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: September 2020
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:

Effective for dates of service on and after April 26, 2013:

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:

The LipiFlow® Thermal Pulsation System is a treatment option for meibomian gland dysfunction (MGD). MGD is recognized as the major cause of dry eye syndrome. The LipiFlow System 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 (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 and is estimated to affect between 14% and 33% of the population worldwide. 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, and approximately 1 to 4.3 million Americans between 65 to 84 years of age. Prevention and treatment of DES 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 (MG) 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. 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 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.

KEY POINTS:

The most recent literature update was performed through January 03, 2020.

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, a nonrandomized comparison study, and longer term follow-up of patients from randomized controlled trials and observational studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. The trials do not provide strong evidence of long-term efficacy. Two randomized controlled trials 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 three 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.

Practice Guidelines and Position Statements:
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 was not mentioned.

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) was cleared by the U.S. Food and Drug Administration (FDA). 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."

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 **(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.

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.