MEDICAL POLICY

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

Effective Date:	**9/1/2023**

I. POLICY

Eyelid thermal pulsation therapy, or intense pulsed light with subsequent meibomian gland expression to treat dry eye are considered **not medically necessary** 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 Rosacea

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross please see additional information below, and subject to benefit variations as discussed in Section VI 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

III. DESCRIPTION/BACKGROUND

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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. DES is considered a significant public health problem. It is estimated to affect between 5% and 50% of the population worldwide. The prevalence of DES increases with age, especially in postmenopausal women. It is estimated that DES affects more than 7 million Americans older than 40 years of age, and approximately 1 to 4.3 million Americans between 65 and 84 years of age. Prevention and treatment of DES 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 (eg, antibiotics, topical corticosteroids) to mitigate infection and inflammation of the eyelids. These treatment options, however, have shown limited clinical efficacy. 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 DES 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 DES 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.

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.

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) have 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.

MGD can cause dry eye. It is common to have a combination of MGD, dry eye and blepharitis.

IV. RATIONALE

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SUMMARY OF EVIDENCE

For individuals who have dry eye symptoms consistent with meibomian gland dysfunction who receive eyelid thermal pulsation, the evidence includes 4 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 American Academy

of Ophthalmology considers eyelid thermal pulsation therapy or intense pulsed light as a step two management for treatment of dry eye syndrome. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS TOP

N/A

VI. BENEFIT VARIATIONS TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER TOP

Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION TOP

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								
0330T	0507T							

Not medically necessary, therefore not covered:

Procedure Codes								
0207T	0563T							

IX. REFERENCES TOP

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X. POLICY HISTORY

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MP 4.033	**CAC 7/30/13 New policy.** BCBSA adopted. Eyelid thermal pulsation for the treatment of dry eye syndrome is considered investigational. FEP variation added.
	CAC 5/20/14 Consensus review. FEP variation revised to refer to the FEP policy manual. For this review, references and rationale were updated. No changes to the policy statements. Codes reviewed.
	CAC 6/2/15 Consensus review. References and rationale updated. No changes to the policy statements**.** Codes reviewed.
	11/2/15 Administrative update. LCD number changed from L31686 to L35094 due to Novitas update to ICD-10.
	CAC 5/31/16 Consensus review. No changes to the policy statement. References and rationale updated**.** Coding reviewed.
	11/15/16 Administrative Update. Variation reformatting
	CAC 7/25/17 Consensus review. Policy statement unchanged. Medicare variation to LCD 35094 added. Description/Background, Rationale and Reference sections updated. Coding Reviewed.
	1/17/18 Administrative update. Medicare variations removed from Commercial Policies effective 1/1/18.
	3/27/18 Consensus review. No changes to the policy statements. References updated. Rationale revised.
	6/25/18 Minor review. Added statement indicating near-infrared dual imaging of the Meibomian glands is considered investigational. Changed title. Formerly Eyelid Thermal Pulsation for the Treatment of Dry Eye Syndrome. New title: Diagnosis and Treatment of Dry Eye Syndrome. References updated. Coding reviewed.
	4/25/19 Consensus. No change to policy statements. Background, summary of evidence and references updated.
	01/01/20 Coding 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.
	3/25/2022 Minor review. Changed eyelid thermal pulsation therapy or IPL to NMN; updated background, references, FEP.
	5/26/2023 Consensus review. No changes to policy statement. Updated background, rationale, references. No coding changes.

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