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Policy Effective Date	**12/01/2024**
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Eyelid Thermal Pulsation

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

This medical policy has become inactive as of the end date above. There is no current active version and this policy is not to be used for current claims adjudication or business purposes.

Eyelid thermal pulsation therapy (e.g., LipiFlow® Thermal Pulsation System, TearCare® System) **is considered experimental, investigational and/or unproven** for all indications including but not limited to dry eye syndrome.

Tear film imaging (e.g., LipiView II® Ocular Surface Interferometer) and near infrared dual imaging (e.g., LipiScan™ Dynamic Meibomian Imager) for the evaluation of meibomian glands **is considered experimental, investigational and/or unproven** for all indications including but not limited to dry eye syndrome.

Policy Guidelines

None.

Description

Thermal pulsation is a treatment option for meibomian gland dysfunction (MGD). 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.

Background

Dry Eye Syndrome

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. 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 is considered to be the most common cause of dry eye syndrome. (3) Prevention and treatment of DES are expected to be of greater importance as the population ages.

Diagnostic Imaging

The tear film is located on the outer surface of the eye and consists of three layers – an oil (lipid) layer, a water (aqueous) layer, and a mucin layer. These three layers work together to help maintain the health of our eyes and ward off infection. When any layer is compromised, it causes irritation, excessive watering, blurred vision, and general eye discomfort. (4)

Some imaging devices that are used as a diagnostic tool to evaluate the tear film include, but are not limited to:

- Tear film imaging (e.g., LipiView® Ocular Surface Interferometer) is a bench-top imaging device containing a computer system and electronics, chin rest and forehead rest, camera and zoom lens, illuminator, and a touch screen display. The LipiView operates on the principle of white light interferometry and provides an interferometry color assessment of the tear film by specular reflection. The computer captures a video image that is recorded since the interference pattern changes as the tear film is distributed across the cornea during blinking. The video image of the ocular surface may be viewed on the computer screen display and in a printed report. (5, 6)
- Near-infrared dual imaging (e.g., LipiScan™ Dynamic Meibomian Imager) utilizes 2 novel imaging technologies, adaptive trans-illumination and dynamic illumination. Each technology generates its own independent image of the meibomian glands, which is then processed, displayed and combined to provide a visualization of the meibomian glands and is used to detect structural change in the meibomian glands. (7)

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, 8-10) 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. (9) 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, 10) 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.

Regulatory Status

Eyelid Thermal Pulsation Systems

Eyelid thermal pulsation systems (FDA product code: ORZ) was 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 (11)	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 (12)	Tear Film Innovations	San Diego, CA	2017	K172645	'For the application of localized heat and pressure therapy in adult patients with chronic diseases of the eyelids, including MGD, also known as evaporative dry eye.'
Systane® iLux2® (13)	Tear Film Innovations	Carlsbad, CA	2020	K200400	'For the application of localized heat and pressure therapy in adult patients with MGD, which is

					associated with evaporative dry eye, and to capture/store digital images and video of the meibomian glands'
TearCare ® System (14)	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 MGD, when used in conjunction with manual expression of the meibomian glands.'
TearCare ® MGX™ (15)	Sight Sciences	Menlo Park, CA	2023	K231084	'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.'

No: number; PMA: premarket approval

*Other 501(k) numbers are associated with more recent versions of the device.

Tear Film Imaging (e.g., LipiView® Ocular Surface Interferometer) and Near Infrared Dual Imaging Systems

On October 23, 2009, the LipiView® Ocular Surface Interferometer (5) was cleared by the U.S. FDA as a class II ophthalmic imaging device for use "by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented." In 2016, the Lipiview II Ocular Surface Interferometer (6) was FDA approved under the 510(k) premarket process. Product code: HKI and HJO

On December 10, 2018, the LipiScan™ Dynamic Meibomian Imager (7) was U.S. FDA approved as an ophthalmic imaging device intended for use by a physician in adult patients in order to capture, archive, manipulate and store digital images of the MG(s). LipiScan™ Dynamic Meibomian Imager has the same imaging indications for the MG(s) as the predicate LipiView® II Ocular Surface Interferometer although the predicate device has additional indications (i.e., tear film imaging and thickness measurement, and ocular surface imaging under white light), which are not included on the FDA approval of LipiScan™ Dynamic Meibomian Imager. Product code: HKI

Refer to <https://accessdata.fda.gov> for a comprehensive list of FDA approved eyelid thermal pulsation systems, tear film imaging (e.g., LipiView® Ocular Surface Interferometer) and near infrared dual imaging systems.

Rationale

Medical policies assess 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 one 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. RCTs 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 (DES) 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 policy.

Populations

The relevant population(s) of interest is individuals with DES. 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.

