KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Nasal Cryoablation, Radiofrequency Ablation & Laser Treatments

- ClariFix® Cryotherapy for Chronic Rhinitis
- VivAer®
- RhinAer®

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	**Clarifix®:** **Effective until February 1, 2024** Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Nasal Cryoablation, Radiofrequency Ablation & Laser Treatments***" for medical necessity determinations. Use the Non-Medicare criteria below. **Clarifix®, VivAer® & RhinAer®** **Effective February 1, 2024** Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Nasal Cryoablation, Radiofrequency Ablation & Laser Treatments***" for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Non-Medicare

Service	Criteria
Cryoablation for allergic or nonallergic chronic rhinitis (e.g., Clarifix® device)	There is insufficient evidence in the published medical literature to show that this therapy is as safe as standard service/therapies and/or provides better long-term outcomes than current standard services/therapies.
Radiofrequency ablation for the treatment of airway obstruction (e.g., VivAer® Stylus device)	**Effective until February 1, 2024** Send all cases to MD for review. **Effective February 1, 2024**

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	There is insufficient evidence in the published medical literature to show that this therapy is as safe as standard service/therapies and/or provides better long-term outcomes than current standard services/therapies
Radiofrequency ablation for allergic or nonallergic chronic rhinitis (e.g., RhinAer® Stylus device)	**Effective until February 1, 2024** Send all cases to MD for review. **Effective February 1, 2024** There is insufficient evidence in the published medical literature to show that this therapy is as safe as standard service/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Chronic rhinitis is long-term inflammatory condition of the nasal mucosa. Its etiology is not precisely understood, but it is thought to result from deregulation of the autonomic innervation of the nasal mucosa leading to increased vascular permeability, mucous secretion and edema. Rhinitis is generally classified as allergic and non-allergic rhinitis. Allergic rhinitis may be seasonal, perennial or both and is mainly characterized by sneezing, runny nose, stuffiness, and itchy watery eyes. The symptoms of non-allergic rhinitis include nasal obstruction, irritability, and hypersecretion (Kompelli 2018, Chang 2019, Krespi 2020).

The first-line treatment of chronic rhinitis involves avoiding known triggers and the use of over the counter or prescription medications including saline irrigation, topical steroids, topical or systemic adrenergic agents, antihistamine therapy, anticholinergic agents, and antileukotrienes. Medication use improves symptoms for the majority of patients, but needs constant daily use, and may not completely control symptoms in some patients (Kompelli 2018, Chang 2019, Krespi 2020).

Different procedural or operative interventions have been developed over the years for the treatment of patients with medically refractory rhinitis. Vidian neurectomy, first described in the early 1960s, aims at disrupting preganglionic parasympathetic innervation (autonomic supply) of the nasal mucosa. The surgery was found to be effective in reducing the symptoms of chronic rhinitis, but had its complications including severe bleeding from the sphenopalatine artery, numbness of the cheek and palate, and persistent dry eye symptoms due to the collateral disruption of the parasympathetic innervation of the lacrimal gland. In addition, the procedure must be performed in an operating room under general anesthesia. Resection of the postganglionic nerve fibers via the posterior nasal nerves (PNN) was proposed as an alternative for vidian neurectomy to avoid the dry eye complication. However, its use is limited by its technical complexity, lack of complete resolution of symptoms in some patients, and similar the vidian neurectomy, it must be performed in an operating room under general anesthesia (Huang 2017, Kompelli 2018, Chang 2019, Yan 2020).

Cryosurgical therapy for the treatment of chronic rhinitis was first proposed in the early 1970s and involves the placement of a cryoprobe in the nasal cavity against the posterior end of the inferior turbinate. Several cryoablation devices were developed over the years including Basco-Cryos, Krymed, Frigitronic, Cryospray, Cooper's cryo Unit, and SAmils Cryo. Cryotherapy for rhinitis, however. was not widely adopted due to its potential complications, lack of endoscopic visualization, non-ergonomic probe design, need for external cryogen reservoirs, and other associated challenges (Hwang 2017, Kompelli 2018, Yan 2020).

More recently a novel cryotherapy device (ClariFix™) was developed for cryosurgical ablation of the PNN region in an office setting and under local or mild sedation. The procedure involves the introduction of a cryosurgical ablation device under endoscopic visualization to deliver cryogen to the posterior middle meatus and freeze the posterior nerve (Yan,2020).

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The ClariFix™ cryoablation device (Arrinex Inc, redwood City, CA, recently acquired by Stryker Corporation, Kalamazoo MI) is a hand-held, single-use, disposable cryosurgical device (cryoprobe) that uses nitrous oxide as the cryogen to freeze the mucosal tissue in a targeted fashion in the nasal cavity. The target tissue lies in the posterior aspect of the middle meatus adjacent to the sphenopalatine foramen and corresponding to the trajectory of the PNN as it emerges from the pterygopalatine fossa. The cryogen cartridge is inserted into the handle of the device immediately prior to the procedure. The Cryoprobe is then placed into contact with the target tissue via direct endoscopic visualization under local anesthesia with the patient seated upright or partially reclined. Once the Cryoprobe is in the desired position, the cryogen is released into the probe tip by the surgeon via a control dial. As cryogen flows into the Cryoprobe, the liquid partially evaporates and the inside of the Cryoprobe cools to -60 to -80°C; a freezing zone forms in the adjacent tissue destroying the unwanted tissue. The treatment is estimated to achieve
-20ºC cryoablation at a depth of 3 millimeters. Nitrous oxide is fully contained within the Cryoprobe and does not come in direct contact with the tissue. Once the Cryoprobe has thawed it can be safely removed from the treatment area. The cryoprobe is activated for a single treatment of 30-60 seconds for each side. Additional treatment cycles can be initiated at the physician's discretion. The device is designed for singe patient use and is disposable. (Huang 2017, Chang 2019, FDA website).

