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

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Cryoablation for chronic rhinitis (allergic or nonallergic) **is considered experimental, investigational, and/or unproven.**

Radiofrequency ablation for chronic rhinitis (allergic or nonallergic) **is considered experimental, investigational, and/or unproven.**

Laser ablation for chronic rhinitis (allergic and nonallergic) **is considered experimental, investigational, and/or unproven.**

Policy Guidelines

None.

Description

Background

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	Timing

			Difference	
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]). 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

Regulatory Status

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.

Rationale

Medical policies review the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Ablative Procedures for Chronic Rhinitis

Clinical Context and Therapy Purpose

The purpose of ablative procedures (cryoablation, radiofrequency ablation, and laser ablation) in individuals with chronic rhinitis who are refractory to medical management is to provide a treatment option that is an alternative to or an improvement on existing surgical invasive options. Chronic rhinitis is a common medical condition that can severely impact quality of life. While the initial medical treatment comprising of pharmacotherapy is adequate for majority of individuals, approximately 10% to 22% of individuals may still have persistent symptoms despite medical therapy. Treatment options for individuals with chronic rhinitis that is refractory to medical management are limited and include vidian neurectomy and invasive surgical options to block posterior nasal nerve. However, these surgical interventions are associated with high frequency of post operative complications and requirement of general anesthesia. To overcome some of these limitations, minimally invasive ablative procedures using cryo, radiofrequency or laser based-interventions have been developed. These interventions do not require general anesthesia and can be performed using an endoscope. In order to evaluate if these minimally invasive ablative interventions improve the net health outcome, trials must enroll individuals with chronic rhinitis who are refractory to medical management and compare these ablative interventions with sham surgery or conventional surgical procedures to block posterior nasal nerve ideally in the setting of a RCT. Nonrandomized trials in similar populations can inform the durability of response after initial efficacy is demonstrated via RCTs.

The following PICO was used to select literature to inform this policy.

Population

The relevant population of interest is adults age 18 years and older with chronic allergic or nonallergic rhinitis refractory to medical management.

Rhinitis is defined as symptomatic inflammation of the paranasal sinuses and nasal cavity. Chronic rhinitis is usually defined as rhinorrhea with or without nasal congestion symptoms despite medical therapy lasting longer than 3 months. Allergic rhinitis is defined as an

immunoglobulin E (IgE)-mediated inflammatory response of the nasal mucous membranes after exposure to inhaled allergens. Symptoms include rhinorrhea (anterior or post-nasal drip), nasal congestion, nasal itching, and sneezing. Allergic rhinitis can be seasonal or perennial, with symptoms being intermittent or persistent.

Interventions

The therapies being considered are cryoablation, radiofrequency ablation and laser ablation. Procedure involves destruction of tissue in the posterior nasal nerve region and is thought to correct the imbalance of autonomic input to the nasal mucosa, reducing nasal antigen responses and vascular hyperreactivity.

- I. Cryoablation: The ClariFix system uses nitrous oxide to freeze nasal tissue, causing nerve damage. The procedure can be performed under local anesthesia.
- II. Radiofrequency ablation: The RhinAer Stylus is a handheld device designed for use under local anesthesia. The device delivers radiofrequency energy at a temperature of 60 degrees Celsius to the posterior nasal nerve region.
- III. Laser ablation: There are currently no laser ablation devices with FDA clearance for treatment of chronic rhinitis.

Comparators

The comparator of interest is other surgical procedures.

Outcomes

The general outcomes of interest are symptoms, change in disease status, quality of life, and treatment-related morbidity.

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 above in Table 1 (see Description). Adverse events can be assessed immediately (perioperative complications and postoperative pain) or over the longer term.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

- Studies with duplicative or overlapping populations were excluded.

Cryoablation

Randomized Controlled Trials

One RCT conducted by Del Signore et al. (2021) (9) compared cryoablation using the ClariFix device with a sham procedure in 133 adults (age ≥ 21 years) with chronic rhinitis (Tables 2 and 3). Duration of follow-up was 3 months. Although the trial results showed a statistically significant difference in response rate in favor of cryoablation group compared to the sham group, it is unclear if the trial enrolled individuals with chronic rhinitis were refractory to medical management. This limitation precludes interpretation of results.

Table 2. RCT of Cryoablation for Chronic Rhinitis - Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Del Signore et al. (2021) (9)	U.S.	12 sites	Not reported	N=133 adults with chronic rhinitis with moderate to severe symptoms (rTNSS rhinorrhea subscore ≥ 2 , congestion subscore ≥ 2 , and total score ≥ 4) Baseline patient characteristics: <ul style="list-style-type: none"> • 66/133 had documented responses to a previous trial of ipratropium; • Of these 66, 16.7% were classified as "nonresponders", 81.8% were classified as "responders", and 1.5% had an unknown response • 47.1% of patients in the active group and 49.2% 	Cryoablation with the ClariFix device; n=68	Sham cryoablation; n=65

				<p>of patients in the sham group were using any allergy/rhinitis medication at baseline</p> <ul style="list-style-type: none"> • Documented trial and failure of medical management alone was not an inclusion criteria • Mean age: 55 years • 58% female • 89% White, 6% Black, 3% Asian, <1% American Indian/Alaska Native <p>Primary endpoint:</p> <ul style="list-style-type: none"> • Comparison between the treatment and sham arms for the percentage of responders at 90 days. Responders were defined as participants with a 30% or greater reduction in rTNSS relative to baseline. 	
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N: number(s); rTNSS: reflective Total Nasal Symptom Score; U.S.: United States; RCT: randomized controlled trial.

