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®, VivAer® & RhinAer®** 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
Nasal Cryoablation, Radiofrequency Ablation & Laser Treatments	
Cryoablation for allergic or nonallergic chronic rhinitis (e.g., Clarifix® device) (CPT 31243)	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) (CPT 31242)	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) (CPT 31242)	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

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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).

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
-20°C 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

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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.*

TEMPERATURE-CONTROLLED RADIOFREQUENCY NEUROLYSIS of THE POSTERIOR NASAL NERVE FOR THE TREATMENT OF CHRONIC RHINITIS USING RHINAER SYSTEM

10/09/2023: MTAC REVIEW

Evidence Conclusion:

- The overall strength of the published evidence on the use of RhinAer device for the treatment of patients with symptomatic chronic rhinitis is low and insufficient to recommend its use for this indication.
- The published studies to date were industry funded and limited by their small number, small population sizes, short follow-up duration, study design, lack of RCTs with active comparators, use of subjective outcome measures, and lack of adjustments for confounding factors.
- More well-designed double-blinded randomized clinical trials directly comparing the RhinAer device therapy with other active surgical or non-surgical therapies with longer follow -up for both the active and control groups and are needed to provide higher quality evidence on the efficacy and safety the temperature-controlled radiofrequency device in the treatment of patients with chronic rhinitis.

Articles: The literature search identified one RCT, two prospective single arm studies and two systematic reviews with meta-analyses of the results of published studies. The RCT and a SR with MA were selected for critical appraisal.

The use of RhinAer for the treatment of Chronic Rhinitis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

TEMPERATURE-CONTROLLED RADIOFREQUENCY TREATMENT OF NASAL AIRWAY OBSTRUCTION USING VIVAER SYSTEM

10/09/2023: MTAC REVIEW

Evidence Conclusion: The strength of the published evidence is low and insufficient to recommend the use of VivAer temperature-controlled radiofrequency device for remodeling the nasal valve in patients with nasal airway obstruction.

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The published studies to date are limited by their small number, small population sizes, short follow-up duration, study design, lack of RCTs with active comparators, use of subjective outcome measures, and lack of adjustments for confounding factors.

More well-designed double blinded randomized clinical trials comparing the VivAer device therapy to other active surgical or non-surgical therapies and using validated outcome measures are needed to provide higher quality evidence on the efficacy and safety the temperature-controlled radiofrequency device treatment of the nasal valve for patients with nasal airway obstruction.

Articles: PubMed and Cochrane database were searched through September 2023, for published studies evaluating the effectiveness and safety of temperature-controlled radiofrequency treatment of nasal airway obstruction using VivAer system. The search strategy used the terms*, airway obstruction, nasal valve, nasal valve collapse, radiofrequency device, temperature-controlled radiofrequency, treatment, VivAer,* and *minimally invasive surgery* with variations.

1. The search was limited to English language publications in peer-reviewed journals. Experimental studies, abstracts, case reports, case series with less than 25 patients, reviews, comments, and editorials were excluded. Preference was given to meta-analyses and randomized controlled trials reporting on clinical outcomes.
2. Reference lists of the retrieved articles were manually searched to for additional studies.
3. To identify ongoing clinical trials, a search of the National Institute of Health Clinical Trials website https://clinicaltrials.gov/ was conducted using the same methodology.

The use of VivAer for Nasal Obstruction does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

CRYOTHERAPY FOR THE TREATMENT OF CHRONIC RHINITIS USING THE CLARIFIX DEVICE

04/08/2024: MTAC REVIEW

Evidence Conclusion:

- There is no published evidence to date to determine the comparative efficacy and safety of cryoablation using ClariFix device to other surgical procedure, alternative non-surgical interventions, or optimal medical therapy used for the treatment of chronic rhinitis.
- The only published RCT on the use of cryoablation with the ClariFix device for the treatment of patients with symptomatic chronic rhinitis, suggests that the intervention may be more effective than a sham procedure in improving patients' chronic rhinitis symptoms in the 90 days follow-up duration of the trial.
- The published studies were industry-funded and limited by their small number, relatively small population sizes, short follow-up duration, lack of an active comparator, use of subjective outcome measures, and no of adjustments for confounding factors.
- More well-designed double-blinded, randomized clinical trials that directly compare the cryotherapy using ClariFix device with other active surgical or non-surgical therapies, and have longer follow-up duration, are needed to provide higher quality evidence on the efficacy and safety of cryoablation with the ClariFix device in the treatment of patients with chronic rhinitis.

Articles: The literature search for studies published after the last MTAC review identified one RCT, three single arm observational studies as well as two systematic reviews of the published studies. The RCT and the systematic review with a meta-analysis, were selected for critical appraisal. The results of an extended follow-of an observational study reviewed earlier was briefly summarized. See Evidence Table.

The use of Cryotherapy for the treatment of Chronic Rhinitis using the Clarifix Device does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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
31242	Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve

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31243	Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve

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, 07/02/2024MPC	05/10/2024

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. 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.
01/09/2024	Added MTAC reviews for RhinAer for the treatment of Chronic Rhinitis and VivAer for the treatment of Nasal Obstruction.
02/22/2024	Added new codes effective 1/1/2024 31242 & 31243. Removed termed code C9771.
05/10/2024	Added MTAC review for Cryotherapy for the treatment of chronic rhinitis using the Clarifix device.

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