Comparators
The following practices are currently being used to treat DES: 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 <10 is considered abnormal (10)

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. (16)

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. (17) In this validation study, the mean SPEED score of symptomatic subjects was 21.0 and the mean of asymptomatic subjects was 6.25.

<u>Study Selection Criteria</u>
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

Tao et al. (2023) reported results of a systematic review that informed an 'Ophthalmic Technology Assessment' commissioned by the American Academy of Ophthalmology. (18) 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 American Academy of Ophthalmology's guidelines. Eight studies were rated as providing level I evidence (well-designed and well-conducted randomized controlled trials 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 9/11 of the 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 identified in the Tao et al. (2023) systematic review are described below in Tables 2 through 5.

Randomized Controlled Trials

Ten RCTs of eyelid thermal pulsation (LipiFlow System) for the treatment of DES have been published. Characteristics of RCTs are shown in Table 2. Results of the RCTs are summarized in Table 3A/3B. Study limitations are briefly described in Tables 4 and 5. Select studies are described below. Several additional RCTs, including trials evaluating systems other than LipiFlow, have been conducted (see Table 6).

In the multicenter RCT by Lane et al. (2012), controls crossed over to treatment after 2 weeks; therefore, only the 2-week follow-up is available (Table 2). (19) Results at 2 weeks showed statistically significant improvements in the primary and secondary outcome measures. Trial limitations included the short-term follow-up (2 weeks) for the primary comparative outcomes, lack of masking, and lack of intention-to-treat analysis. In addition, the control intervention did not include massage along with the warm compress, which is a common treatment for MGD.

An RCT by Finis et al. (2014), which reported on outcomes prior to crossover at 3 months, found a significant effect of treatment compared with controls for the primary outcome measure (Ocular Surface Disease Index [OSDI] score), but not for any other outcome measures. (20) The clinical significance of the 11.6-point improvement in OSDI score is unclear because final OSDI

scores at 3 months (34.6 for LipiFlow, 40.0 for control) would still be classified as severe dry eye disease.

In a 2-stage multicenter RCT, Blackie et al. (2016) evaluated treatment effects of the LipiFlow System for patients with MGD and dry eye symptoms. (21) The first stage involved the open-label evaluation of treatment effects over the short term. Trialists compared the single, in-office, LipiFlow treatment with conventional treatments consisting of warm compress and eyelid hygiene control therapy, conducted twice daily for 3 months. Significant treatment effects relative to controls were observed for OSDI scores and meibomian gland secretion score (higher scores reflect less dysfunction) (Table 2). The second stage involved an observational crossover study to evaluate the long-term effects (from 3 to 12 months) of a single session using the LipiFlow System or in combination with other conventional treatments when considered necessary. Sustained treatment effects for the single LipiFlow treatment compared with the combination treatment subgroups were observed over the long-term for OSDI scores, but not for meibomian glad secretion scores. Trial limitations included lack of masking and lack of massage combined with warm compression, the usual treatment approach. The clinical significance of the 17 to 22-point improvement in OSDI scores observed across treatment and controls may be relatively small because final OSDI scores indicated that patients in both groups improved from severe disease to mild disease (treatment) or moderate disease (controls). The lack of blinding might also have led to an overestimation of the treatment effect of LipiFlow.

Tauber reported on a single-center RCT (2020) comparing the LipiFlow System to twice-daily administration of lifitegrast ophthalmic solution 5% in patients with inflammatory MGD (N=50; 25 patients per group). (22) The co-primary outcomes were change in eye discomfort and tear lipid layer thickness from baseline to day 42. Results demonstrated that changes in the eye discomfort scores were significantly greater in the group that received lifitegrast, while changes in the lipid layer thickness did not reach statistical significance between groups (Table 2). Trial limitations included lack of masking, attrition in the lifitegrast group (3 patients discontinued therapy), and selection of patients that had both MGD and inflammation (results may have differed in populations with MGD without inflammation).

Table 2. Summary of Characteristics of Randomized Controlled Trials of LipiFlow

Study	**Countries**	**Sites**	**Dates**	**Participants**	**Interventions**	
					Active	*Comparator*
Lane et al. (2012) (19)	U.S.	9	Mar-May 2009	Adults with MGD	Single LipiFlow treatment n=69	Daily warm compress for 2 weeks n=70
Finis et al. (2014) (20)	Germany	NR	Apr 2012-Jun 2013	Adults with MGD requiring treatment	Single LipiFlow treatment n=20	Twice daily lid warming and massage

