9.03.29	Eyelid Thermal Pulsation for the Treatment of Dry Eye Syndrome		
Original Policy Date:	June 30, 2015	**Effective Date:**	May 1, 2025
Section:	9.0 Other	**Page:**	Page 1 of 13

Policy Statement

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

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding

See the Codes table for details.

Description

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

Summary of Evidence

For individuals who have dry eye symptoms consistent with meibomian gland dysfunction (MGD) who receive eyelid thermal pulsation, the evidence includes systematic reviews, randomized controlled trials (RCTs), and observational studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. A 2024 Cochrane meta-analysis evaluated the LipiFlow system's efficacy and safety for dry eye disease through 13 randomized controlled trials (RCTs) with 1155 participants. The findings showed that LipiFlow was comparable to other treatments like warm compresses, thermostatic devices, prescription eye drops, and doxycycline, with no notable differences in symptoms or signs. However, the evidence was deemed of low to very low certainty due to a high risk of bias. Similarly, another systematic review commissioned by the American Academy of Ophthalmology revealed that thermal pulsation with LipiFlow was more effective for meibomian gland dysfunction (MGD) and dry eye than conventional therapies such as warm compresses or eyelid hygiene. However, the review also highlighted some limitations, particularly concerning the treatment's long-term durability. Since the publication of systematic reviews, two industry-sponsored RCTs examining eyelid thermal pulsation for dry eye syndrome have been published. A randomized, assessor-masked trial comparing the efficacy and safety of LipiFlow versus thermo-mechanical action was conducted in participants with MGD across five US centers. The study involved 106 participants with primary efficacy outcomes assessed at baseline, 4 weeks, and 12 weeks post-treatment. Results showed significant TBUT improvements in both groups, with thermo-mechanical action proving non-inferior to LipiFlow , and no device-related adverse events were reported. A second randomized, assessor-masked controlled superiority trial was conducted to compare the TearCare thermal pulsation system with topical cyclosporine 0.05% (CsA) in 345 participants across 19 clinics in 11 US states. The trial found significant TBUT improvements in both groups, with TearCare showing greater enhancement, and notable OSDI improvements without significant differences between treatments. Both therapies were safe, with mild to moderate treatment-related adverse events occurring in a small proportion of participants. Observational studies on LipiFlow have shown sustained treatment effects for most outcomes up to 3 years. Additional RCTs are needed before any definitive conclusions can be drawn about the comparative benefits and risks of eyelid thermal pulsation therapy. These trials should include adequate masking, standardized testing methodologies, and longer follow-up periods. This will help ensure that the results are reliable and

applicable to a broader population. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information
Not applicable.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

Eyelid thermal pulsation systems (FDA product code: ORZ) cleared by the U.S. Food and Drug Administration (FDA) are summarized in Table 1.

Table 1. Eyelid Thermal Pulsation Systems Cleared by the FDA

Device	Manufacturer	Location	Original Date Cleared/Approved	Original De Novo or 510(k) No. or PMA	Indication
LipiFlow® Thermal Pulsation System	TearScience	Morrisville, NC	2011*	DEN100017*	'For the application of localized heat and pressure therapy 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.'
iLux® System	Tear Film Innovations[a]	San Diego, CA	2017	K172645	'For the application of localized heat and pressure therapy in adult patients with chronic diseases of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye.'
Systane® iLux2®	Tear Film Innovations[a]	Carlsbad, CA	2020	K200400	'For the application of localized heat and pressure therapy in adult patients with Meibomian Gland Dysfunction (MGD),

Device	Manufacturer	Location	Original Date Cleared/Approved	Original De Novo or 510(k) No. or PMA	Indication
					which is associated with evaporative dry eye, and to capture/store digital images and video of the meibomian glands'
TearCare® System	Sight Sciences	Menlo Park, CA	2021	K213045	'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.'
TearCare® MGX™	Sight Sciences	Menlo Park, CA	2023	K231084	'For the application of localized heat 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.'

*Other 501(k) numbers are associated with more recent versions of the device.
[a] Alcon, a division of Novartis, acquired Tear Film Innovations in 2018.

