

Corporate Medical Policy

Eyelid Thermal Pulsation for the Treatment of Dry Eye Syndrome

File Name: eyelid_thermal_pulsation_for_the_treatment_of_dry_eye_syndrome
Origination: 4/2015
Last Review: 6/2023

Description of Procedure or Service

Dry eye syndrome (DES), 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. It is estimated to affect between 5% and 50% of the population worldwide. Based on data from 2013, an estimated 16.4 million Americans have dry eye syndrome. The prevalence of dry eye syndrome increases with age, especially in postmenopausal women. For both sexes, prevalence is more than 3 times higher in individuals 50 years of age or older compared to those 18 to 49 years of age. Meibomian gland dysfunction (MGD) is considered to be the most common cause of dry eye syndrome. Prevention and treatment of dry eye syndrome are expected to be of greater importance as the population ages.

Current treatment options for Meibomian gland dysfunction (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. 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. 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.

Regulatory Status

The LipiFlow® System (assigned the generic name of eyelid thermal pulsation system) was cleared by FDA in 2011. FDA classified the LipiFlow® System into class II (special controls) to provide a “reasonable assurance of safety and effectiveness” of the device. The LipiFlow® System is 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.”

In 2017 and 2020, 2 eyelid thermal pulsation systems (iLux® System and Systane® iLux2®, respectively) were also cleared by the FDA. The FDA classified these devices as class II (special controls) to provide a “reasonable assurance of safety and effectiveness” of the device. All 3 devices were identified by FDA as a “Battery-operated, handheld device that the physician uses in an in-office procedure to control the application of warmth and massage to the eyelids. The handheld device connects to a single-use disposable unit made of biocompatible polycarbonate and silicone that is inserted around the patient's eyelids. The device provides controlled warmth to the inner eyelid surface, close to the location of the meibomian glands, and intermittent massage to the outer eyelid surface to facilitate release of lipid from the cystic meibomian glands.” All 3 devices are indicated for “the application of localized heat and pressure therapy in adult patients with Meibomian Gland Dysfunction

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(MGD), which is associated with evaporative dry eye." The Systane® iLux2® system is also indicated "to capture/store digital images and video of the meibomian glands."

Additionally FDA-cleared eyelid thermal pulsation systems include, but are not limited to, the TearCare® System (Sight Sciences, Inc., K213045, December 2021). The TearCare® System is indicated for "the application of localized heat and pressure therapy in adult patients with evaporative dry eye disease due to Meibomian Gland Dysfunction (MGD), when used in conjunction with manual expression of the meibomian glands."

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Eyelid thermal pulsation for the treatment of dry eye syndrome is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Eyelid Thermal Pulsation for the Treatment of Dry Eye Syndrome is covered

Not applicable.

When Eyelid Thermal Pulsation for the Treatment of Dry Eye Syndrome is not covered

Eyelid thermal pulsation for the treatment of dry eye syndrome is considered **investigational**. BCBSNC does not provide coverage for investigational services or procedures.

Policy Guidelines

The LipiFlow® Thermal Pulsation System (TearScience, Morrisville, NC) is a treatment option for meibomian gland dysfunction (MGD). MGD 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.

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

Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 0207T, 0330T, 0563T

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.29, 3/12/15

Medical Director review 3/2015

Specialty Matched Consultant Advisory Panel- 6/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.29, 3/10/16

Specialty Matched Consultant Advisory Panel- 6/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.29, 3/9/17

Specialty Matched Consultant Advisory Panel- 6/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.29, 3/8/18

Specialty Matched Consultant Advisory Panel- 6/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.29, 3/14/19

Specialty Matched Consultant Advisory Panel- 6/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.29, 3/12/20

Specialty Matched Consultant Advisory Panel- 6/2020

Medical Director review 6/2020

Medical Director review 10/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.29, 3/11/21

Specialty Matched Consultant Advisory Panel- 6/2021

Medical Director review 6/2021

Hura AS, Epitropoulos AT, Czyz CN, et al. Visible Meibomian Gland Structure Increases After Vectored Thermal Pulsation Treatment in Dry Eye Disease Patients with Meibomian Gland Dysfunction. *Clin Ophthalmol.* 2020; 14: 4287-4296. PMID 33324034

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Food and Drug Administration. 510(k) Premarket Notification.
accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K112704; Accessed February 25, 2022

Specialty Matched Consultant Advisory Panel- 6/2022

Medical Director review 6/2022

Specialty Matched Consultant Advisory Panel- 6/2023

Medical Director review 6/2023

American Academy of Ophthalmology - Preferred Practice Patterns - Dry Eye Syndrome, 2018
<https://www.aaof.org/education/preferred-practice-pattern/dry-eye-syndrome-ppp-2018>

Policy Implementation/Update Information

- 5/26/15 New medical policy developed. Eyelid Thermal Pulsation for the Treatment of Dry Eye Syndrome is considered investigational. Senior medical director review 3/2015. (lpr)
- 7/28/15 Deleted incorrect CPT code 0030T and replaced with correct CPT code 0330T in “Billing/Coding” section. Specialty Matched Consultant Advisory Panel review 6/24/2015. No change to policy statement. (lpr)
- 4/29/16 Updated Policy Guidelines. Reference added. No change to policy statement. (lpr)
- 8/30/16 Specialty Matched Consultant Advisory Panel review 6/29/2016. No change to policy statement. (lpr)
- 4/28/17 Updated Policy Guidelines section. Reference added. No change to policy statement. (lpr)
- 7/28/17 Specialty Matched Consultant Advisory Panel review 6/28/2017. No change to policy statement. (lpr)
- 8/10/18 Specialty Matched Consultant Advisory Panel review 6/2018. Reference added. No change to policy statement. (lpr)
- 7/16/19 Updated Description and Policy Guidelines sections. Specialty Matched Consultant Advisory Panel review 6/19/2019. Reference added. No change to policy statement. (lpr)
- 6/30/20 Specialty Matched Consultant Advisory Panel review 6/17/2020. Reference added. No change to policy statement. Medical Director review 6/2020. (lpr)
- 11/10/20 Added CPT code 0563T to Billing/Coding section. Medical Director review 10/2020. No change to policy statement. (lpr)
- 7/13/21 Specialty Matched Consultant Advisory Panel review 6/16/2021. Updated Description section. Reference added. Medical Director review 6/2021. No change to policy statement. (lpr)
- 7/26/22 Specialty Matched Consultant Advisory Panel review 6/2022. Updated description section and added references. Medical Director review 6/2022. (lpr)

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7/18/23 Specialty Matched Consultant Advisory Panel review 6/21/2023. Medical Director review 6/2023. No change to policy statement. Reference added. (lpr)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.