studies.

SUMMARY OF EVIDENCE

For individuals with chronic rhinitis who receive cryoablation, the evidence includes 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. Randomized controlled trials are needed to confirm improvements reported in nonrandomized studies. 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.

RADIOFREQUENCY ABLATION

RANDOMIZED CONTROLLED TRIALS

Stolovitsky (2021) conducted an RCT comparing radiofrequency ablation using the RhinAer device with sham treatment.[9,] The trial enrolled 117 adults (age, 18 to 85 years; mean age, 57 years) with chronic rhinitis. Use of medication to treat chronic rhinitis was allowed in both groups (Table 11). Based on an intention to treat analysis that accounted for all randomized participants, after 3-months follow-up, the proportion of participants with a ≥30% improvement in rTNSS score was higher in the active radiofrequency ablation group (66.7%; 95% CI, 55.1% to 76.9%) than in the sham group (41.0%; 95% CI, 25.6% to 57.9%; p=.01). A similar number of participants in the active (9.1% [7/77]) and sham (12.8% [5/39]) groups increased their medication use during the study (Table 12). The study was unblinded at 3 months, and individuals in the control group were allowed to crossover to the active intervention group.

Takashima (2022) reported 12-month follow-up for patients (n=77) initially randomized to the active intervention group.[10] Study results for the active intervention group at 6- and 12-months were shown to be different across treatment and sham groups. Treatment response and mean change from baseline remained stable through 12 months in the active intervention group, while concomitant medication use increased. Follow-up is only reported for the treatment group in this study and excludes the sham group. Additional long-term follow-up with appropriate comparators, such as carefully controlled medical management, are needed.

NONRANDOMIZED STUDIES

The effectiveness of radiofrequency ablation with the RhinAer device has been assessed in two industry-sponsored, nonrandomized, uncontrolled, open-label studies. Both studies included patients with chronic rhinitis. Lee (2022) enrolled 129 patients and reported outcomes of radiofrequency ablation up to 6 months.[11] Ehmer (2021) enrolled 50 patients, 47 of whom had 1-year follow-up; 2-year results were subsequently reported in an extension study of 34 patients.[12, 13] Both studies found symptom response rates and the proportion of responders durable at time points ranging from 3 months to 2 years. Lee et al reported quality of life outcomes using the miniRQLQ, a validated measure with an established MCID of 0.4 points. At 3 and 6 months post-treatment, the mean change in miniRQLQ scores from baseline was -1.6 and -1.8, respectively, indicating clinically important improvement in symptom-related quality of life. These studies are limited by nonrandomized, open-label designs and lack of control groups.

LASER ABLATION

NONRANDOMIZED STUDIES

Krespi (2020) conducted a nonrandomized study evaluating laser ablation for treatment of chronic rhinitis.[14] The study enrolled 32 adults treated with an endoscopic diode laser in an outpatient setting. Duration of follow-up was 3 months. Mean rTNSS was reduced from 6.0 (standard deviation [SD], 0.7) at baseline to 2.3 (SD, 0.4) at 3-month follow-up. Adverse events were not reported. The study had multiple limitations, including the small sample size, uncontrolled design, and duration of follow-up less than 6 months. Randomized studies comparing laser ablation with medical management and with longer follow-up are needed to determine efficacy and safety.

PRACTICE GUIDELINE SUMMARY

No practice guidelines were identified.

SUMMARY

There is not enough research to show that cryoablation, radiofrequency ablation, or laser ablation for chronic rhinitis improves health outcomes. In addition, no practice guidelines recommend cryoablation, radiofrequency ablation, or laser ablation for chronic rhinitis. Therefore, cryoablation, radiofrequency ablation, or laser ablation for chronic rhinitis is considered investigational.

REFERENCES

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CODES

Codes	Number	Description
CPT	30999	Unlisted procedure, nose
	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
	31299	Unlisted procedure, accessory sinuses
HCPCS	~~C9771~~ None	~~Nasal/sinus endoscopy, cryoablation nasal tissue(s) and/or nerve(s), unilateral or bilateral~~ (Deleted 01/01/2024)

Date of Origin: *December 2021*