Table 3. RCT of Cryoablation for Chronic Rhinitis - Results

Study	Symptoms (Proportion with $\geq 30\%$ Improvement)	Symptoms (rTNSS Mean Change from Baseline)	RQLQ Score (Mean Change from Baseline)	Concomitant Allergy/Rhinitis Medication Use (Proportion)	Adverse Events
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	(in rTNSS from Baseline)			with Use at 3 Months)	
Del Signore et al. (2021) (9)					
Cryoablation with ClariFix	73.4% (47/64)	-3.7 (95% CI, -4.3 to -3.1)	-1.5 (95% CI, -1.8 to -1.2)	40.0% (26/65)	Post-procedural pain: 36.8% (25/68) Headache: 5.9% (4/68)
Sham cryoablation	36.5% (23/63)	-1.8 (95% CI, -2.5 to -1.1)	-0.8 (95% CI, -1.1 or -0.5)	34.4% (22/64)	Post-procedural pain: 1.5% (1/65) Headache: 0% (0/68)
p-value	<.001	<.001	<.001	.51	Post-procedural pain: .002 Headache: .15

CI: confidence interval; RQLQ: Rhinoconjunctivitis Quality of Life Questionnaire; rTNSS: reflective Total Nasal Symptom Score; RCT: randomized control trials.

The purpose of the study limitations tables (see Tables 4 and 5) is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of evidence supporting the position statement. The major limitation is the lack of clarity on whether the enrolled study participants were refractory to medical management or not. An adequately powered randomized sham-controlled trial that enrolls participants who are refractory to medical management is necessary to clearly ascertain the effect of cryoablation on the net health outcome in patients with chronic rhinitis.

Table 4. Study Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
Del Signore et al. (2021) (9)	1. The intended use population is unclear (it is not clear if the trial enrolled participants were refractory to medical management).		2: Other (An alternative comparator could be other surgical interventions).		1, 2: Follow-up limited to 3 months.

	3. The studies were all comprised of racially homogenous participants with over 89% White and thus the conclusions may not be generalizable to the U.S. population.				
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The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^aPopulation key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.

^bIntervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.

^cComparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

^dOutcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.

^eFollow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 5. Study Design and Conduct Limitations

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Del Signore et al. (2021) (9)	3. Allocation concealment unclear.	2, 4: Patients were blinded; blinding was not reported for study staff or outcome assessors.				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^aAllocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.

^bBlinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

^cSelective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.

^dData Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6.

Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.

^ePower key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.

^fStatistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Nonrandomized Studies

Three single-arm prospective studies including 149 patients evaluated efficacy and safety of cryoablation for patients with chronic rhinitis. Characteristics and results of these studies are shown in Tables 6a/6b and 7a/7b. Out of the 3 studies, 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. Key limitations of these studies are summarized in Tables 8 and 9. Although all 3 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 and minimally clinically important differences (MCID) were not prespecified for important outcome measures.

Table 6a. Nonrandomized Studies of Cryoablation for Chronic Rhinitis - Characteristics

Study	Study Design	Location	Dates	Inclusion/Exclusion Criteria
Hwang et al. (2017) (10)	Prospective, single-arm, open-label	3 sites, U.S.	Not reported	<p>Inclusion:</p> <ul style="list-style-type: none">• Adult patients with rhinorrhea with or without nasal congestion symptoms despite medical therapy longer than 3 months• Minimum rhinorrhea and/or congestion subscores of 2 as part of the TNSS <p>Exclusion:</p> <ul style="list-style-type: none">• Patient-reported history of chronic rhinosinusitis• Severe septal deviation precluding visualization of the middle meatus• Endoscopic findings of polyps or purulence in the middle meatus, septal perforation, or prior sinus or nasal surgery that significantly altered the anatomy of the posterior nasal cavity
Chang et al. (2020) (11),	Prospective, single-arm,	6 sites, U.S.	2017-2020	Inclusion:

Ow et al. (2021) (12); NCT03181594	open-label			<p>Age 21 years or older, with all of the following:</p> <ul style="list-style-type: none"> • Moderate-to-severe symptoms of rhinorrhea (defined as individual symptom rating of 2 or 3 on the rTNSS) • Mild-to-severe symptoms of congestion (individual symptom rating of 1, 2, or 3 on the rTNSS) and minimum total score of 4 (out of 12) on the rTNSS at the time of the treatment visit • Chronic symptoms for 6 months or longer • Inadequate symptom relief from at least 4 weeks of treatment with intranasal steroids <p>Exclusion:</p> <ul style="list-style-type: none"> • Clinically significant nasal or sinus anatomy that limits the ability to visualize/access the posterior nasal cavity or to accommodate the device • Rhinitis medicamentosa, moderate-to-severe ocular symptoms, nasal or sinus infection, or recent history of epistaxis • Coagulation disorder or anti-coagulant treatment • Known sensitivity to the planned anesthetic agent(s) • Cryoglobulinemia, paroxysmal cold hemoglobinuria, cold urticaria, or Raynaud's disease • Pregnancy
Gerka Stuyt et al. (2021) (13)	Prospective, single-arm, open-label	7 sites, U.S.	Not reported	<p>Inclusion:</p> <ul style="list-style-type: none"> • Age over 18 years, diagnosis of chronic rhinitis, and failure of medical therapy for a duration of at least 3 months <p>Exclusion:</p>

