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

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Policy Number: 843
BCBSA Reference Number: 7.01.168 (For Plan internal use only)
NCD/LCD: N/A

Related Policies
Balloon Ostial Dilation for Treatment of Chronic and Recurrent Acute Rhinosinusitis #582
Steroid-Eluting Sinus Stents and Implants #800

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

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.

Prior Authorization Information
Inpatient
- For services described in this policy, precertification/preauthorization IS REQUIRED for all products if the procedure is performed inpatient.

Outpatient
- For services described in this policy, see below for products where prior authorization might be required if the procedure is performed outpatient.

<table>
<thead>
<tr>
<th>Product</th>
<th>Inpatient</th>
<th>Outpatient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>This is not a covered service.</td>
<td></td>
</tr>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>This is not a covered service.</td>
<td></td>
</tr>
<tr>
<td>Medicare HMO BlueSM</td>
<td>This is not a covered service.</td>
<td></td>
</tr>
<tr>
<td>Medicare PPO BlueSM</td>
<td>This is not a covered service.</td>
<td></td>
</tr>
</tbody>
</table>

CPT Codes / HCPCS Codes / ICD Codes
Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following HCPCS code is considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9771</td>
<td>Nasal/sinus endoscopy, cryoablation nasal tissue(s) and/or nerve(s), unilateral or bilateral</td>
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</table>

**Description**

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.

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.

Six months of follow-up is considered necessary to demonstrate efficacy. Adverse events can be assessed immediately (perioperative complications and postoperative pain) or over the longer term.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Measures</th>
<th>Description</th>
<th>Minimal Clinically Important Difference</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms</td>
<td>Reflective Total Nasal Symptom Score (rTNSS)</td>
<td>Sum of 4 individual subject-assessed symptom scores for rhinorrhea, nasal congestion, nasal itching, and sneezing, each evaluated using a scale of</td>
<td>Not established; 30% change from</td>
<td>At least 6 months or longer</td>
</tr>
<tr>
<td>Method</td>
<td>Scoring System</td>
<td>Notes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------------------------------------------------------</td>
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</tr>
<tr>
<td>The Chronic Sinusitis Survey (CSS)</td>
<td>0 = none, 1 = mild, 2 = moderate, or 3 = severe.</td>
<td>baseline has been proposed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td>Not established</td>
<td>At least 6 months or longer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visual Analog Scale (VAS)</td>
<td>Patient-reported.</td>
<td>Not established</td>
<td>At least 6 months or longer</td>
<td></td>
</tr>
<tr>
<td>Disease-Specific Quality of Life</td>
<td>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”).</td>
<td>SNOT-20: change in score of 0.8 or greater SNOT-22: change in score of 8.9 points</td>
<td>At least 6 months or longer</td>
<td></td>
</tr>
<tr>
<td>Rhinocconjunctivitis Quality of Life Questionnaire (RQLQ)</td>
<td>Measures the functional (physical, emotional, and social) problems associated with rhinitis.</td>
<td>Not established</td>
<td>At least 6 months or longer</td>
<td></td>
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<tr>
<td>VAS</td>
<td>Patient-reported.</td>
<td>Not established</td>
<td>At least 6 months or longer</td>
<td></td>
</tr>
<tr>
<td>Adverse events</td>
<td>Various; patient- and clinician reported</td>
<td>Potential procedure- and device-related adverse events include postoperative pain, epistaxis, and dry eyes.</td>
<td>Not applicable</td>
<td>Immediately post procedure to 6 months or longer</td>
</tr>
</tbody>
</table>
Summary
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.

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 with a clearly defined patient population directly comparing cryoablation with medical management and with follow-up for active and control groups ≥6 months are needed to confirm the efficacy of cryoablation for treatment of chronic rhinitis. 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 2 nonrandomized studies. 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 3 months follow-up. 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.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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</table>
New medical policy describing ongoing investigational indications. Cryoablation for Chronic Rhinitis was transferred from MP #400 Medical Technology Assessment Investigational (Non-Covered) Services List.

Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:
- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

References