Ablation Therapy for the Treatment of Chronic Rhinitis

Policy # 00723
Original Effective Date: 05/01/2021
Current Effective Date: 08/09/2021

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Nasal Swell Body Ablation Reduction in the Treatment of Nasal Obstruction is addressed separately in medical policy 00724.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers intranasal ablation of the posterior nasal nerves and/or sphenopalatine ganglion for the treatment of allergic and non-allergic rhinitis (e.g., by means of the Clarifix®‡ or RhinAer®‡ device) to be **investigational.***

Background/Overview

Rhinitis is a common condition characterized by one or more of the following symptoms: sneezing, rhinorrhea (anterior or posterior), nasal congestion (stuffiness), and nasal itching. The most common forms of rhinitis are allergic, nonallergic, and mixed allergic. Allergic and nonallergic rhinitis are estimated to impact over 58 million people in the United States.

Patients with seasonal allergic rhinitis are typically sensitized to pollens and may have associated allergic conjunctivitis. Indoor allergens are common triggers of perennial rhinitis. Nonallergic rhinitis is a diagnosis of exclusion, distinguished clinically by the absence of nasal and ocular itching, a later age of onset, no relevant specific IgE sensitivity, and different triggers.

Management of allergic rhinitis combines allergen avoidance and pharmacologic therapy. Intranasal glucocorticoids are the most effective single therapy for allergic rhinitis in patients with significant or persistent symptoms. Oral antihistamines can also be helpful for nasal obstruction in patients with persistent allergic rhinitis.

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Patients with chronic nonallergic rhinitis are less responsive to pharmacologic therapy. However, intranasal glucocorticoids and the topical antihistamines can be useful in treating symptoms of chronic nonallergic rhinitis.

It has been noted that pharmacotherapy of both allergic and nonallergic rhinitis is not always effective. Surgical management including cryotherapy have been evaluated for the safety, efficacy, and durability of treatment response in treating chronic rhinitis.

The vidian nerve supplies most of the parasympathetic innervation to the secretory nasal mucosa, giving rise to postganglionic innervation via the posterior nasal nerves (PNN). Transection of the vidian nerve has been thought to correct the imbalance of autonomic input to the nasal mucosa, reducing nasal antigen responses and vascular hyperreactivity.

Endoscopic PNN resection has been described as an efficacious surgical treatment of allergic and nonallergic rhinitis, but the requirement for surgery under general anesthesia has limited its acceptance. Office-based cryosurgical ablation of the PNN has been studied. According to the manufacturer, ClariFix®‡ Cryotherapy can be performed in-office or in surgical setting, under topical or local anesthesia. The device uses nitrous oxide to freeze the tissue, causing 2nd degree nerve damage. Cryotherapy offers the advantage of ablating soft tissue and nerve with predictable depth of penetration, while preserving vascular supply and minimizing the risk of necrosis.

The RhinAer®‡ Stylus is a disposable handheld device capable of delivering bipolar radiofrequency energy to tissue. The RhinAer Stylus consists of a handle, shaft and treatment tipA temperature sensor is located on the tip to monitor tissue temperature. The Stylus is attached to a temperature-controlled radiofrequency generator via a flexible cable. The RhinAer Stylus treats symptoms of chronic rhinitis by modifying the tissues of the nasal airway through the use of low doses of radiofrequency energy to destroy tissue in the posterior nasal nerve regions. The low-power radiofrequency energy generates heat within the submucosal tissue, destroying local tissue, mucous cells, and glands, and creating a coagulation lesion. The RhinAer Stylus tip is temporarily inserted into the nose to access the treatment area. The procedure requires local anesthesia only.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In February 2017, the U.S. Food and Drug Administration replied regarding ClariFix Cryosurgical Unit and Accessories (Section 510(k) premarket notification of intent to market the device) that the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

RhinAer Stylus by Aerin Medical was cleared by the FDA in March 2020. The RhinAer Stylus treats symptoms of chronic rhinitis by modifying the tissues of the nasal airway through the use of low-power radiofrequency energy to destroy tissue in the posterior nasal nerve regions.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Allergic and Non-Allergic Rhinitis

For individuals with chronic rhinitis who receive cryotherapy (using ClariFix device), the evidence includes small case series and systematic review. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A systematic review (2018) identified studies with the primary objective of assessing the efficacy of cryotherapy on chronic rhinitis. Of 110 abstracts, 15 were included in this review. Epistaxis and nasal obstruction were commonly reported complications, with no reported serious adverse events. For obstructive symptoms, improvement was reported in 63-100% of patients. Improved rhinorrhea was experienced by 77-100% of patients. The authors concluded that although cryotherapy appeared safe and effective, heterogeneous investigations with low-quality evidence made strong, evidence-based recommendations difficult to make and noted that further study with validated metrics and controlled

populations is needed and should be encouraged. The evidence is insufficient to determine that the technology results in a meaningful improvement in the net health outcomes.

The RhinAer official website details a prospective non-randomized multi-center clinical study of 50 participants followed for 52 weeks, however no published peer-reviewed evidence is available at this time. The evidence is insufficient to determine that the technology results in a meaningful improvement in the net health outcomes.

References

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Policy History

Original Effective Date: 05/01/2021
Current Effective Date: 08/09/2021
02/04/2021 Medical Policy Committee review
02/10/2021 Medical Policy Implementation Committee approval. New policy.

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07/01/2021 Medical Policy Committee review
07/14/2021 Medical Policy Implementation Committee approval. Title changed from "Cryotherapy for the Treatment of Chronic Rhinitis" to "Ablation Therapy for the Treatment of Chronic Rhinitis for the Treatment of Chronic Rhinitis". Changed "cryotherapy" to "intranasal ablation of the posterior nasal nerves and/or sphenopalatine ganglion" in the investigational statement for the treatment of allergic and non-allergic rhinitis. Added the RhinAer device as an example in the investigational statement.
Next Scheduled Review Date: 07/2022

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2020 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0442T, 30117, 30999, 31299
HCPCS	C9771
ICD-10 Diagnosis	J30.0-J30.9, J31.0

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.