BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:
Eyelid Thermal Pulsation for the Treatment of Dry Eye Syndrome

Policy #: 522
Category: Surgery
Latest Review Date: March 2021
Policy Grade: B

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **eyelid thermal pulsation for the treatment of dry eye syndrome** as a **non-covered benefit** and as **investigational**

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Thermal pulsation is a treatment option for meibomian gland dysfunction (MGD). MGD is recognized as the major cause of dry eye syndrome. Thermal pulsation 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.

Dry Eye Syndrome (DES)

Dry eye syndrome, 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. It is estimated to affect between five percent and fifty percent 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 three 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.

Treatment

Current treatment options for Meibomian gland dysfunction include physical expression to relieve the obstruction, administration of heat (warm compresses) to the eyelids to potentially liquefy solidified meibomian gland contents, eyelid scrubs to relieve external meibomian gland orifice blockage, and medications (e.g., antibiotics, topical corticosteroids) to mitigate infection and inflammation of the eyelids. These treatment options however have shown limited clinical efficacy and often require a trial-and-error approach. 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 dry eye syndrome 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 dry eye syndrome may result in increased ocular discomfort, blurred vision, reduced quality of life, and decreased productivity.

KEY POINTS:

The most recent literature update was performed through January 26, 2021.

Summary of Evidence

For individuals who have dry eye symptoms consistent with MGD who receive eyelid thermal pulsation, the evidence includes four 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 three months). Observational studies have shown sustained treatment effects for most outcomes up to three years. The nonrandomized study showed similar outcomes for eyelid thermal pulsation and standard treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

American Academy of Ophthalmology

In 2018, the American Academy of Ophthalmology updated preferred practice patterns guidelines on dry eye syndrome. These guidelines list "In-office, physical heating and expression of the meibomian glands (including device-assisted therapies, such as LipiFlow, or intense pulse light treatment)" as one of several step-up treatments for patients who do not respond to conventional management, including the elimination of environmental factors and offending medications, dietary modifications, ocular lubricants, and lid hygiene and warm compresses.

In 2018, the American Academy of Ophthalmology updated preferred practice patterns guidelines on blepharitis. These guidelines cover the three clinical subcategories of blepharitis: staphylococcal, seborrheic, and meibomian gland dysfunction (posterior blepharitis specifically affects the meibomian glands). The following statements are made relevant to thermal pulsation treatment:

> "There are also several in-office procedural treatments available that may theoretically unclog the inspissated meibomian gland orifices using intense pulsed light (IPL) or mechanical means (e.g., microblepharoexfoliation of the eyelid margin, meibomian gland probing, and/or devices using thermal pulsation). Although there have been industry-sponsored studies, independent, randomized, masked clinical trials have yet to be performed to assess efficacy of these costly, primarily fee-for-service treatments."

U.S. Preventive Services Task Force Recommendations

Not applicable.

KEY WORDS:

LipiFlow®, Dry eye, Dry eye syndrome, Meibomian gland dysfunction

APPROVED BY GOVERNING BODIES:

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). In 2017 and 2020, two 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 three 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 three devices are indicated for "the application of localized heat and pressure therapy in adult patients with Meibomian Gland Dysfunction (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."

FDA product code: ORZ.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

0207T	Evacuation of meibomian glands, automated, using heat and intermittent pressure, unilateral
0330T	Tear film imaging, unilateral or bilateral, with interpretation and report (e.g., LipiView Ocular Surface Interferometer, which is being marketed for use with eyelid thermal pulsation treatment)
0507T	Near-infrared dual imaging (i.e. simultaneous reflective and trans-illuminated light) of meibomian glands, unilateral or bilateral, with interpretation and report: This service may be used in conjunction with the LipiScan Thermal Pulsation System.
0563T	Evacuation of Meibomian glands, using heat delivered through wearable, open-eye eyelid treatment devices and manual gland expression, bilateral **(eff 01/01/20)**

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POLICY HISTORY:

Adopted for Blue Advantage, March 2013
Available for comment March 12 through April 25, 2013
Medical Policy Group, March 2014
Medical Policy Group, March 2015
Medical Policy Group, March 2016
Medical Policy Group, March 2017
Medical Policy Group, February 2018: CPT codes 0207T and 0330T are also referenced in LCD for Non-covered Category III CPT Codes (L34555) effective 02/26/18.
Medical Policy Group, March 2018
Medical Policy Group, March 2019
Medical Policy Group, March 2020: LCD for Non-covered Category III CPT Codes (L34555), retired effective 03/23/20.
Medical Policy Group, March 2021

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.