

**VHA Office of Integrated Veteran Care**  
**Clinical Determination and Indication**  
**Eyelid Thermal Evacuation Therapy and Intense Pulsed Light Therapy**  
**for Meibomian Gland Dysfunction**

**CDI Number: 00011**

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**I. Disclaimer**

This document is currently in draft and is intended to be used as a reference for non-VA providers and not intended to replace clinical judgment when determining care pathways. These guidelines do not guarantee benefits or constitute medical advice.

**II. Clinical Determinations and Indications**

**a. Indications**

**i. Indications for Eyelid Thermal Evacuation Therapy**

Any eyelid thermal evacuation therapy for the treatment of meibomian gland dysfunction (MGD) is considered investigational and experimental because there is insufficient evidence from peer-reviewed medical literature to support the safety and efficacy of this treatment. Therefore, eyelid thermal evacuation therapy is considered **not medically necessary**.

**ii. Indications for Intense Pulsed Light Therapy**

Intense pulsed light (IPL) therapy for the treatment of MGD is considered investigational and experimental because there is insufficient evidence from peer-reviewed medical literature to support the safety and efficacy of this treatment. Therefore, IPL is considered **not medically necessary**.

**III. Background and Supporting Information**

The following information is for reference purposes only in accordance with the medical benefits package outlined in 38 C.F.R. § 17.38 (b). Each subsection supports VA's determinations for medical necessity and alignment with generally accepted standards of medical practice.

**a. Background of Meibomian Gland Dysfunction**

Meibomian glands are large sebaceous glands that line the edge of the eyelid. These glands produce meibum, which is an oily secretion that mixes with tear film to decrease the evaporation of tears and prevent the eyes from

drying out too quickly. If the secretions become too thick, they can cause a blockage of the meibomian duct, which not only removes the secretions from the tear film but can also lead to swelling of the gland as they continue to produce meibum. The absence of oil in the tear film can subsequently lead to dry eyes. Obstructive meibomian gland dysfunction (MGD) is one of the most common causes of evaporative dry eye syndrome (DES). Risk factors for MGD include increased age, hormonal disturbances and environmental influences such as the use of contact lenses.

Treatment goals for MGD are improving the flow of meibomian secretions and reestablishment of tear film stability. Traditional treatment options for MGD include application of heat, physical expression or massage, and eyelid scrubs to help break down the obstruction of the gland. Treatment options may also include medications such as antibiotics or topical corticosteroids to minimize eyelid inflammation and reduce the risk of infection.

The FDA has granted 510(k) marketing clearance to several eyelid thermal evacuation devices that apply automated heat and pressure therapy to the eyelids for the treatment of MGD, such the LipiFlow and TearCare systems. These devices apply heat to the eyelid to help soften and express the obstructed meibomian gland secretions. Some devices also use a massaging pulsation or probing in combination with the heat therapy. These combined actions work to try and open the gland and express the oil as its being warmed and liquified by the heat. Manual expression of the meibomian gland may follow some treatments to help clear obstructions released by the gland.

Intense pulsed light therapy, first introduced by dermatologists in 1994 as a skin treatment for photoaging, uses short bursts of lights to gently heat the skin around the meibomian glands to help liquefy the clogged duct and clear the obstruction. After the IPL treatment, the meibomian glands are then expressed using special instruments. A total of four treatments are typically performed at three-week intervals.

## **b. Research/Clinical Trials**

### **i. Eyelid Thermal Evacuation Therapy for the Treatment of Meibomian Gland Dysfunction**

Finis et.al. (2014) compared results from 31 participants who were randomized to receive either a single LipiFlow treatment or self-perform a twice daily lid warming and massage over the course of 3 months. Data was collected using the Ocular Surface Disease Index (OSDI), which is a 12-item questionnaire used to assess dry eye symptoms and their effect on vision related functions. Both treatments were found to show an improvement of symptoms, but no discernable difference was found between the two treatment groups. An additional

study limitation was that the study was observer-masked only, which may lead to a placebo effect in the reported subjective symptoms.

Hagen et.al. (2018) performed a prospective, randomized, parallel group study that included 28 participants with moderate to severe MGD. Participants were randomized to receive either a single LipiFlow treatment or a daily dose of oral doxycycline for 3 months. Data was gathered using the Standard Patient Evaluation of Eye Dryness (SPEED) questionnaire as well as physical assessment of the meibomian gland function. While results showed participants experienced improvement of symptoms with the single LipiFlow treatment, many of the measurement improvements such as tear breakup time and corneal stain were not shown to be statistically significant. Further studies are needed that include treatment comparison to more conventional methods such as manual lid warming and massage.

Greinier (2016) performed a prospective, cohort, observational single study to examine the 3-year effects of a single LipiFlow treatment on patients with evaporative dry eye disease (DED) secondary to MGD. The study included 20 patients and used the meibomian gland secretion scores (MGS), tear film break-up time (TBUT), OSDI and the SPEED questionnaire to gather data at baseline, 1 month and 3 years. Findings showed that a single LipiFlow treatment may be an effective option for DED secondary to MGD as there was significant improvements in MGS and SPEED scores. However, this study was small, and findings will need to be validated with larger, well-designed studies.