				<ul style="list-style-type: none"> • Active or chronic nasal/sinus infections • Structural abnormalities restricting device from accessing the posterior middle meatus • Cerebrospinal fluid leaks • Rhinitis medicamentosa • Confounding systemic conditions (i.e., granulomatosis with polyangiitis, Sjogren's syndrome, cystic fibrosis, primary ciliary dyskinesia) • Active intranasal recreational drug use • Recurrent history of epistaxis, coagulopathy, pregnancy, or nasopharyngeal malignancy
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rTNSS: Reflective Total nasal symptom score; SD: standard deviation; U.S.: United States; TNSS: Total Nasal Symptom Score.

Table 6b. Nonrandomized Studies of Cryoablation for Chronic Rhinitis – Characteristics

Study	Patient Characteristics	Treatment	Duration of Follow-up
Hwang et al. (2017) (10)	N=27 <ul style="list-style-type: none"> • Mean age, 53.3 (SD, 3.3) years • 63% female • Race not reported • 48% were atopic 	Cryoablation performed in an office setting under local anesthesia	1 year
Chang et al. (2020) (11), Ow et al. (2021) (12); NCT03181594	N=98 <ul style="list-style-type: none"> • Mean age, 58.6 (SD, 16.2) years • 64.3% female • 91.8% identified as Caucasian • 70 (71.4%) with nonallergic rhinitis and 28 (28.6%) with allergic rhinitis 	Cryoablation performed in an office setting under local anesthesia	2 years (n=62) Primary data collection at 9 months
Gerka Stuyt et al. (2021) (13)	N=24	Cryoablation	1 year

	<ul style="list-style-type: none"> • Mean age 60.04 (SD, 16.7) years • 50% female • Race not reported • 16 (67%) with non-allergic rhinitis; 3 (12.5%) with allergic; 5 (20.8%) with mixed 	performed in an office setting under local anesthesia	
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N: number; SD: standard deviation.

Table 7a. Nonrandomized Studies of Cryoablation for Chronic Rhinitis - Results

Study	Symptoms	Quality of Life	Concomitant medication use
Hwang et al. (2017) (10)	<p>Mean reduction from baseline in rTNSS (SD):</p> <ul style="list-style-type: none"> • 30 days (n=27): 2.6 (0.3); p<.001 • 90 days (n=27): 2.7 (0.4); p<.001 • 180 days (n=21): 2.3 (0.5); p<.001 • 1 year (n=15): 1.9 (0.3); p<.001 	Not assessed	Not assessed
Chang et al. (2020) (11) (Outcomes through 9 months), Ow et al. (2021) (12) (Outcomes from 12 through 24 months); NCT03181594	<p>Mean change from baseline in rTNSS score (SD):</p> <ul style="list-style-type: none"> • 30 days (n=97): 2.9 (1.9); p<.001 • 90 days (n=96): 3.0 (2.3); p<.001 • 180 days (n=95): 3.0 (2.1); p<.001 • 270 days (n=92): 3.0 (2.4); p<.001 <p>Median change from baseline in rTNSS score (IQR):</p>	<p>Mean change from baseline in RQLQ score (SD)</p> <ul style="list-style-type: none"> • 90 days (n=96): 1.5 (1.2); p<.001 <p>Median change from baseline in RQLQ score (IQR)</p> <ul style="list-style-type: none"> • 18 months (n=54): -2.1 (-3.1, -1.1); p<.001 • 24 months (n=57): -2.1 (-3.0, -0.8); p<.001 	<p>5 patients started using ipratropium bromide during the study period due to persistent rhinitis symptoms. Of 154 medications that 98 patients were using at baseline, 33 (21.4%) medications were discontinued during the study period</p>

	<ul style="list-style-type: none"> • 12 months (n=54): -3.0 (-4.0, -1.0); p<.001 • 18 months (n=54): -3.0 (-5.0, -2.0); p<.001 • 24 months (n=57): -4.0 (-5.0, -2.0); p<.001 		
Gerka Stuyt et al. (2021) (13)	<p>Mean 12-hour TNSS score (SD):</p> <ul style="list-style-type: none"> • Baseline: 6.92 (2.8); p<.001 • 30 days: 3.17 (2.4); p<.001 • 90 days: 2.92 (1.4); p<.001 • 1 year: 3.08 (2.6); p<.001 <p>Mean 2-week TNSS score (SD):</p> <ul style="list-style-type: none"> • Baseline: 7.75 (3.1); p<.001 • 30 days: 3.79 (2.1); p<.001 • 90 days: 3.88 (1.8); p<.001 • 1 year: 3.76 (2.1); p<.001 	Not assessed	12/18 patients assessed (66.7%) had eliminated or reduced the use of medication to manage their rhinitis when compared to their preoperative baseline

IQR: interquartile range; RQLQ: Rhinoconjunctivitis Quality of Life Questionnaire; rTNSS: reflective Total Nasal Symptom Score; SD: standard deviation; TNSS: Total nasal symptom score.

