Healthy Blue

Medical Policy

Subject:	Rhinophototherapy		
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Description/Scope

This document addresses rhinophototherapy as a treatment of allergic rhinitis and potentially other nasal or sinus conditions. Rhinophototherapy involves the use of a light emitting device inserted into the nose to expose sinus and nasal tissues to ultraviolet (UV) and visible light, with the goal of decreasing the symptoms and disease processes associated with various nasal conditions.

Position Statement

Investigational and Not Medically Necessary:

The use of rhinophototherapy is considered **investigational and not medically necessary** for all conditions, including but not limited to the treatment of allergic rhinitis and other nasal or sinus conditions.

Rationale

There have been a limited number of articles published in the peer-reviewed literature addressing the use of rhinophototherapy, a technique which exposes the sinus cavity to light (5% UVB, 25% UVA and 70% visible light).

Koreck and colleagues (2005) describe the use of a device (Rhinolight®, Rhinolight Ltd., Szeged, Hungary) that emits a mixture of ultraviolet A (UVA), ultraviolet B (UVB), and visible light in the treatment of allergic rhinitis. This double-blind study included 49 subjects with ragweed-induced hay fever unresponsive to antiallergic drugs. Study participants were randomized to treatment with either low-level visible light or with rhinophototherapy. Treatment and control groups received their respective interventions 3 times a week for 3 weeks. Light intensity was increased over the course of treatment. The authors reported significant reductions in sneezing, itching, rhinorrhea and total nasal score in the rhinophototherapy group compared to the visible light group. Nasal obstruction, as measured by acoustic rhinometry, was significantly less in the rhinophototherapy group. Examination of nasal lavage samples found significantly lower concentrations of eosinophils, eosinophil cationic protein, and IL-5 in the rhinophototherapy group.

In a small case series of 8 subjects with allergic rhinitis (Koreck, 2007), following treatment with rhinophototherapy, a modified Comet assay technique was used to assess the degree of DNA damage detected in nasal mucosal cells using the UV-specific photoproduct cyclobutane pyrimidine dimers. The results of this study

concluded that the UV-induced mucosal damage was repaired after 2 months. This study did not investigate the impact of rhinophototherapy on symptomology or clinical health outcomes.

Garaczi and colleagues (2011) studied 31 subjects randomly assigned to receive either rhinophototherapy 3 times a week for 2 weeks, or 180 mg fexofenadine HCl per day for 2 weeks. The authors reported that in the rhinophototherapy group, the individual total nasal score (TNS), a sum of scores for nasal symptoms, significantly decreased compared with baseline for all of the parameters. In the fexofenadine HCl group, only sneezing improved significantly at the end of treatment. Study limitations include a lack of blinding, small numbers of subjects in each group, and the absence of objective study measures.

Albu and Baschir (2013) described the results of a randomized controlled trial comparing rhinophototherapy to azelastine in 77 subjects with allergic rhinitis. The authors reported that both azelastine and intranasal phototherapy significantly improved the TNS ($p<0.05$), but that phototherapy reduced nasal obstruction better than azelastine ($p=0.038$). The authors concluded that while rhinophototherapy demonstrated significant benefits, they indicated that this treatment method should be appraised in future studies and clinical trials.

Tatar and colleagues (2013) published the results of a prospective, non-blinded, randomized study involving 65 subjects with persistent allergic rhinitis. Subjects were assigned to receive treatment with either topical mometasone furoate (200 mcg per day) and levocetirizine (5 mg per day) for 1 month (n=33), or the same medical regimen augmented with rhinophototherapy, administered twice a week for 3 weeks (n=32). At the first and third month time points, the authors reported a statistically significant difference in favor of the rhinophototherapy group for measures of nasal obstruction, sneezing, rhinorrhea, and nasal itching ($p<0.05$ for each). Similarly, significantly improved results were reported on all seven domains on the Rhinoconjunctivitis Quality of Life (RQOL) questionnaire at both 1 and 3 months (limited activity, sleep quality, non-nasal non-eye symptoms, practical problems, nasal symptoms, eye symptoms and emotional functions) ($p<0.05$ for each time point). Thirty-four subjects had mild to moderate dryness of nasal mucosa during the study and 1 subject had anosmia, which disappeared after 1 week. There was no data indicating what groups these subjects were in, or if there was any differences between groups with regard to adverse events.

