MEDICAL POLICY

POLICY TITLE	DIAGNOSIS AND TREATMENT OF DRY EYE SYNDROME
POLICY NUMBER	MP 4.033

Clinical Benefit:	☒ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**2/1/2026**

POLICY

Eyelid thermal pulsation therapy, or intense pulsed light with subsequent meibomian gland expression to treat dry eye are considered **investigational** as a management of Dry Eye Syndrome. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Near-infrared dual imaging of the Meibomian glands is considered **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-References:
MP 2.071 Nonpharmacologic Treatment of Rosacea

PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:
https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

DESCRIPTION/BACKGROUND

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.

Dry Eye Syndrome

Dry eye syndrome (DES), dry eye disease, or dysfunctional tear syndrome, either alone or in combination with other conditions, is a frequent cause of ocular irritation that leads patients to seek ophthalmologic care. It is estimated to affect between 5% and 50% of the population worldwide. Based on data from 2013, an estimated 16.4 million Americans have dry eye

syndrome. The prevalence of dry eye syndrome increases with age, especially in postmenopausal women. For both sexes, prevalence is more than 3 times higher in individuals 50 years of age or older compared to those 18 to 49 years of age. Meibomian gland dysfunction (MGD) is considered to be the most common cause of dry eye syndrome.

In a 2022 meta-analysis of three United States studies, the prevalence of dry eye ranged from 5% to 14% with an estimated pooled prevalence of 8%. The prevalence of MGD ranged from 10% to 55%. Over a 5-year period, the incidence of dry eye was 3% among individuals aged 18 and older, and 8% among those aged 68 and older. Prevention and treatment of dry eye syndrome are expected to be of greater importance as the population ages.

Treatment

Current treatment options for Meibomian gland dysfunction include physical expression to relieve the obstruction, administration of heat (warm compresses) to the eyelids to liquefy solidified meibomian gland contents, eyelid scrubs to relieve external meibomian gland orifice blockage, and medications (e.g., antibiotics, topical corticosteroids) to mitigate infection and inflammation of the eyelids. These treatment options, however, have shown limited clinical efficacy, and often require a trial-and-error approach. For example, physical expression can be very painful given the amount of force needed to express obstructed glands. Warm compress therapy can be time-consuming and labor intensive, and there is limited evidence that medications relieve MGD. While the symptoms of dry eye syndrome often improve with treatment, the disease usually is not curable and may lead to substantial patient and physician frustration. Dry eyes can be a cause of visual morbidity and may compromise results of corneal, cataract, and refractive surgery. Inadequate treatment of dry eye syndrome may result in increased ocular discomfort, blurred vision, reduced quality of life, and decreased productivity.

Thermal pulsation therapy is a relatively new therapy in management of dry eye syndrome resulting from Meibomian gland dysfunction. Using a device such as the LipiFlow® Thermal Pulsation System, the system delivers heat and pressure to the eyelids to assist in expressing blockages from clogged Meibomian glands. Temperature and pressure are closely monitored during the procedure, and the system is designed to protect other delicate structures of the eye.

Intense pulsed light is another procedure in which wavelengths (550-1200nm) of light are emitted over the eyelids, causing a warming effect. Often times, the procedure is followed by manual expression of the Meibomian glands.

Recent research on these therapies, while somewhat minimal, has shown both safety and efficacy. Several studies have shown significant improvement in dry eye symptoms in the majority of patients receiving these therapies. Another study reveals that a single treatment with thermal pulsation therapy had similar effects in comparison to 3 months of standard treatment with twice daily warm compresses. While one study suggested intense pulsed light treatment provided benefit for up to 9 months, another long-term study showed continued benefit from thermal pulsation treatment at a 3 year follow up.

In a review and meta-analysis to investigate the efficacy and safety of a vectored thermal pulsation system in the treatment of dry eye disease resulting from Meibomian gland

dysfunction (MGD), Hu et al. (2022) reviewed ten qualified RCTs incorporating 761 patients. The treatment was determined to improve the subjective and objective outcomes of MGD and did not increase the incidence of adverse events. The authors concluded that additional well-designed, large-scale RCTs are required to reach a firmer conclusion.