Table 7b. Nonrandomized Studies of Cryoablation for Chronic Rhinitis- Results

Study	Adverse events	Periprocedural Pain
Hwang et al. (2017) (10)	Day 1 post procedure: 100% reported no or mild bleeding, 44% severe ear blockage, 4% severe nasal dryness; there was 1 moderate nosebleed 27 days post-procedure	74% reported no or mild pain/discomfort

Chang et al. (2020) (11) (Outcomes through 9 months), Ow et al. (2021) (12) (Outcomes from 12 through 24 months); NCT03181594	31 treatment-related adverse events (2 serious: nosebleed)	16 of 72 (22.2%) patients assessed reported no pain or discomfort 17 reported severe headache, 5 severe nasal pain, 2 severe sinus pain
Gerka Stuyt et al. (2021) (13)	No patients developed epistaxis, palate numbness, or dry eye complications	Patients experienced only minimal discomfort during and post-procedure

Table 8. Study Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
Hwang et al. (2017) (10)	1. The intended use population is unclear (it is not clear if the trial enrolled participants who were refractory to medical management)				
Chang et al. (2020) (11), Ow et al. (2021) (12): NCT03181594				5. Clinically significant difference for Total Nasal Symptom Score was not prespecified	
Gerka Stuyt et al. (2021) (13)					

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 9. Study Design and Conduct Limitations

Study	Hwang et al. (2017) (10)	Chang et al. (2020) (11), Ow et al. (2021) (12); NCT03181594	Gerka Stuyt et al. (2021) (13)
Allocation^a	1. Not randomized	1. Not randomized	1. Not randomized
Blinding^b	1. Open label	1. Open label	1. Open label
Selective Reporting^c	1. Not registered		1. Not registered
Data Completeness^d	1. 6/27 (22%) lost to follow-up at 180 days, 12 (44%) lost to follow-up at 1 year	1. Through 9 months, 7/98 (7.1%) excluded from analysis: 4 lost to follow-up, 3 excluded due to resumption of ipratropium use during the study period 62 of 98 patients (63.2%) enrolled in the longer-term follow-up study 72/98 (73.5%) patients completed post-procedure pain questionnaire	1. 6 of 24 lost to follow-up at 1 year (25%)
Power^e	1. Power calculation not reported	1. Power calculation not reported	1. Power calculation not reported
Statistical^f			

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

^b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

^d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

^f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Cryoablation

Evidence for the use of cryoablation for the treatment of individuals with chronic rhinitis who are refractory to medical management includes one RCT and several nonrandomized studies. One RCT that compared cryoablation using the ClariFix device with a sham procedure showed a statistically significant difference in response rate in favor of the cryoablation group compared to the sham group. However, it is unclear if the trial enrolled individuals with chronic rhinitis were refractory to medical management. This limitation precludes meaningful interpretation of these results as the intended use of the 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. Two (of 3) 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 to 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 a lack of a comparator group and the open-label nature of the study design, which likely introduces biases. Additionally, loss to follow-up was high.

Radiofrequency Ablation

Randomized Controlled Trials

Stolovitsky et al. (2021) conducted an RCT comparing radiofrequency ablation using the RhinAer device with sham treatment. (14) The trial enrolled 117 adults (age, 18 to 85 years; mean age, 57 years) with chronic rhinitis. Use of medication to treat chronic rhinitis throughout the trial was allowed in both groups (Table 10). Approximately 72.7% of patients in the active treatment group and 71.8% in the sham group were using antihistamines at baseline. Although the trial results showed a statistically significant difference in response rate in favor of the radiofrequency ablation group compared to the sham group, it is unclear if the trial enrolled individuals with chronic rhinitis who were refractory to medical management. This limitation precludes interpretation of results. The study was unblinded at 3 months, and individuals in the control group were allowed to crossover to the active intervention group. Takashima et al. (2022) and Takashima et al. (2024) reported 12- and 24-month follow-up for patients initially randomized to the active intervention group. (15, 16) Study results for the active intervention group at 6-, 12-, and 24-months are reported in Table 11. The study is ongoing, with planned 3-year follow-up.

Table 10. RCT of Radiofrequency Ablation for Chronic Rhinitis – Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Stolovitsky et al. (2021) (14)	U.S.	16 sites	July 2020 to	N=117 adults with ≥6 months chronic rhinitis	Radiofrequency ablation with	Sham radio-frequency

			December 2020	<p>with moderate to severe symptoms (rTNSS rhinorrhea subscore 2 to 3, congestion subscore 1 to 3, and total score ≥ 6)</p> <ul style="list-style-type: none"> • Mean age: 57 years • 65% female • 90% White, 6% Black, 1% Asian, 3% mixed race or not reported 	the RhinAer device; n=77	ablation; n=39
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rTNSS: Reflective Total nasal symptom score; RCT: randomized controlled trials; U.S.: United States; N/n: number.