Badawi (2018) performed a prospective, single-center randomized, parallel group clinical trial comparing treatments of a single TearCare versus 4-weeks of daily warm compress therapy. The study included 24 participants that were followed through 6 months post-treatment. Outcome measures included TBUT, meibomian gland assessment, corneal and conjunctival staining scores and assessment of dry eye symptoms using questionnaires. Results showed that the TearCare subjects displayed a greater improvement in TBUT scores, corneal and conjunctival staining scores and dry eye symptoms measured through the questionnaires when compared to the warm compress group. While the author concluded that the findings of this pilot study suggest TearCare is an effective treatment option for DED, this study was limited by lack of masking to the intervention. To enhance the evidence base for this treatment option, a larger number of participants enrolled

at different centers is needed. Additionally, the author disclosed this study was funded by the manufacturer of the TearCare device.

Badawi (2019) performed a 6-month single-center, randomized, parallel-group pilot study that was an extension of an initial 6-month study that compared a single TearCare treatment versus 4-weeks of daily warm compress therapy. The extension study involved an additional TearCare treatment for participants originally assigned to the TearCare group. Twelve participants were included in this study, with outcome measures including TBUT scores, meibomian gland scores, corneal and conjunctival staining scores and dry eye symptoms measured through the questionnaires. Results showed an improvement in TBUT scores, corneal and conjunctival staining scores and dry eye symptoms following the retreatment. The author concluded that a second TearCare treatment 6 months after the initial treatment provides additional improvement in the signs and symptoms of DED. This study is limited by the fact that it was a single treatment, single investigator study with a small study population. Additionally, the author disclosed this study was funded by the manufacturer of the TearCare device.

Based on a review of current medical research, there is not enough high-quality evidence regarding the clinical effectiveness or safety of LipiFlow or TearCare for the treatment of MGD.

## ii. **Intense Pulsed Light for the Treatment of Meibomian Gland Dysfunction**

The American Academy of Ophthalmology (AAO)'s Preferred Practice Pattern on "Blepharitis" (2018) stated that "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, 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."

A 2020 Cochrane Review was based on three randomized control trials (RCTs) that took place in New Zealand, Japan and China. The three trials enrolled a total of 114 patients and evaluated the effect of IPL as a treatment for MGD. Information was gathered using the SPEED questionnaire. This systematic review found little RCT evidence to show the effectiveness and safety of IPL for the treatment of MGD.

Liu et.al. (2020) performed a systematic review and meta-analysis to identify clinical trials that researched the effectiveness of IPL as a treatment for MGD. Information was gathered from four RCTs and a total of 242 total participants were randomized between a control group and a group treated with IPL. While there was an increase in the non-invasive tear break-up time (NIBUT) scores, the authors concluded that SPEED scores between the two groups were not statistically different and that the study findings did not provide conclusive evidence to prove that IPL was an effective therapy for the management of MGD. Researchers also stated that additional prospective, well-designed RCTs utilizing a larger sample would provide better evidence to assess the effectiveness of IPL for treatment of MGD.

Leng et.al (2021) conducted a systematic review and meta-analysis to research the safety and effectiveness of IPL for the treatment of MGD. Nine RCTs with a total of 539 participants were included in this review to compare IPL and IPL with meibomian gland expression (MGX) against a control group. The authors concluded that IPL in combination with MGX may be an effective treatment for MGD, but that IPL alone was not proven to be more effective than MGX.

Based on a review of current medical research, there is not enough high-quality evidence regarding the clinical effectiveness or safety of IPL for the treatment of MGD.

#### c. Medicare Coverage Determinations

There are no available Medicare coverage determinations for eyelid thermal evacuation therapy or intense pulsed light (IPL) therapy for the treatment of meibomian gland dysfunction (MGD). VA and Medicare are governed by separate laws and regulations; thus, VA coverage determinations may be different.

## IV. Definitions

Term	Definition
Blepharitis	Inflammation of the eyelids
Inspissated	Thick or thickened in consistency
Meibomian gland	Oil glands along the edge of the eyelids where the eyelashes are located
Microblepharoexfoliation	An eyelid exfoliation procedure that removes bacteria and oil that cause inflammation and other eye discomfort
Meibum	An oily substance secreted by the meibomian glands that help prevent the evaporation of tears

Term	Definition
Photoaging	The premature aging of the skin caused by prolonged sun exposure
Placebo Effect	A positive health outcome resulting from a person's anticipation that the intervention will help their symptoms
Sebaceous Glands	Glands in the skin that create and secrete sebum, which is a substance that provides a protective coating to help retain moisture
Tear Film	A thin fluid layer that lubricates the surface of the eye

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## VI. CDI History/Revision Information

- Explanation of changes to the CDI

Revision Type	Date of Revision	Update(s) Made to CDI
	MM/DD/YYYY	•
	MM/DD/YYYY	•