A Cochrane Review published in 2020 stated that the quality of evidence for safety and efficacy of IPL as a treatment for MGD was low or very low. The authors also noted a scarcity of RCT evidence. Whether IPL is of value for modifying the symptoms or signs of evaporative dry eye disease is currently uncertain. While there are multiple RCTs currently in progress, the Cochrane review ultimately concluded that there is limited high-quality research to determine whether the procedure is effective or safe.

A new Cochrane Review was published in February 2024 comparing the LipiFlow system to other dry eye disease treatments. The authors concluded that "the best available evidence was deemed to have a high level of bias, leading to low or very low certainty evidence. Additional research with adequate masking, a standardized testing methodology, and a sample representative of the MGD population is therefore needed before any firm conclusions can be drawn regarding comparative benefits and harms."

The American Academy of Ophthalmology published a Preferred Practice Pattern guideline on Dry Eye Syndrome in 2018. This guideline suggests that thermal pulsation therapy and intense pulsed light be considered as second line therapy in managing dry eye syndrome after a trial of more conservative step 1 therapy (lid hygiene, dietary/environmental modifications, removal of offending agents, patient education, addition of ocular lubricants) proved to be inadequate. Other therapies listed under step two therapy measures include ocular lubricants, tea tree oil, tear conservation, or prescription drug management. This Preferred Practice Pattern was updated in 2023 and published in early 2024. The stance on thermal pulsation devices remained unchanged, suggesting it should be considered as a "step 2" therapy if more conservative "step 1" options are inadequate. Comment on intense pulsed light was removed from this practice pattern.

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). FDA classified the LipiFlow® System as class II (special controls) to provide a "reasonable assurance of safety and effectiveness" of the device. The LipiFlow® System was identified by FDA "as an electrically powered device intended for use in the application of localized heat and pressure therapy to the eyelids. The device is used 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." FDA product code: ORZ.

Near-Infrared Dual Imaging High Definition Meibography

Near-infrared dual imaging uses a patented technique that takes high-definition images of the glands using a transilluminator and near-infrared technology. LipiScan Dynamic Meibomian Imager (Johnson & Johnson Vision) its predecessor (LipiView, TearScience) has a

transilluminator, which everts the eyelid and uses a proprietary infrared light source to image the lid.

The device is described as an office screening tool to identify patients with meibomian gland dysfunction (MGD). It is also listed as useful in the screening of both refractive surgery and cataract surgery candidates to identify coexisting MGD that can lead to dry eye. It may be used as a tool to determine treatment expectations.

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[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. Relevant outcomes are symptoms, morbid events, and functional outcomes. A 2024 Cochrane meta-analysis evaluated the LipiFlow system's efficacy and safety for dry eye disease through 13 randomized controlled trials (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 meibomian gland dysfunction (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. Since the publication of systematic reviews, two 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 five 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 thermal pulsation system with topical cyclosporine 0.05% (CsA) in 345 participants across 19 clinics in 11 US states. The trial found significant TBUT improvements in both groups, with TearCare showing greater enhancement, and notable OSDI 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 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, 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.

DEFINITIONS

N/A

DISCLAIMER

Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as required by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These polices are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational, therefore not covered:

Procedure Codes								
0207T	0330T	0507T	0563T					

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POLICY HISTORY

MP 4.033	**01/01/2020 Administrative Update.** New 2020 code added to policy, 0563T.
	07/15/2020 Consensus Review. References and coding reviewed. No change to policy statements.
	03/31/2021 Consensus Review. References and coding reviewed. No change to policy statement.

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POLICY NUMBER	MP 4.033

	03/25/2022 Minor Review. Changed eyelid thermal pulsation therapy or IPL to NMN; updated background, references, FEP.
	05/26/2023 Consensus Review. No changes to policy statement. Updated background, rationale, references. No coding changes.
	06/20/2024 Consensus Review. No changes to policy statement. Updated background, references. Coding reviewed, no changes.
	06/16/2025 Consensus Review. No change to policy statement. Cross referenced policies, Background, and Rationale updated. References added.