Table 11. RCT of Radiofrequency Ablation for Chronic Rhinitis – Results

Study	Symptoms (Proportion with $\geq 30\%$ Improvement in rTNSS from Baseline)	Symptoms (rTNSS Mean Change from Baseline)	Concomitant Medication Use (Proportion with Increased Use)	Periprocedural Pain (VAS 0-10)	Adverse Events
Stolovitsky et al. (2021) (14), Takashima et al. (2022) (15), and Takashima et al. (2024) (16)					
Radiofrequency ablation with RhinAer	<ul style="list-style-type: none"> • 3 months: 67.5% (95% CI, 55.9 to 77.8) • 6 months: 75.0% (95% CI, 63.4 to 84.5) • 12 months: 80.6% (95% CI, 69.1 to 89.2) • 24 months: 87.3% (95% 	<ul style="list-style-type: none"> • 3 months: -3.6 (95% CI, -4.2 to -3.0) • 6 months: -4.4 (95% CI, -5.0 to -3.8) • 12 months: -4.8 (95% CI, -5.5 to -4.1) • 24 months: -5.3 (95% CI, -5.8 to -4.8) 	<ul style="list-style-type: none"> • 3 months: 9.1% (7/77) • 6 months: 16.8% (13/77) • 12 months: 20.8% (16/77) • 24 months: $\leq 6.3\%$ ($<5/77$) 	<ul style="list-style-type: none"> • Immediately post-procedure: 2.1 (95% CI, 1.6 to 2.6) 	<ul style="list-style-type: none"> Any treatment-related adverse event 12 months: 10.4% (8/77)

	CI, 78 to 93.8)				
Sham radiofrequency ablation	3 months: 41.0%	3 months: -2.2 (95% CI, -3.2 to -1.3)	12.8% (5/39)	Immediately post-procedure: 1.4 (95% CI, 0.7 to 2.0)	Not reported
p-value	3 months: .009	3 months: .013	3 months: .53	Immediately post-procedure: .078	Not calculable

CI: confidence interval; rTNSS: reflective Total Nasal Symptom Score; VAS: visual analog scale; RCT: randomized control trial.

The purpose of the study limitations tables (see Tables 12 and 13) is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of evidence supporting the position statement. The major limitation is the lack of clarity on whether the enrolled study participants were refractory to medical management or not. An adequately powered randomized sham-controlled trial that enrolls participants who are refractory to medical management is necessary to clearly ascertain effect of radiofrequency ablation on the net health outcome in patients with chronic rhinitis.

Table 12. Study Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
Stolovitsky et al. (2021) (14)	1. The intended use population is unclear (it is not clear if the trial enrolled participants who were refractory to medical management).		2: Other (An alternative comparator could be other surgical interventions)	3: Only adverse events deemed related to treatment were reported for the active intervention group; there was no adverse event reporting for the control group.	1, 2: Follow-up of randomized active treatment and control groups limited to 3 months; 12-month follow-up reported in Takashima et al. (2022) provided for active treatment group only.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^aPopulation key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.

^bIntervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.

^cComparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

^dOutcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.

^eFollow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 13. Study Design and Conduct Limitations

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Stolovitsky et al. (2021) (14)	3: Allocation concealment unclear	2, 4: Patients were blinded; blinding was not reported for study staff or outcome assessors; it is unclear if the treating physician was the outcome assessor; patients were unblinded at 3 months.				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^aAllocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.

^bBlinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

^cSelective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.

^dData Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.

^ePower key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.

^fStatistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Nonrandomized Studies

Two single-arm prospective studies including 179 patients evaluated efficacy and safety of radiofrequency ablation for patients with chronic rhinitis. (17, 18) Characteristics and results of these studies are shown in Tables 14a/14b and 15a/15b. One (of 2) studies enrolled individuals who were refractory to medical management. (18) Refractory was defined as an inadequate response after at least 4 weeks usage of intranasal steroids and rTNSS score ≥ 6 . Results of long-term follow-up for 2-years were reported in an extension study of 34 patients. (19) Key limitations of these studies are summarized in Tables 16 and 17. Although both 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 and minimally clinically important differences were not prespecified for important outcome measures.

Table 14a. Nonrandomized Studies of Radiofrequency Ablation for Chronic Rhinitis - Characteristics

Study	Study Design	Location	Dates	Inclusion/Exclusion Criteria
Lee et al. (2022) (17)	Prospective, single-arm, open label	16 sites, U.S. and Germany	2020-2021	<p>Adults with chronic rhinitis ≥ 6 months duration and total rTNSS ≥ 6, rTNSS rhinorrhea subscore 2 to 3, and rTNSS congestion subscore 1 to 3</p> <ul style="list-style-type: none"> • Documented trial and failure of medical management was not an inclusion criterion
Ehmer et al. (2021 [18] and 2022 [19])	Prospective, single-arm, open label	5 sites, U.S.	2018-2021	Chronic rhinitis of at least 6 months duration refractory to medical management (defined as an inadequate response after at least 4 weeks usage of intranasal steroids) and rTNSS score ≥ 6

rTNSS: reflective Total Nasal Symptom Score; U.S.: United States.

Table 14b. Nonrandomized Studies of Radiofrequency Ablation for Chronic Rhinitis - Characteristics

Study	Patient Characteristics	Treatment	Duration of Follow-up
Lee et al. (2022) (17)	N=129 Mean age 57.9 years (SD, 13.4); 54% female; 91% White, 4% Black, 3% Asian, 2% other race/ethnicity; 72%	Radiofrequency ablation with the RhinAer device heated to 60° C performed in an office setting	6 months

	<p>nonallergic rhinitis, 8% allergic rhinitis, <1% mixed allergic and nonallergic rhinitis, 20% unknown etiology</p> <ul style="list-style-type: none"> • 50% of patients at baseline were on antihistamines • 64.1% of patients at baseline were on intranasal steroids • 25.8% of patients at baseline were on intranasal anticholinergic sprays 		
Ehmer et al. (2021 [18] and 2022 [19])	<p>N=50</p> <ul style="list-style-type: none"> • Mean age 57.9 years (SD, 11.9); • 42% female; • 94% White, 4% Asian, 2% American Indian/Alaska Native; • 42% allergic rhinitis, 34% non-allergic rhinitis, 24% unknown etiology 	<p>Radiofrequency ablation with the RhinAer device heated to 60° C performed in an office setting</p>	2 years

SD: standard deviation; N: number.

