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Introduction

Dry eye syndrome is most frequently caused by problems with a gland called the meibomian gland. This gland produces oil, which is needed for the tear film that covers the eye. If the gland is blocked or otherwise can’t produce enough oil, the tear film that covers the eye evaporates quickly, which leads to dry eye syndrome. Ways to treat these blocked glands include warm compresses, eyelid scrubs, special ointments, and squeezing the gland to clear the blockage. Thermal eyelid pulsation devices, like the LipiFlow system, apply heat and pressure in an effort to treat the blockage. There is not enough medical evidence to show if these systems bring better results than the usual treatments. For this reason they are considered investigational.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Eyelid thermal pulsation therapy to treat dry eye syndrome is considered investigational.

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

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The LipiFlow Thermal Pulsation System is a treatment option for meibomian gland dysfunction. Meibomian gland dysfunction is recognized as the major cause of dry eye syndrome. The LipiFlow System 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.
Background

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 14% and 33% of the population worldwide.\textsuperscript{1,2} 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,\textsuperscript{1} and approximately 1 to 4.3 million Americans between 65 to 84 years of age.\textsuperscript{3} Prevention and treatment of DES are expected to be of greater importance as the population ages.

Treatment

Current treatment options for Meibomian gland dysfunction (MGD) 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.\textsuperscript{4,5} 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.\textsuperscript{5} 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.

Summary of Evidence

For individuals who have dry eye symptoms consistent with meibomian gland dysfunction who receive eyelid thermal pulsation, the evidence includes 3 randomized controlled trials (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 evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
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<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02894658</td>
<td>LipiFlow Versus Warm Compresses in Parkinson’s Disease</td>
<td>25</td>
<td>April 2021 (suspended)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial

Practice Guidelines and Position Statements

American Academy of Ophthalmology

In 2013, the American Academy of Ophthalmology published preferred practice patterns guidelines on dry eye syndrome. A number of treatment options were recommended. The use of thermal pulsation treatment devices is not mentioned.

Medicare National Coverage

There is no national coverage determination.

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.

References


**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/08/13</td>
<td>New Policy. Policy created with literature search through November 7, 2012; considered investigational. New CPT 0330T (effective 7/1/13) and unlisted code 67999 included in policy.</td>
</tr>
<tr>
<td>06/13/14</td>
<td>Annual Review. Policy updated with literature review through February 5, 2014. References 9-12 added; others renumbered/removed. Policy statement unchanged. ICD-10-CM codes removed; not part of adjudication.</td>
</tr>
<tr>
<td>05/01/18</td>
<td>Annual Review, approved April 18, 2018. Policy updated with literature review through January 2018; no references added. Policy statement unchanged.</td>
</tr>
<tr>
<td>06/01/19</td>
<td>Annual Review, approved May 7, 2019. Policy updated with literature review through February 2019; no references added. Policy statement unchanged.</td>
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