Medical Policy
Eyelid Thermal Pulsation for the Treatment of Dry Eye Syndrome

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Policy Number: 613
BCBSA Reference Number: 9.03.29

Related Policies
None

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO BlueSM and Medicare PPO BlueSM Members

Eyelid thermal pulsation therapy to treat dry eye syndrome is INVESTIGATIONAL.

Prior Authorization Information
Commercial Members: Managed Care (HMO and POS)
This is NOT a covered service.

Commercial Members: PPO, and Indemnity
This is NOT a covered service.

Medicare Members: HMO BlueSM
This is NOT a covered service.

Medicare Members: PPO BlueSM
This is NOT a covered service.

CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.
Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

### CPT Codes

<table>
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<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tr>
<td>0207T</td>
<td>Evacuation of meibomian glands, automated, using heat and intermittent pressure, unilateral</td>
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### ICD-9 Diagnosis Codes

Investigational for all diagnoses.

### ICD-9 Procedure Codes

There is no specific ICD-9 procedure code for this service.

### Description

The LipiFlow® Thermal Pulsation System (TearScience Inc., Morrisville, NC) is a new treatment option for addressing meibomian gland dysfunction (MGD). MGD is recognized as the major cause of dry eye syndrome. The LipiFlow® System allows heat to be applied 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.

### Background

Dry eye syndrome, dry eye disease (DED) 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. (1) DED is considered a significant public health problem and is estimated to affect between 14% and 33% of the population worldwide. (2, 3) The prevalence of DED increases with age, especially in postmenopausal women. (2, 3) It is estimated that DED affects more than 7 million Americans older than 40 years of age, (2) and approximately 1 million to 4 million Americans between 65 to 84 years of age. (1) The prevention and treatment of DED is expected to be of greater importance as the population ages.

DED is often classified into either the aqueous-deficient subtype or the evaporative subtype. (2, 3) Although the initial classification of the DED may be either of these, the classification is not mutually exclusive. (2, 3) Meibomian gland dysfunction (MGD), characterized by changes in gland secretion with or without concomitant gland obstruction, is recognized to be the most common cause of evaporative dry eye and may also play a role in aqueous-deficient dry eye. (3, 4)

Current treatment options for MGD include physical expression to relieve the obstruction, administration of heat (warm compresses) to the eyelids to potentially liquefy solidified meibomian gland (MG) 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. (4, 5) These treatment options however have shown limited clinical efficacy. (5) Physical expression, for example, can be very painful given the significant amount of force needed to express obstructed glands. Warm compress therapy can be both time-consuming and labor intensive, and there is limited evidence that medications can relieve MGD. (5) While the symptoms of DED often improve with treatment, the disease usually is not curable and may lead to substantial patient and physician frustration. (1) Dry eyes can be a cause of visual morbidity and may compromise results of corneal, cataract, and refractive surgery. Inadequate treatment of DED may result in increased ocular discomfort, blurred vision, reduced quality of life, and decreased productivity. (2) DED is a multi-factorial disease of the ocular surface that may require a combination approach to treatment. (2)

The LipiFlow® Thermal Pulsation System (TearScience Inc., Morrisville, NC) is a new device developed to address the limitations of current treatment options to relieve MGD. (6, 7) This device is designed to safely heat the palpebral surfaces of both the upper and lower eyelids, while simultaneously applying
graded pulsatile pressure to the outer eyelid surfaces. The device massages the outer eyelids from the base of the meibomian glands in the direction of the gland orifices, thereby expressing the meibomian glands during heating. The LipiFlow® System is composed of 2 primary components, an ocular component (The Disposable) and a handheld control system. The Disposable has 2 parts, a lid warmer and an eyecup. (6, 7)

**Summary**
The LipiFlow® Thermal Pulsation System (TearScience Inc., Morrisville, NC) is a new treatment option for addressing meibomian gland dysfunction (MGD). The evidence to date on the LipiFlow® System is based on five publications for treatment of MGD, all of which have been funded by the manufacturer of this device. This evidence consists of one case-report (reported in two separate publications at two periods of follow-up), one small case series, and one randomized clinical trial (RCT) with crossover and a follow-up analysis in a sub-cohort of patients.

The RCT reported short-term benefits for LipiFlow® on measures of MG function and dry eye symptoms. However, this single trial is insufficient to determine the effect of LipiFlow® on health outcomes. The comparative results were short term (2 weeks), and the clinical significance of the differences is not clear. Further prospective RCTs are needed to assess the impact on health outcomes of the LipiFlow® System compared to alternative treatment options. These trials will require longer follow-up to assess durability of effect and to accurately predict the optimal frequency of treatment with the LipiFlow® System for individual patients. Based on review of the evidence to date the, use of the LipiFlow® Thermal Pulsation System is considered investigational for dry eye disease (DED).

**Policy History**

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**Information Pertaining to All Blue Cross Blue Shield Medical Policies**
Click on any of the following terms to access the relevant information:
- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

**References**