Table 15a. Nonrandomized Studies of Radiofrequency Ablation for Chronic Rhinitis - Results

Study	Symptoms	Concomitant Medication Use
Lee et al. (2022) (17)	<p>Mean rTNSS score:</p> <p>A. Baseline: 7.8</p> <p>B. 3 months: 3.6; mean change from baseline - 4.2 (95% CI, -4.6 to -3.7)</p> <p>C. 6 months: 2.9; mean change from baseline - 4.9 (95% CI, -5.5 to -4.3)</p> <p>Proportion of responders based on ≥30% improvement from baseline in rTNSS score:</p>	

	<p>A. 3 months: 76.2% (95% CI, 68.1 to 82.8) B. 6 months: 83.5% (95% CI, 75.8 to 89.0)</p>	
Ehmer et al. (2021 [18] and 2022 [19])	<p>Mean rTNSS score:</p> <ul style="list-style-type: none"> Baseline: 8.5 (95% CI, 8.0 to 9.0) 12 weeks: 3.4 (95% CI, 2.8 to 4.1) 1 year: 3.6 (95% CI, 3.0 to 4.3) 2 years: 2.9 (95% CI, NR); mean change from baseline -5.5 (95% CI, -6.4 to -4.6) <p>Proportion of responders based on $\geq 30\%$ improvement from baseline in rTNSS score:</p> <ul style="list-style-type: none"> 12 weeks: 87.8% (95% CI, 75.8 to 94.3) 26 weeks: 91.7% (95% CI, 80.4 to 96.7) 1 year: 80.9% (95% CI, 67.5 to 89.6) 2 years: 88.2% (95% CI, 73.4 to 95.3) 	<p>Proportion with increased concomitant medication use at 1 year:</p> <ul style="list-style-type: none"> Antihistamines/decongestants: 12.8% Decongestant nasal spray: 4.3% Steroid nasal spray: 6.4%

CI: confidence interval; NR: not reported; rTNSS: reflective Total Nasal Symptom Score.

Table 15b. Nonrandomized Studies of Radiofrequency Ablation for Chronic Rhinitis - Results

Study	Quality of Life	Adverse Events	Periprocedural Pain
Lee et al. (2022) (17)	<p>MiniRQLQ score, adjusted mean change from baseline:</p> <ul style="list-style-type: none"> 3 months: -1.6 (95% CI, -1.8 to -1.4) 6 months: -1.8 (95% CI, -2.1 to -1.5) <p>MiniRQLQ, proportion of patients with ≥ 0.4 point improvement from baseline:</p> <ul style="list-style-type: none"> 3 months: 80.3% (95% CI, 72.6 to 86.3) 6 months: 87.7% (95% CI, 80.7 to 92.4) 	<p>Any treatment-related adverse event: 6.2% (8/129)</p>	<p>Mean pain score (VAS 0 to 100): 19.0 (95% CI, 14.7 to 23.3)</p>
Ehmer et al. (2021 [18] and 2022 [19])		<p>1 year: Serious adverse events: 2 (N=NR); any adverse event: 16 (N=8)</p> <p>2 years: NR; narrative report of no treatment-related adverse</p>	<p>Mean post-treatment pain score (VAS 0 to 100): 18.1</p>

		events from year 1 to year 2	
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CI: confidence interval; miniRQLQ: mini Rhinoconjunctivitis Quality of Life Questionnaire; NR: not reported; VAS: visual analog score.

Table 16. Study Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
Lee et al. (2022) (17)	1. The intended use population is unclear (it is not clear if the trial enrolled participants who were refractory to medical management)				
Ehmer et al. (2021 [18] and 2022 [19])					

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^aPopulation key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

^bIntervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

^cComparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

^dOutcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported.

^eFollow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 17. Study Design and Conduct Limitations

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Lee et al. (2022) (17)	1. Not randomized	1. Open label			1. Power calculations not reported	
Ehmer et al. (2021)	1. Not randomized	1. Open label		1. High loss to follow-up or missing data	1. Power calculations not reported	

[18] and 2022 [19])				(of the 50 participants in the original study, 34 reconsented for the extension study and completed the 24-month follow-up visit)		
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The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

^b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

^d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

^f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Radiofrequency Ablation

Evidence for the use of radiofrequency ablation for the treatment of individuals with chronic rhinitis who are refractory to medical management includes one RCT and several nonrandomized studies. One RCT that compared radiofrequency using the RhinAer device with a sham procedure showed a statistically 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. One (of 2) studies 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.