Alyasin and colleagues (2016) performed a randomized single-blind study, which involved 62 subjects above 25 years of age with moderate to severe allergic rhinitis. The authors do not specify who was blinded. The subjects were randomly divided into two groups, which each consisted of 31 subjects. A mixture of UVA, UVB, and visible light was used in the treatment group. In the control group, only visible light was used as the placebo. An evaluation of the level of response to treatment was performed on both groups, which was compared according to TNS, Global Severity Scores, and RQOL questionnaires. The authors found that phototherapy in the treatment group in comparison with placebo was effective in treatment of allergic rhinitis ($p<0.001$); however, the authors recommended further investigations.

Bella and colleagues (2017) studied 34 subjects with persistent allergic rhinitis in two randomized, double-blind groups; however, only 25 subjects completed the study. This 26% decrease in study participation resulted from subject poor compliance or withdrawal. The treatment group received a combination of UVB, UVA, and high-intensity visible light, and the control group received low-intensity visible white light intranasal phototherapy on a

total of 13 occasions in 6 weeks. The assessment was based on the diary of symptoms, nasal inspiratory peak flow, quantitative smell threshold, mucociliary transport function, and intracellular adhesion molecule 1 expression of the epithelial cells. A significant improvement in symptoms was found in the treatment group versus the control group immediately after treatment ($p<0.05$) and after 4 weeks of follow-up ($p<0.05$). A study limitation is the small sample size. The authors stated this made statistical evaluation difficult and necessitates a larger, multicenter study to confirm the results.

Dulguerov and colleagues (2017) investigated the efficacy of rhinophototherapy in subjects with chronic rhinosinusitis (CRS) without nasal polyps through a randomized triple-blind (subject, investigators, and statistician), placebo-controlled trial. The trial consisted of 50 subjects, who received either mixed visible and ultraviolet light source application (n=26) or visible light alone (n=24) for 3 weeks. The authors found no significant difference between the two groups immediately after the completion of treatment (T1) and 4 weeks after the treatment (T2) in reducing Rhinosinusits Disability Index (T1 p=0.84; T2 p=0.96), nasal obstruction visual analog scale (VAS) (T1 p=0.63; T2 p=0.17), sense of smell VAS (T1 p=0.54; T2 p=0.85), rhinorrhea VAS (T1 p=0.09; T2 p=0.26), facial pain VAS (T1 p=0.43; T2 p=0.87), total nasal resistance (T1 p=0.88; T2 p=0.38), olfactory threshold (T1 p=0.68; T2 p=0.76), and nasal nitric oxide production (T1 p=0.21; T2 p=0.17).

In 2019, Jiang and Wang published the results of a non-blinded, randomized controlled trial that evaluated the effect of rhinophototherapy on nasal patency in individuals with allergic rhinitis. Individuals were randomized to either the study group (n=30) or the control group (n=30). After all participants received a nasal patency test using both anterior rhinomanometry and acoustic rhinometry, the study group received one treatment session of rhinophototherapy. Individuals were questioned about the severity and the level of change of their rhinitis symptoms, and any adverse events. Mometasone furoate nasal spray, 4 sprays, once a day, along with levocetirizine 5 mg every day was given for continued management of the allergic rhinitis. Finally, 2 days post-treatment, individuals were asked the same questions as 30 minutes post-treatment. Individuals in the control group were treated with mometasone furoate nasal spray, 4 sprays, once a day, along with levocetirizine 5 mg every day, and asked the same questions as the study group 2 days post-treatment. While all rhinitis symptoms significantly improved 30 minutes after the rhinophototherapy (total rhinitis score: $p<0.0001$), rhinitis symptoms in the study group significantly worsened between the 30 minute post-treatment evaluation and the 2-day post-treatment evaluation (total rhinitis score: $p<0.0001$). For the control group, all rhinitis symptoms significantly improved 2 days post-treatment (total rhinitis score: $p<0.0001$). No significant improvements in nasal patency were found after treatment with rhinophototherapy. There were no major adverse events reported. The results of this trial show that treatment of allergic rhinitis with rhinophototherapy does not result in any improvement.

The studies described are too small and of poor quality to allow wider application of their results to the general population, to other types of allergic rhinitis, or other sinus or nasal conditions. Additionally, there are concerns regarding the use of UV light on sensitive tissues such as sinus membranes. UV light may have a deleterious effect on skin and other tissue and further data is needed regarding any potential adverse effects of UV irradiation on the nasal mucosa and surrounding skin of the face, as delivered by rhinophototherapy.

