



FEP Medical Policy Manual

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

Annual Effective Policy Date: July 1, 2026

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. Other office-based devices that deliver constant rather than pulsed heat to the eyelid (for example, MiBoFlow/MiBo Thermoflo, Blephasteam) are not discussed in this policy.

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 ^a	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 ^a	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.

^a Alcon, a division of Novartis, acquired Tear Film Innovations in 2018.

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 systematic reviews, randomized controlled trials (RCTs), and observational studies. A 2024 Cochrane meta-analysis evaluated the LipiFlow system's efficacy and safety for dry eye disease through 13 RCTs with 1155 participants. The findings showed that LipiFlow was comparable to other treatments like warm compresses, thermostatic devices, prescription eye drops, and doxycycline, with no notable differences in symptoms or signs. However, the evidence was deemed of low to very low certainty due to a high risk of bias. Similarly, another systematic review commissioned by the American Academy of Ophthalmology revealed that thermal pulsation with LipiFlow was more effective for MGD and dry eye than conventional therapies such as warm compresses or eyelid hygiene. However, the review also highlighted some limitations, particularly concerning the treatment's long-term durability. Another systematic review of multiple therapies for MGD found similar efficacy between thermal pulsation devices and comparator treatments. Since the publication of the systematic reviews, 2 industry-sponsored RCTs examining eyelid thermal pulsation for dry eye syndrome have been published. A randomized, assessor-masked trial comparing the efficacy and safety of LipiFlow versus thermo-mechanical action was conducted in participants with MGD across 5 US centers. The study involved 106 participants with primary efficacy outcomes assessed at baseline, 4 weeks, and 12 weeks post-treatment. Results showed significant TBUT improvements in both groups, with thermo-mechanical action proving non-inferior to LipiFlow, and no device-related adverse events were reported. A second randomized, assessor-masked controlled superiority trial was conducted to compare the TearCare pulsation system with topical cyclosporine 0.05% (CsA) in 345 participants across 19 clinics in 11 US states. The trial found significant tear break-up time improvements in both groups, with TearCare showing greater enhancement, and notable Ocular Surface Disease Index improvements without significant differences between treatments. Both therapies were safe, with mild to moderate treatment-related adverse events occurring in a small proportion of participants. Observational long-term follow-up found that efficacy was maintained in 134 patients at 24 months without need for retreatment, but 32 patients required additional treatment with TearCare. Observational studies on LipiFlow have shown sustained treatment effects for most outcomes up to 3 years. Additional RCTs are needed before any definitive conclusions can be drawn about the comparative benefits and risks of eyelid thermal pulsation therapy. These trials should include adequate masking, standardized testing methodologies (eg, evidence-based controls), and longer follow-up periods. This will help ensure that the results are reliable and applicable to a broader population. 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 (AAO) updated preferred practice patterns guidelines on dry eye syndrome.⁷ 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 one 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 AAO 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."

In 2023, the AAO updated preferred practice pattern guidelines on dry eye syndrome. These guidelines list thermal pulsation devices as a second-stage option for treatment of dry eye disease.²³ First-line treatment includes eyelid hygiene, warm compresses, and ocular lubrication. Other second-line treatment options include topical secretagogues, topical immunomodulators (such as cyclosporine), liftegrast, and short-term topical antibiotics and/or corticosteroids (for blepharitis).

In 2023, the AAO updated preferred practice pattern guidelines for blepharitis.²⁴ These guidelines indicate that multiple industry-sponsored studies have demonstrated that a single vectored thermal pulsation (VTP) treatment can be effective at improving meibomian gland function and reducing dry eye symptoms for a year or more post procedure. However, there have been no independent randomized controlled trials confirming or refuting these industry-sponsored studies.

"There are several in-office procedural treatments available that may improve the inspissated meibomian gland orifices using intense pulsed light (IPL) or theoretically unclog the meibomian glands by 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 clinical trials have yet to be performed to assess efficacy or superiority of any one of these treatments over another. [moderate quality, discretionary recommendation]"

Tear Film & Ocular Surface Society

The Tear Film & Ocular Surface Society is an industry-sponsored international organization that hosts periodic workshops on the topic of dry eye syndrome.²⁵ The management and therapy report of the latest dry eye workshop (DEWS) was published in 2025; the document includes a conflict of interest disclosure, but there is no description of the literature review methodology or system of evidence grading. For patients with a lipid-based dry eye etiology or with dry eye caused by meibomian gland dysfunction, the report concludes that the efficacy of lid heating devices is supported by randomized, placebo-controlled trials and are one of several treatment options. No recommendations are made for a preferred thermal pulsation device, but the report does comment on comparative efficacy. Regarding LipiFlow, non-industry sponsored studies have found that LipiFlow has similar efficacy as warm compresses and eyelid hygiene. Regarding iLux, the report states that it has statistically similar efficacy as LipiFlow. Regarding TearCare, a randomized study found similar efficacy between TearCare and LipiFlow overall, but patients with more severe symptoms did better with TearCare.

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" 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.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.

Date	Action	Description
June 2024	Replace policy	Policy updated with literature review through January 18, 2024; references added. Policy statement unchanged.
June 2025	Replace policy	Policy updated with literature review through February 12, 2025; references added. Policy statement unchanged.
June 2026	Replace policy	Policy updated with literature review through January 26, 2026; references added. Policy statement unchanged.