BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 9.03.29 Eyelid Thermal Pulsation for the Treatment of Dry Eye Syndrome

Annual Effective Policy Date: July 1, 2024

Original Policy Date: June 2013

Related Policies:

None

Eyelid Thermal Pulsation for the Treatment of Dry Eye Syndrome

Description

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Thermal pulsation is a treatment option for meibomian gland dysfunction. Meibomian gland dysfunction is recognized as the major cause of dry eye syndrome. Thermal pulsation applies heat to the palpebral surfaces of the upper and lower eyelids directly over the meibomian glands, while simultaneously applying graded pulsatile pressure to the outer eyelid surfaces, thereby expressing the meibomian glands.

OBJECTIVE

The objective of this evidence review is to determine whether use of eyelid thermal pulsation improves the net health outcome in individuals with dry eye symptoms consistent with meibomian gland dysfunction.

POLICY STATEMENT

Eyelid thermal pulsation therapy to treat dry eye syndrome is considered **investigational**.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

Eyelid thermal pulsation systems (FDA product code: ORZ) cleared by the U.S. Food and Drug Administration (FDA) are summarized in Table 1.

Table 1. Eyelid Thermal Pulsation Systems Cleared by the FDA

Device	Manufacturer	Location	Original Date Cleared/Approved	Original De Novo or 510(k) No. or PMA	Indication
LipiFlow Thermal Pulsation System	TearScience	Morrisville, NC	2011*	DEN100017*	'For the application of localized heat and pressure therapy in adult patients with chronic cystic conditions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye.'
iLux System	Tear Film Innovations	San Diego, CA	2017	K172645	'For the application of localized heat and pressure therapy in adult patients with chronic diseases of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye.'
Systane iLux2	Tear Film Innovations	Carlsbad, CA	2020	K200400	'For the application of localized heat and pressure therapy in adult patients with Meibomian Gland Dysfunction (MGD), which is associated with evaporative dry eye, and to capture/store digital images and video of the meibomian glands'
TearCare System	Sight Sciences	Menlo Park, CA	2021	K213045	'For the application of localized heat and pressure therapy in adult patients with evaporative dry eye disease due to Meibomian Gland Dysfunction (MGD), when used in conjunction with manual expression of the meibomian glands.'
TearCare MGX™	Sight Sciences	Menlo Park, CA	2023	K231084	'For the application of localized heat therapy in adult patients with evaporative dry eye disease due to meibomian gland dysfunction (MGD), when used in conjunction with manual expression of the meibomian glands.'

*Other 501(k) numbers are associated with more recent versions of the device.

RATIONALE

Summary of Evidence

For individuals who have dry eye symptoms consistent with meibomian gland dysfunction (MGD) who receive eyelid thermal pulsation, the evidence includes 10 randomized controlled trials (RCTs), nonrandomized comparison studies, and longer term follow-up of patients from RCTs and observational studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. The RCTs have evaluated only the LipiFlow system. Study populations have been predominately White or Asian. The duration of MGD and previous treatments for MGD were unclear in the study populations. The majority of the RCTs have reported greater efficacy with LipiFlow compared to standard warm compress therapy and eyelid hygiene and improvements were generally seen in both objective metrics of MGD and in patient-reported symptoms for up to 3 months. Limited longer-term follow-up is available. The method for collecting adverse events in the studies was unclear but no serious adverse events were reported in any studies. Several additional RCTs have been conducted but have not been published. Observational studies have shown sustained treatment effects for most outcomes up to 3 years. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Ophthalmology

In 2018, the American Academy of Ophthalmology updated preferred practice patterns guidelines on dry eye syndrome.[6,] These guidelines list "In-office, physical heating and expression of the meibomian glands (including device-assisted therapies, such as LipiFlow, or intense pulse light treatment)" as 1 of several step-up treatments for patients who do not respond to conventional management, including the elimination of environmental factors and offending medications, dietary modifications, ocular lubricants, and lid hygiene and warm compresses.

In 2018, the American Academy of Ophthalmology updated preferred practice patterns guidelines on blepharitis.[3,] These guidelines cover the 3 clinical subcategories of blepharitis: staphylococcal, seborrheic, and meibomian gland dysfunction (posterior blepharitis specifically affects the meibomian glands). The following statements are made relevant to thermal pulsation treatment:

"There are also several in-office procedural treatments available that may theoretically unclog the inspissated meibomian gland orifices using intense pulsed light (IPL) or mechanical means (e.g., microblepharoexfoliation of the eyelid margin, meibomian gland probing, and/or devices using thermal pulsation). Although there have been industry-sponsored studies, independent, randomized, masked clinical trials have yet to be performed to assess efficacy of these costly, primarily fee-for-service treatments."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
June 2013	New policy	
June 2014	Replace policy	Policy updated with literature review, references 9-11 added. The policy statement is unchanged.
June 2015	Replace policy	Policy updated with literature review, Rationale revised: references 10-11 added; policy statement unchanged.
September 2016	Replace policy	Policy updated with literature review, reference 8 added. Policy statement unchanged.
June 2018	Replace policy	Policy updated with literature review through January 8, 2018; no references added. Policy statement unchanged except "not medically necessary€š corrected to "investigational€š due to FDA Class II status.
June 2019	Replace policy	Policy updated with literature review through February 26, 2019; no references added. Policy statement unchanged.
June 2020	Replace policy	Policy updated with literature review through January 3, 2020; no references added. Policy statement unchanged.
June 2021	Replace policy	Policy updated with literature review through January 26, 2021; references added. Policy statement unchanged.
June 2022	Replace policy	Policy updated with literature review through December 20, 2021; no references added. Policy statement unchanged.
June 2023	Replace policy	Policy updated with literature review through December 19, 2023; no references added. Policy statement unchanged.
June 2024	Replace policy	Policy updated with literature review through January 18, 2024; references added. Policy statement unchanged.