Rationale

Background

Dry Eye Syndrome

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 5% and 50% of the population worldwide.[1,] Based on data from 2013, an estimated 16.4 million Americans have dry eye syndrome.[2,] 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.[3,]

In a 2022 meta-analysis of three United States studies, the prevalence of dry eye ranged from 5% to 14% with an estimated pooled prevalence of 8%. The prevalence of MGD ranged from 10% to 55%. Over a 5-year period, the incidence of dry eye was 3% among individuals aged 18 and older, and 8% among those aged 68 and older.[4,]Prevention and treatment of dry eye syndrome are expected to be of greater importance as the population ages.

Treatment

Current treatment options for 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 (e.g., antibiotics, topical corticosteroids) to mitigate infection and inflammation of the eyelids.[3,5,6,7,]These treatment options, however, have shown limited clinical efficacy, and often require a trial-and-error approach. 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.[6,] 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.[3,7,] 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.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Dry Eye Syndrome

Clinical Context and Therapy Purpose

The purpose of eyelid thermal pulsation in individuals who have dry eye syndrome is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population(s) of interest is individuals with dry eye syndrome. Dry eye syndrome is often classified into the aqueous-deficient subtype or the evaporative subtype, although classification is not mutually exclusive. Dry eye syndrome is a multifactorial disease of the ocular surface that may require a combination approach to treatment. Meibomian gland dysfunction (MGD), characterized by changes in gland secretion with or without concomitant gland obstruction, is recognized as the most common cause of evaporative dry eye and may also play a role in aqueous-deficient dry eye.

Interventions

The therapy being considered is eyelid thermal pulsation. The LipiFlow Thermal Pulsation System is one of the devices developed to relieve MGD. This device heats 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 glands during heating. The TearCare System is another FDA-cleared device intended for the application of localized heat therapy in adult patients with evaporative dry eye disease due to MGD, when used in conjunction with manual expression of the meibomian glands. The system uses

two wearable devices affixed to the eyelids and a central controller to gradually raise the eyelid temperature to 45°C, melting gland obstructions. This thermal procedure is followed by manual gland expression using the provided purpose-designed device.

Comparators
The following practices are currently being used to treat dry eye syndrome: standard treatment with warm compresses and eyelid massage. Current treatment options for 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 (e.g., antibiotics, topical corticosteroids) to mitigate infection and inflammation of the eyelids.

Outcomes
The general outcomes of interest are symptoms, morbid events, and functional outcomes.

Tear break-up time (TBUT) is measured in seconds. Practice parameters from the American Academy of Ophthalmology (2013) have indicated that a tear break-up time of <10s is considered abnormal.[7,]

The Ocular Surface Disease Index (OSDI) assesses the patient's frequency and severity of dry eye symptoms in specific contexts during the week prior to the examination. The minimal clinically important difference for the OSDI ranges from 4.5-7.3 for mild or moderate disease. The overall OSDI score defines the ocular surface as normal (0-12 points) or as having mild (13-22 points), moderate (23-32 points), or severe (33-100 points) disease.[8,]

The Standard Patient Evaluation for Eye Dryness (SPEED) questionnaire is a self-reported measure of the frequency and severity of dryness, grittiness, scratchiness, soreness, irritation, burning, watering, and eye fatigue. It was developed by TearScience and validated in a 2013 study funded by TearScience.[9,] In this validation study, the mean SPEED score of symptomatic subjects was 21.0 and the mean of asymptomatic subjects was 6.25.

The Meibomian Gland Expression Score (MGES) is a numerical rating used to evaluate the ease with which the meibomian glands in the eyelids can release oil (meibum). A higher score suggests more difficulty in oil expression, potentially indicating MGD. Typically, the score is determined by the number of glands that can be expressed without difficulty, where 0 indicates all glands express oil easily, and 3 indicates none of the glands express oil at all. The preferred approach is to record the sum of scores for each gland expressed, to achieve a composite score. If eight glands are expressed, then the score range is 0 – (8 x 3) = 24.[10,]

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. Studies with duplicative or overlapping populations were excluded.

