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 CAP Review:	6/2018
Next CAP Review:	6/2019
Last Review:	6/2018

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. DED is considered a significant public health problem and is estimated to affect between 14% and 33% of the population worldwide. 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, and approximately 1 million to 4 million Americans between 65 to 84 years of age. 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. 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.

The LipiFlow® Thermal Pulsation System (TearScience, 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.

Regulatory Status
The LipiFlow® System (assigned the generic name of eyelid thermal pulsation system) was cleared by FDA in June 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."

******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 new treatment option for addressing 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 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.

Billing/Coding/Physician Documentation Information

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.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: *0207T, 0330T*

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

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)