Laser Ablation

Nonrandomized studies

Krespi et al. (2020) conducted a nonrandomized study evaluating laser ablation for the treatment of chronic rhinitis. (20) The study enrolled 32 adults who were treated with an endoscopic diode laser in an outpatient setting. While the study stated that study participants were resistant to medical management, the authors did not define treatment resistance. Duration of follow-up was 3 months. Mean rTNSS was reduced from 6.0 (SD, 0.7) at baseline to 2.3 (SD, 0.4) at 3-month follow-up. Adverse events were not reported. Although the study reported improvement in symptom control, the major limitation is lack of a comparator group and the open-label nature of the study design, which likely introduces biases.

Section Summary: Laser Ablation

Evidence for the use of laser ablation for the treatment of individuals with chronic rhinitis who are refractory to medical management includes one nonrandomized study. Although the single-arm prospective study reported improvement in symptom control, the major limitation is a lack of a comparator group and the 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.

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 statistically 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. Two (of 3) 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 statistically 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. One (of 2) studies 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.

Practice Guidelines and Position Statements

American Academy of Allergy, Asthma, and Immunology

The 2023 International Consensus Statement on Allergy and Rhinology stated the following for cryotherapy/radiofrequency ablation of posterior nasal nerve: (21)

- Aggregate grade of evidence: C (Level 3: 2 studies, level 4: 4 studies, level 5: 5 studies)
- Benefit: Improvement in rhinorrhea.
- Harm: Risk of complications (e.g., epistaxis, temporary facial pain and swelling, headaches), limited long-term results.
- Cost: Surgical/procedural costs, cost of device, potential time off from work.
- Benefits-harm assessment: Potential benefit must be balanced with low risk of harm, especially considering limited long-term results.
- Value judgments: Patients may experience an improvement in symptoms.
- Policy level: Option.
- Intervention: Cryoablation and radiofrequency ablation of the posterior nasal nerve may be considered in allergic rhinitis patients that have failed medical management, particularly for rhinorrhea.

Grade of evidence "C" implies that body of evidence consisted of observational studies (case control and cohort design). Policy level "Option" implies "either that the evidence quality that exists is suspect or that well-designed, well conducted studies have demonstrated little clear advantage to one approach versus another. Options offer clinicians flexibility in their decision-making regarding appropriate practice, although they may set boundaries on alternatives. Patient preference should have a substantial role in influencing clinical decision-making, particularly when policies are expressed as options." As per the consensus statement, "because the current evidence is primarily based on industry-sponsored studies with limited long-term data, these office-based interventions remain an option for properly selected patients."

American Academy of Otolaryngology

In January 2023, the American Academy of Otolaryngology issued a position statement on peripheral nerve ablation for the treatment of chronic rhinitis. (22) The position statement was not based on a systematic review or strength of evidence rating. According to the position statement, " Based on these safety and efficacy data, the American Academy of Otolaryngology endorses the use of posterior nasal nerve ablation for the treatment of medically-refractory chronic rhinitis. We do not consider these treatments to be experimental."

American Rhinologic Society

In January 2022, the American Rhinologic Society issued a position paper on posterior nasal nerve ablation. (23) The position statement was not based on a systematic review or strength of evidence rating. According to the position statement, "The American Rhinologic Society supports the use of posterior nasal nerve ablation for the treatment of chronic rhinitis, including both allergic and non-allergic subtypes. This procedure should not be considered experimental but should be considered as an effective option in treating chronic rhinitis and improving patient quality of life in those suffering from rhinorrhea and nasal congestion based on the following data."

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 18.

Table 18. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT04154605 ^a	ClariFix Rhinitis Randomized Controlled Trial	133	Jul 2022 (unknown status)
NCT04533438 ^a	The RhinAer Procedure for Treatment of Chronic Rhinitis-A Prospective, Multicenter Randomized Controlled Trial Comparing RhinAer to Sham Control (RHINTRAC)	116	Apr 2025

Unpublished			
NCT05648565	Effects of Radiofrequency Ablation of Posterior Nasal Nerves on Inflammatory Cytokines, Peak Nasal Inspiratory Flow, and Nasal Blood Flow in Patients with Chronic Rhinitis	17	Feb 2024

NCT: national clinical trial; No: number.

^aDenotes industry-sponsored or cosponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	30117, 30999, 31242, 31243, 31299
HCPCS Codes	[Deleted 12/31/2023: C9771]

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

References

1. Settipane RA, Charnock DR. Epidemiology of rhinitis: allergic and nonallergic. Clin Allergy Immunol. 2007; 19:23-34. PMID 17153005
2. Lieberman P, Kaliner MA, Wheeler WJ. Open-label evaluation of azelastine nasal spray in patients with seasonal allergic rhinitis and nonallergic vasomotor rhinitis. Curr Med Res Opin. Apr 2005; 21(4):611-618. PMID 15899111
3. Halderman A, Sindwani R. Surgical management of vasomotor rhinitis: a systematic review. Am J Rhinol Allergy. 2015; 29(2):128-134. PMID 25785754
4. Marshak T, Yun WK, Hazout C, et al. A systematic review of the evidence base for vidian neurectomy in managing rhinitis. J Laryngol Otol. Jul 2016; 130 Suppl 4:S7-S28. PMID 27488341
5. Senanayake P, Wong E, McBride K, et al. Efficacy of Vidian Neurectomy and Posterior Nasal Neurectomy in the Management of Nonallergic Rhinitis: A Systematic Review. Am J Rhinol Allergy. Nov 2022; 36(6):849-871. PMID 35695191
6. Zubair A, Hohman MH, Lasrado S. Vidian Neurectomy. [Updated 2024 February 24]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan. Available at <<https://www.ncbi.nlm.nih.gov>> (accessed March 11, 2024).
7. Food & Drug Administration. Clarifix 510(k) Premarket Notification. 2019 (K190356). Available at <<https://www.accessdata.fda.gov>> (accessed December 18, 2024).