Review of Evidence
Systematic Reviews
In a 2024 Cochrane review, Pucker et al. evaluated the effectiveness of LipiFlow for treating dry eye disease and the safety of this treatment compared to sham and/or other treatments for MGD.[11,]Across thirteen RCTs, published through October 2022, a total of 1155 participants were randomized, with each study ranging from 28 to 236 participants. Of these trials, six took place in the

USA, three in China, two in Thailand, one in France, and one in Italy. Eight trials were single-center, four were multicenter, and one did not specify the number of centers involved. The participants consisted of 66% females, ranging in age from 19 to 86 years. The LipiFlow treatment was assessed as a stand-alone intervention against basic warm compresses in five trials, a thermostatic device in another five, an oral intervention in one trial, and topical dry eye medications in another. Additionally, one trial evaluated LipiFlow combined with an eyelid hygiene product versus eyelid hygiene products alone.

Five trials compared the efficacy of LipiFlow with the application of a basic warm compress, varying in duration and frequency. Only one trial included the addition of eyelid massage to the warm compress regimen. The analysis of symptom scores using the OSDI and the SPEED questionnaires revealed inconsistent results, showing no significant difference in symptoms between LipiFlow and warm compresses after 4 weeks. Furthermore, there was an absence of evidence indicating any significant difference in meibomian gland expression, meibum quality, or TBUT when comparing LipiFlow to basic warm compresses. Similarly, another five trials contrasted LipiFlow with thermostatic devices. The analysis at 4 weeks revealed that thermostatic devices managed to reduce OSDI scores by a mean difference (MD) of 4.59 (95% confidence interval [CI] 1.23 to 7.95; I^2=0, p =.007; 553 participants; very low certainty evidence) compared to LipiFlow. Additionally, when LipiFlow combined with eyelid hygiene was compared to eyelid hygiene alone, no significant differences in signs or symptoms were observed at any evaluated time point. In a single trial, LipiFlow was compared against a topical dry eye disease medication, lifitegrast 5%. The trial suggested that lifitegrast 5% might enhance meibomian gland expression scores more effectively than LipiFlow by day 42 (MD −1.21, 95% CI −2.37 to −0.05; 50 participants; low certainty evidence), utilizing a MGES from 0 to 8. Another trial compared LipiFlow with an oral intervention, doxycycline, revealing that LipiFlow might significantly improve SPEED scores over doxycycline at 3 months (MD −4.00, 95% CI −7.33 to −0.67; 24 participants; very low certainty evidence). No other notable differences in signs or symptoms were observed between LipiFlow and doxycycline at 3 months. Additionally, no other statistically significant differences in symptoms or signs were identified in any other analyses conducted during this review within the 4 week timeframe. No trial reported any intervention-related, vision-threatening adverse events. LipiFlow shows comparable efficacy to other commonly used dry eye disease treatments in terms of signs and symptoms. However, the best level of evidence was deemed to have a high level of bias, resulting in low to very low certainty. Additional research with adequate masking, a standardized testing methodology, and a sample representative of the MGD population is needed before any definitive conclusions can be drawn regarding comparative benefits and harms of eyelid thermal pulsation therapy.

Tao et al (2023) reported results of a systematic review that informed an 'Ophthalmic Technology Assessment' commissioned by the American Academy of Ophthalmology (AAO).[12,] The review was designed to assess the efficacy and safety of thermal pulsation in improving signs or symptoms of MGD and dry eye compared with no therapy or conventional (nonthermal pulsation) therapy such as warm compress or eyelid hygiene. The literature search was performed in March 2023. For each study, the quality of study methodology was rated according to the AAO 's guidelines. 8 studies were rated as providing level I evidence (well-designed and well-conducted RCTs and systematic reviews) and 3 studies were rated as providing level II evidence (well-designed cohort studies and nonrandomized controlled cohort or follow-up trials). All included studies evaluated the LipiFlow device. The review did not include a meta-analysis. The authors stated that 9 (of 11) studies reported greater efficacy with LipiFlow compared to standard warm compress therapy and eyelid hygiene. In general, improvements were detected in both subjective and objective metrics of MGD within 1 to 12 months of thermal pulsation treatment compared with nontreatment. The authors noted that durability beyond several months is uncertain.

The RCTs included in these systematic reviews can be compared in Appendix Table A1.

