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# FEP Medical Policy Manual

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

**Effective Policy Date: July 1, 2023**

**Original Policy Date: June 2013**

**Related Policies:**

None

# Eyelid Thermal Pulsation for the Treatment of Dry Eye Syndrome

## Description

## Description

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

In 2011, the LipiFlow Thermal Pulsation System (TearScience; assigned the generic name of eyelid thermal pulsation system) was cleared by the U.S. Food and Drug Administration (FDA).[7,] In 2017 and 2020, 2 eyelid thermal pulsation systems (iLux System and Systane iLux2, respectively) were also cleared by the FDA. The FDA classified these devices as class II (special controls) to provide a "reasonable assurance of safety and effectiveness" of the device. All 3 devices were identified by FDA as a "Battery-operated, handheld device that the physician uses in an in-office procedure to control the application of warmth and massage to the eyelids. The handheld device connects to a single-use disposable unit made of biocompatible polycarbonate and silicone that is inserted around the patient's eyelids. The device provides controlled warmth to the inner eyelid surface, close to the location of the meibomian glands, and intermittent massage to the outer eyelid surface to facilitate release of lipid from the cystic meibomian glands." All 3 devices are indicated for "the application of localized heat and pressure therapy in adult patients with Meibomian Gland Dysfunction (MGD), which is associated with evaporative dry eye." The Systane iLux2 system is also indicated "to capture/store digital images and video of the meibomian glands."

Additionally FDA-cleared eyelid thermal pulsation systems include, but are not limited to, the TearCare System (Sight Sciences, Inc., K213045, December 2021). The TearCare System is indicated 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."

FDA product code: ORZ.

# RATIONALE

## Summary of Evidence

For individuals who have dry eye symptoms consistent with meibomian gland dysfunction who receive eyelid thermal pulsation, the evidence includes 4 randomized controlled trials (RCTs), a nonrandomized comparison study, and longer term follow-up of patients from RCTs and observational studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. The trials do not provide strong evidence of long-term efficacy. Two RCTs have demonstrated positive findings for most outcome measures over the short term (up to 3 months). Observational studies have shown sustained treatment effects for most outcomes up to 3 years. The nonrandomized study showed similar outcomes for eyelid thermal pulsation and standard treatment. 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.

# REFERENCES


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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, corrected to "investigational, 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. |