8. Food & Drug Administration. RhinAer (RHIN1 Stylus) 510(k) Premarket Notification. 2019 (K192471). Available at <<https://www.accessdata.fda.gov>> (accessed December 17, 2024).
9. Del Signore AG, Greene JB, Russell JL, et al. Cryotherapy for treatment of chronic rhinitis: 3-month outcomes of a randomized, sham-controlled trial. *Int Forum Allergy Rhinol.* Jan 2022; 12(1):51-61. PMID 34355872
10. Hwang PH, Lin B, Weiss R, et al. Cryosurgical posterior nasal tissue ablation for the treatment of rhinitis. *Int Forum Allergy Rhinol.* Oct 2017; 7(10):952-956. PMID 28799727
11. Chang MT, Song S, Hwang PH. Cryosurgical ablation for treatment of rhinitis: A prospective multicenter study. *Laryngoscope.* Aug 2020; 130(8):1877-1884. PMID 31566744
12. Ow RA, O'Malley EM, Han JK, et al. Cryosurgical ablation for treatment of rhinitis: Two-Year results of a prospective multicenter study. *Laryngoscope.* Sep 2021; 131(9):1952-1957. PMID 33616224
13. Gerka Stuyt JA, Luk L, Keschner D, et al. Evaluation of in-office cryoablation of posterior nasal nerves for the treatment of rhinitis. *Allergy Rhinol (Providence).* 2021; 12: 2152656720988565. PMID 33598336
14. Stolovitzky JP, Ow RA, Silvers SL, et al. Effect of radiofrequency neurolysis on the symptoms of chronic rhinitis: A randomized controlled trial. *OTO Open.* 2021; 5(3): 2473974X211041124. PMID 34527852
15. Takashima M, Stolovitzky JP, Ow RA, et al. Temperature-controlled radiofrequency neurolysis for treatment of chronic rhinitis: 12-month outcomes after treatment in a randomized controlled trial. *Int Forum Allergy Rhinol.* 2023; 13(2):107-115. PMID 35714267
16. Takashima M, Stolovitzky JP, Ow RA, et al. Temperature-controlled radiofrequency ablation for the treatment of chronic rhinitis: Two-year outcomes from a prospective multicenter trial. *Int Forum Allergy Rhinol.* Jul 2024; 14(7):1182-1194. PMID 38266636
17. Lee JT, Abbas GM, Charous DD, et al. Clinical and Quality of Life Outcomes Following Temperature-Controlled Radiofrequency Neurolysis of the Posterior Nasal Nerve (RhinAer) for Treatment of Chronic Rhinitis. *Am J Rhinol Allergy.* Nov 2022; 36(6):747-754. PMID 35818709
18. Ehmer D, McDuffie CM, Scurry WC, et al. Temperature-controlled radiofrequency neurolysis for the treatment of rhinitis. *Am J Rhinol Allergy.* Jan 2022; 36(1):149-156. PMID 34382444
19. Ehmer D, McDuffie CM, McIntyre JB, et al. Long-term Outcomes Following Temperature-Controlled Radiofrequency Neurolysis for the Treatment of Chronic Rhinitis. *Allergy Rhinol (Providence).* 2022; 13:21526575221096045. PMID 35663498
20. Krespi YP, Wilson KA, Kizhner V. Laser ablation of posterior nasal nerves for rhinitis. *Am J Otolaryngol.* 2020; 41(3):102396. PMID 31948695
21. Wise SK, Damask C, Roland LT, et al. International consensus statement on allergy and rhinology: Allergic rhinitis - 2023. *Int Forum Allergy Rhinol.* Apr 2023; 13(4):293-859. PMID 36878860
22. American Academy of Otolaryngology. Position Statement: PNN ablation for the treatment of chronic rhinitis. January 2023. Available at <<https://www.entnet.org>> (accessed March 11, 2025).
23. American Rhinologic Society. Posterior Nasal Nerve Ablation ARS Position Statement. January 2022. Available at <<https://www.american-rhinologic.org>> (accessed March 11, 2025).

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <<https://www.cms.hhs.gov>>.

Policy History/Revision	
Date	Description of Change
06/15/2025	Document updated with literature review. Coverage unchanged. Reference 16 added; others updated/removed.
06/15/2024	Document updated with literature review. Coverage unchanged. References 1-6 and 20-22 added.
01/01/2024	Document updated with literature. Coverage unchanged. References 10, 11, 13, and 16 added.
11/01/2022	New medical document. Cryoablation for chronic rhinitis (allergic or nonallergic) is considered experimental, investigational, and/or unproven. Radiofrequency ablation for chronic rhinitis (allergic or nonallergic) is considered experimental, investigational, and/or unproven. Laser ablation for chronic rhinitis (allergic and nonallergic) is considered experimental, investigational, and/or unproven. Information and Coverage for cryoablation for chronic rhinitis was previously located on SUR706.001 Nasal and Sinus Surgery.