Randomized Controlled Trials

Two RCTs of eyelid thermal pulsation for the treatment of dry eye syndrome have been published since publication of the above systematic reviews. Both trials are industry-sponsored studies.

Sadri et al (2024) conducted a randomized (assessor-masked) trial (NCT05162261) to determine the efficacy and safety of thermo-mechanical action compared to LipiFlow in MGD.[13,] Participants, recruited between 2022 and 2023 across 5 US centers, who had OSDI scores between 23 and 79 and fluorescein TBUT of <10 seconds in each eye, were treated with either bilateral thermo-mechanical action (TMA) using the Tixel device (Novoxel) or thermal pulsation (TP) with LipiFlow. The TMA cohort underwent three treatment sessions two weeks apart, while the TP group received a single session. Primary efficacy outcomes, including TBUT and OSDI, were assessed at baseline, at the 4-week mark, and 12 weeks post the final treatment session. Among the 106 participants (53 per group), TBUT showed significant improvements (p <.001), increasing by 3.0 ± 3.2 and 3.1 ± 4.3 seconds after TMA, and 2.7 ± 2.7 and 3.3 ± 3.6 seconds after TP, at Week 4 and Week 12, respectively. Notably, the change in TBUT for TMA was proven to be non-inferior to TP (linear mixed-effects model, p <.001). OSDI improved by 26.4 ± 21.1 and 28.6 ± 22.4 after TMA and 18.8 ± 21.0 and 21.9 ± 18.5 after TP, at Week 4 and Week 12, respectively. No device-related adverse events occurred in either group.

Ayres et al. (2023) conducted a randomized (assessor-masked) controlled superiority trial (SAHARA, NCT04795752) to determine the efficacy and safety of TearCare (TC, Sight Sciences) in comparison to topical cyclosporine 0.05% (CsA) for addressing dry eye disease in adults.[14,]The trial enlisted 345 participants (172 in the TC group and 173 in the CsA group, recruited between 2021 and 2022) across 19 ophthalmic and optometric clinics in 11 US states. Primary efficacy outcomes were changes from baseline in TBUT and OSDI at 6 months, with safety evaluations including adverse events, best corrected visual acuity, intraocular pressure, and slit-lamp observations. TBUT improved at all time points in both groups (p <.0001), with TC demonstrating a notably greater enhancement compared to CsA (p =.0006). The OSDI also exhibited significant improvement in both groups at all time points (p <.0001), though no significant differences were observed between the two treatment arms. Both therapies were largely safe and well-tolerated. Of the 19 treatment-emergent adverse events recorded in each group (constituting 11%), only 2 in the TC group (1%) and 8 in the CsA group (5%) were adjudged as related to the study treatment. All related adverse events were rated as mild (n=9) or moderate (n=1) in severity.

Observational Studies

Four observational studies have assessed the long-term outcomes of subjects who underwent LipiFlow treatment. Greiner et al (2013)[15,] evaluated 18 (of 30) participants from a single site of the Lane (2012) RCT (cited in the Tao systematic review above),[16,] observing that while several outcomes remained significantly improved from baseline, the improvements were less pronounced at 1 year compared to 1 month. Finis et al (2014) monitored 26 patients 6 months post-treatment, noting sustained improvements in several outcome measures.[17,] Greiner et al (2016) study of 20 patients found that most outcomes remained significantly improved up to 3 years compared to baseline.[18,] A retrospective cohort study by Hura et al (2020) compared dry eye disease markers and meibomian gland imaging between patients who underwent LipiFlow treatment (n=30) and those who declined this therapy (n=13).[19,] At 1 year, the treatment group showed sustained improvements in visible meibomian gland structure, TBUT, corneal staining, and meibomian gland evaluation scores over the control group. However, SPEED scores and tear osmolarity did not show sustained improvement 1-year post-therapy.

Supplemental Information

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

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Ophthalmology
In 2018, the American Academy of Ophthalmology (AAO) updated preferred practice patterns guidelines on dry eye syndrome.[7,] 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 1 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 AAO updated preferred practice patterns guidelines on blepharitis.[3,] These guidelines cover the 3 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."