The most common side effects associated with ClariFix cryotherapy are temporary increased congestion and transient pain or discomfort. Other reported adverse events include moderate or severe nasal dryness, nose bleeds, headache, ear blockage, dry eyes, watery eyes, oral numbness and sinusitis.

Hayes Conclusion

There is insufficient published evidence to evaluate the use of ClariFix for treatment of chronic rhinitis.

Reference

Cryotherapy Using ClariFix (Arrinex Inc.) for Treatment of Chronic Rhinitis. (2019, October 24). Retrieved July 10, 2020, from https://evidence.hayesinc.com/report/hss.clarifix4569

Medical Technology Assessment Committee (MTAC)

CRYOTHERAPY FOR THE TREATMENT OF CHRONIC RHINITIS USING THE CLARIFIX DEVICE

7/13/2020: MTAC REVIEW

The literature search did not identify any published randomized controlled trials, to date, that compared cryoablation therapy for chronic rhinitis using the ClariFix device versus any medical therapy, surgery, or a sham procedure. The published literature on ClariFix consisted of a small pilot study (Evidence table 1), and a prospective observational multicenter single-arm open-label study (Evidence table 2). The two studies were sponsored by the manufacturer and were subject to selection and observational bias.

Evidence Conclusion:

There is insufficient published evidence to date, to support Cryosurgery using ClariFix device for the treatment of chronic rhinitis.

The use of ClariFix® Cryotherapy for Chronic Rhinitis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Hayes Conclusion

VivAer (Aerin Medical Inc.) for Nasal Airway Remodeling to Treat Nasal Obstruction

A review of full-text clinical studies suggests minimal support for using the VivAer radiofrequency (RF) procedure for remodeling the nasal valve area when collapse of the nasal valve is associated with chronic nasal obstructive symptoms. This level of support reflects:

- Four clinical studies were identified, 3 of which were rated poor or very poor quality.
- Only 1 study compared VivAer with sham. No studies evaluated VivAer with another active treatment.
- Results were consistent across studies in direction and significance (both clinical and statistical) for patient-reported outcomes.
- The rate of clinical response exceeded 85%, and all studies reported improvements in symptom scores. VivAer also appears to improve nasal patency and may improve quality of life (QOL), especially as a result of improved sleep.

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- VivAer appears to be safe, with most adverse effects (AEs) being mild, transient, and infrequently reported.
- The duration of effect was reported to last up to 4 years in 1 study. However, the follow-up duration of the sham-controlled part of the randomized controlled trial (RCT) was only 3 months.
- Only 1 study reported objective measures of nasal patency and airflow

RhinAer Procedure (Aerin Medical) for Treatment of Chronic Rhinitis

A review of full-text clinical studies suggests minimal support for using the RhinAer procedure to treat chronic rhinitis. This level of support reflects:

- 2 studies (1 poor quality, 1 fair quality) reported most patients had clinically significant nasal symptom relief after treatment
- 1 also reported more patients improved after RhinAer than sham
- No studies compared RhinAer with another treatment, so the current evidence does not inform whether its outcomes are better, worse, or the same as any other treatment.

Applicable Codes

Considered Not Medically Necessary - experimental, investigational or unproven:

CPT® or HCPCS Codes	Description
30117	Excision or destruction (eg, laser), intranasal lesion; internal approach **frequently submitted with this code, although code 30999 "Unlisted procedure, nose" is most appropriate per manufacturer guidance*
C9771	Nasal/sinus endoscopy, cryoablation nasal tissue(s) and/or nerve(s), unilateral or bilateral

ICD-10 Codes	Description
J30.0	Vasomotor rhinitis
J30.1-J30.9	Allergic rhinitis
J31.0	Chronic rhinitis
J31.1	Chronic nasopharyngitis
J34.89	Other specified disorders of nose and nasal sinuses
R09.81	Nasal congestion
R09.82	Postnasal drip

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

******To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
09/01/2020	09/01/2020 MPC, 09/07/2021 MPC, 09/06/2022MPC, 09/05/2023MPC	09/05/2023

MPC Medical Policy Committee

Revision History	Description
09/01/2020	MPC approved to endorse a non-coverage policy for ClariFix/cryotherapy for chronic rhinitis
09/05/2023	MPC approved the clinical criteria name change to Nasal Cryoablation, Radiofrequency Ablation & Laser Treatments.

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	MPC approved to adopt non-coverage indications for Radiofrequency ablation for the treatment of airway obstruction (e.g., VivAer® Stylus device) and Radiofrequency ablation for allergic or nonallergic chronic rhinitis (e.g., RhinAer® Stylus device). Requires 60-day notice, effective February 1, 2024.

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