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
NCD/LCD: Local Coverage Determination (LCD): Category III CPT® Codes (L33392)

Related Policies
None

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

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

Medicare HMO BlueSM and Medicare PPO BlueSM Members

This is not a covered service.

Local Coverage Determination (LCD): Category III CPT® Codes (L33392)

For medical necessity criteria and coding guidance for Medicare Advantage members living outside of Massachusetts, please see the Centers for Medicare and Medicaid Services website for information regarding your specific jurisdiction at https://www.cms.gov.

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Outpatient</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>This is not a covered service.</td>
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<tr>
<td>Commercial PPO and Indemnity</td>
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</table>
The following CPT codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>0207T</td>
<td>Evacuation of meibomian glands, automated, using heat and intermittent pressure, unilateral</td>
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<tr>
<td>0330T</td>
<td>Tear film imaging, unilateral or bilateral, with interpretation and report</td>
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**Description**

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. DED is considered a significant public health problem and is estimated to affect between 14% and 33% of the population worldwide.1,2 The prevalence of DED increases with age, especially in postmenopausal women. It is estimated that DED affects more than 7 million Americans older than 40 years of age,1 and approximately 1 million to 4 million Americans between 65 to 84 years of age.3 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. Although the initial classification of DED may be either of these, the classification is not mutually exclusive. DED is a multifactorial disease of the ocular surface that may require a combination approach to treatment. 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.

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 (eg, antibiotics, topical corticosteroids) to mitigate infection and inflammation of the eyelids.4,5 These treatment options however have shown limited clinical efficacy. 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. 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.

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. This device is designed to heat the palpebral surfaces of both the upper and lower eyelids, while applying graded pulsatile pressure to the outer eyelid surfaces. The LipiFlow® System is composed of a disposable ocular component and a handheld control system. Following application of a topical anesthetic, the heated inner portion of the
LipiFlow eyecup is applied to the conjunctival surface of the upper and lower eyelids. The outer portion of the device covers the skin surface of the upper and lower eyelids. The device massages the eyelids with cyclical pressure from the base of the meibomian glands in the direction of the gland orifices, thereby expressing the meibomian glands during heating. It is proposed that a single 12-minute session is at least as effective as twice daily lid warming and massage over 3 months.

Summary

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.

The literature on eyelid thermal pulsation for the treatment of dry eye syndrome includes 2 randomized controlled trials (RCTs) with subsequent follow-up of some of the patients treated with the LipiFlow® System. There are numerous limitations of one of the trials, and questions remain regarding the clinical significance of results in the second trial. Thus, the evidence at this time is insufficient to permit conclusions regarding the effect of this procedure on health outcomes. Further prospective RCTs are needed to assess the impact on health outcomes of the LipiFlow® System compared with 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.

Policy History

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<tr>
<th>Date</th>
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<tr>
<td>4/2017</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>4/2016</td>
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<tr>
<td>8/2013</td>
<td>BCBSA National medical policy review.</td>
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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