MEDICAL POLICY – 9.03.29
Eyelid Thermal Pulsation for the Treatment of Dry Eye Syndrome

BCBSA Ref. Policy: 9.03.29
Effective Date: June 1, 2019
Last Revised: May 7, 2019
Replaces: N/A
RELATED MEDICAL POLICIES:
None

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

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.

Policy Coverage Criteria
Procedure

Eyelid thermal pulsation therapy

Investigational

Eyelid thermal pulsation therapy to treat dry eye syndrome is considered investigational.

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<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>

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

N/A

Evidence Review

Description

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>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></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**

*Ameircan 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>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2019 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
• Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  • Qualified sign language interpreters
  • Written information in other formats (large print, audio, accessible electronic formats, other formats)
• Provides free language services to people whose primary language is not English, such as:
  • Qualified interpreters
  • Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in any other way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.

Call 800-722-1471 (TTY: 800-842-5357).

Arabic:
لا يسمح هذا الإشعار بممارسة التمييز على أي أساس. لا يمنع هذا الإشعار خدمات غير مالية مخصصة للذباق، أو
• الترجمة الشفية المؤهلة
• معلومات كتابية في منتجات أخرى

明らか والأعراب

ويحوي هذا الإشعار معلومات هامة. قد يعود هذا الإشعار معلومات محددة مخصصة للذباق، أو
• الترجمة الشفية المؤهلة
• معلومات كتابية في منتجات أخرى

باسم

中文 (Chinese):
本通知有重要的讯息。本通知可能有关於您透過 Premera Blue Cross 提交的申请或保险的重要讯息。本通知内可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或者費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357)。

Oromo (Cushite):

Frenč (Français):

Deutsche (German):

Ilokano (Ilocano):
Daytoy a Pakdaak kat naglaon iti Napateg nga Impomarsion. Daytoy a pakdaak mabalin nga adda kat naglaon iti napateg nga impomarsion maiapanggep iti aplikasyonono yenno coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a petsa iti daytoy a pakdaak. Mabalin nga adda rumbeg nga aramidenyen nga addang saksay dagiti partikular a naituding nga aldaw tapno mapagtalinaedyo ti coverage ti salun-atypo yenno tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impomarsion ken tulong iti bukodo a pagasasao nga awan ti bayadanyen. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):
Premera Blue Cross may contain important dates. You may need these dates to maintain your coverage or help with costs. You will need these dates if you file an appeal or request for coverage. You may also need them if you take a leave of absence. You may need them if you file a claim. You may also need them if you file a grievance. You may also need them if you file a complaint. You may also need them if you file a report. You may also need them if you file a petition. You may also need them if you file a lawsuit. You may also need them if you file a complaint. You may also need them if you file a report. You may also need them if you file a petition. You may also need them if you file a lawsuit.