In 2023, the American Academy of Ophthalmology (AAO) updated preferred practice pattern guidelines on dry eye syndrome. These guidelines list thermal pulsation devices as a second-stage option for treatment of dry eye disease.[20,]

In 2023, the AAO updated preferred practice pattern guidelines for blepharitis.[21,]These guidelines indicate that multiple industry-sponsored studies have demonstrated that a single vectored thermal pulsation (VTP) treatment can be effective at improving meibomian gland function and reducing dry eye symptoms for a year or more post procedure. However, there have been no independent RCTs confirming or refuting these industry-sponsored studies.

"There are several in-office procedural treatments available that may improve the inspissated meibomian gland orifices using intense pulsed light (IPL) or theoretically unclog the meibomian glands by 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 clinical trials have yet to be performed to assess efficacy or superiority of any one of these treatments over another. [moderate quality, discretionary recommendation]"

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently ongoing or unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05306561[a]	A Single Arm, Single Center Phase 4 Study to Evaluate Impact of a Single Systane iLux MGD Treatment Device Thermal Pulsation Treatment on Contact Lens Wearing Time and Tolerability, Meibomian Gland Secretion Scores, and Subjective Dry Eye Symptoms in Soft Contact Lens Wearing Subjects With Meibomian Gland Dysfunction	30	Dec 2023
NCT06542276[a]	Single Vectored Thermal Pulsation Treatment in Patients Using Topical Immunomodulators in the Management of Dry Eye Disease	30	Sep 2024
NCT05577910	Vectored Thermal Pulsation, Intense Pulsed Light, and Eyelid Warm Compress (VIEW) Therapies for Meibomian Gland Dysfunction- a Randomized, Assessor-masked, Active-controlled Clinical Trial	360	Jun 2025
Unpublished			
NCT03857919	Randomized, Controlled Trial to Evaluate the Safety and Effectiveness of the TearCare® System in the Treatment of the Signs and Symptoms of Dry Eye Disease (OLYMPIA)	138	Oct 2019 (Last Updated Posted: Sep 2019)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

Appendix 1

Table A1. Comparison of RCTs Included in Systematic Reviews & Meta-Analyses

Study	Pucker (2024)[a11,]	Tao (2023)[12,]
Baumann (2014)	●	
Blackie (2016)		●
Blackie (2018)		●
Booranapong (2020)	●	
Finis (2014)		●
Gupta (2022)	●	
Hagen (2018)	●	
Holland (2022)	●	
Kasetsuwan (2020)	●	●
Lane et al (2012)		●
Li (2022)	●	
Mencucci (2023)	●	●
Meng (2023)	●	
Park (2021)		●
Tauber (2020a)	●	
Tauber (2020b)	●	
Wesley (2022)	●	
Zhao (2021)		●

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	0207T	Evacuation of meibomian glands, automated, using heat and intermittent pressure, unilateral
	0330T	Tear film imaging, unilateral or bilateral, with interpretation and report
	0507T	Near-infrared dual imaging (i.e., simultaneous reflective and trans-illuminated light) of meibomian glands, unilateral or bilateral, with interpretation and report
	0563T	Evacuation of meibomian glands, using heat delivered through wearable, open-eye eyelid treatment devices and manual gland expression, bilateral
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
06/30/2015	BCBSA Medical Policy adoption
06/01/2016	Policy revision without position change
04/01/2017	Policy revision without position change
05/01/2018	Policy revision without position change Coding update
05/01/2019	Policy revision without position change
05/01/2020	Annual review. No change to policy statement. Literature review updated.
05/01/2021	Annual review. No change to policy statement. Literature review updated.
05/01/2022	Annual review. No change to policy statement. Literature review updated.
05/01/2023	Annual review. No change to policy statement. Literature review updated.
05/01/2024	Annual review. No change to policy statement. Policy guidelines and literature review updated.
05/01/2025	Annual review. No change to policy statement. Literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished

at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Eyelid Thermal Pulsation for the Treatment of Dry Eye Syndrome 9.03.29 **Policy Statement:** I. Eyelid thermal pulsation therapy to treat dry eye syndrome is considered **investigational**.	**Eyelid Thermal Pulsation for the Treatment of Dry Eye Syndrome 9.03.29** **Policy Statement:** I. Eyelid thermal pulsation therapy to treat dry eye syndrome is considered **investigational**.