Currently, no device has been approved or cleared by the U.S. Food and Drug Administration (FDA) for provision of rhinophototherapy.

Background/Overview

Rhinophototherapy is a medical therapy proposed for the treatment of allergic rhinitis and other nasal conditions. This treatment method involves the use of a device that emits a combination of UVA, UVB, and visible light to cause a reaction in the nasal tissue and decrease the symptoms of allergic rhinitis.

Currently, only one device has been proposed for administration of this therapy, the Rhinolight (Rhinolight Ltd., Szeged, Hungary), which has not received FDA PMA approval or 510k clearance for use in the United States.

Definitions

Allergic rhinitis: A group of symptoms affecting the nose. These symptoms occur when someone breathes in something they are allergic to, such as dust, dander, insect venom, or pollen.

Rhinophototherapy: A proposed treatment for allergic rhinitis that involves exposure of the sinuses to a combination of ultraviolet and visible light.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

30999	Unlisted procedure, nose [when specified as rhinophototherapy, intranasal application of ultraviolet and visible light]

ICD-10 Diagnosis

All diagnoses

References

Peer Reviewed Publications:

1. Albu S, Baschir S. Intranasal phototherapy versus azelastine in the treatment of seasonal allergic rhinitis. Auris Nasus Larynx. 2013; 40(5):447-451.

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3. Bella Z, Kiricsi Á, Viharosné ÉD, et al. Rhinophototherapy in persistent allergic rhinitis. Eur Arch Otorhinolaryngol. 2017; 274(3):1543-1550.
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6. Jiang RS, Wang JJ. Effect of red light rhinophototherapy on nasal patency in patients with allergic rhinitis. Int J Otolaryngol. 2018; 2018:6270614.
7. Koreck AI, Csoma Z, Bodai L, et al. Rhinophototherapy: a new therapeutic tool for the management of allergic rhinitis. J Allergy Clin Immunol. 2005; 115(3):541-547.
8. Koreck A, Szechenyi A, Morocz M, et al. Effects of intranasal phototherapy on nasal mucosa in patients with allergic rhinitis. J Photochem Photobiol B. 2007; 89(2-3):163-169.
9. Tatar EÇ, Korkmaz H, Sürenoğlu UA, et al. Effects of rhinophototherapy on quality of life in persistant allergic rhinitis. Clin Exp Otorhinolaryngol. 2013; 6(2):73-77.

Websites for Additional Information

1. American Academy of Otolaryngology−Head and Neck Surgery. Nose. Available at: https://www.enthealth.org/nose-landing-page. Accessed on August 31, 2020.
2. National Library of Medicine. Medical Encyclopedia: Allergic Rhinitis. Last updated August 25, 2020. Available at: http://www.nlm.nih.gov/medlineplus/ency/article/000813.htm. Accessed on September 10, 2020.

Index

Rhinolight
Rhinophototherapy
Ultraviolet Light
UVA
UVB

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	11/05/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale and Websites section.

Reviewed	11/07/2019	MPTAC review. Updated Rationale, References, and Websites sections.
Reviewed	01/24/2019	MPTAC review. Updated Websites section.
Reviewed	02/27/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated Rationale, References, and Websites sections.
Reviewed	02/02/2017	MPTAC review. Updated Rationale and References sections.
Reviewed	02/04/2016	MPTAC review. Removed ICD-9 codes from Coding section.
Reviewed	02/05/2015	MPTAC review. Updated Rationale and Reference Sections.
Reviewed	02/13/2014	MPTAC review. Updated Rationale and Reference Section.
Reviewed	02/14/2013	MPTAC review.
Reviewed	02/16/2012	MPTAC review. Updated Rationale and Reference sections.
	01/01/2012	Updated Coding section with 01/01/2012 CPT changes; removed code 0168T deleted 12/31/2011.
Reviewed	02/17/2011	Medical Policy & Technology Assessment Committee (MPTAC) review.
Reviewed	02/25/2010	MPTAC review.
Reviewed	02/26/2009	MPTAC review.
Revised	02/21/2008	MPTAC review. Updated Reference section. The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
New	03/08/2007	MPTAC review. Initial document development.