						n=20
Blackie et al. (2016) (21)	U.S.	9	Feb-Oct 2012	Adults with MGD and evaporative dry eye	Single LipiFlow treatment n=101	Twice daily warm compress and eyelid hygiene control therapy for 3 months n=99
Blackie et al. (2018); NCT 02102464 (23)	U.S., Canada	6	May 2014-Feb 2015	Adult contact lens wearers with MGD and dry eye symptoms Mean age, 42 y 86% Female 21% Asian 17% Black/ African American 59% White Mean baseline MGS score, 8.1	Single LipiFlow treatment with eyelid margin cleaning prior to treatment n=29	No treatment for 3 mo; crossover to LipiFlow at 3 mo n=26
Tauber (2020) (22)	U.S.	1	Sept 2017-Aug 2018	Adults with inflammatory MGD	Single LipiFlow treatment n=50	Twice daily lifitegrast ophthalmic solution 5% n=50
Kasetsu-wan et al. (2020) (24)	Thailand	1	Oct 2015-Nov 2016	Adults using anti-glaucoma medications with MGD Mean age, 68 y 52% Female Mean	Standard lid hygiene twice daily plus a single LipiFlow treatment n=26	Standard lid hygiene twice daily n=22

				baseline MGS score, 22		
Park et al. (2021); NCT 04457999 (25)	Korea	1	April 2019-Dec 2019	Adults with cataract, eligible for cataract surgery MGD before cataract surgery was NOT required but was allowed Mean age, 64 to 65 y 56% Female	Single LipiFlow treatment following preoperative evaluations for cataract surgery n=62	No treatment n=62
Mencucci (2023); NCT 05062564 (26)	Italy	1	Sep 2021-Feb 2022	Adults with mild to moderate MGD who had been scheduled for unilateral cataract surgery Mean age, 74 y 65% Female	Single LipiFlow treatment 5 weeks before cataract surgery n=23	Warm compresses and eyelid massages twice a day for 1 month before cataract surgery n=23
Matossian (2023); NCT 03708367 (27)	U.S.	5	Oct 2018-Jan 2020	Adults, at least 22 years of age, with mild-to-moderate MGD and cataract with planned cataract surgery Mean age, 65 y	Single LipiFlow treatment 2 to 4 weeks prior to cataract surgery n=117 eyes	No treatment prior to surgery, single LipiFlow treatment 3 mo after cataract surgery n=115 eyes

				59% Female 77% White 6% Asian 17% Black or African American		
Meng et al. (2023) (28)	China	1	NR	Adults with MGD Mean age, 58 y 48% Female	Single LipiFlow treatment n=50 eyes	Warm compress n=50 eyes

m: months; MGD: meibomian gland dysfunction; MGS: Meibomian gland secretion score (0-45); NCT: National Clinical Trial; NR: not reported.; y: years; U.S.: United States.

Table 3A. Summary of Key Results of Randomized Controlled Trials of LipiFlow

Study	MGS Score[a]	TBUT, s[b]	OSDI Score[c]	SPEED Score[d]
Lane et al. (2012) (20)				
LipiFlow	7.9	1.5	14.7	6.2
Controls	0.5	0.1	8.1	3.5
p	<0.001	<0.001	<0.001	<0.001
LipiFlow	3.0	2.0	11.6	2.3
Controls	2.5	0.2	0.1	1.2
p	NS	NS	0.029	NS
Blackie et al. (2016) (21)				
LipiFlow	11.6		-23.4	
Controls	4.5		-17.8	
p	<0.001		0.007	
Blackie et al. (2018) (23)	At 3 mo Mean (SD)	At 3 mo Mean (SD)	At 3 mo Mean (SD)	At 3 mo Mean (SD)
LipiFlow	20.4 (9.1)	6.5 (4.0)	13.4 (15.5)	6.1 (4.6)
Controls	9.6 (5.7)	4.3 (1.7)	37.5 (23.8)	14.5 (5.3)
p	<.01	<.01	<.01	<.01
Tauber (2020) (22)				
LipiFlow				
Controls				
p				

Kasetsuwan et al. (2020) (24)	At 6 mo Change from baseline, mean (95% CI)	At 6 mo Change from baseline, mean (95% CI)	At 6 mo Change from baseline, mean (95% CI)	
LipiFlow	4.7 (2.2 to 7.2)	-0.3 (-1.5 to 0.9)	-10.0 (-12.2 to -7.8)	
Controls	3.0 (0.3 to 5.7)	-0.6 (-2.0 to 0.9)	-11.8 (-13.5 to -10.1)	
p	.40	.65	.57	
Park et al. (2021) (25)	At 3 mo Mean (SD)	At 3 mo Mean (SD)	At 3 mo Mean (SD)	
LipiFlow	0.87 (0.87)	4.4 (1.8)	22.3 (16.5)	
Controls	1.71 (0.82)	3.6 (1.6)	29.8 (20.8)	
p	<.01	.03	.04	
Mencucci et al. (2023) (26)				At 1 mo Mean (SD)
LipiFlow				4.0 (1.8)
Controls				6.0 (1.2)
p				<.01
Matossian et al. (2023) (27)	At 3 mo Mean (SD) change from baseline	At 1 mo Mean (SD) change from baseline		At 3 mo Mean (SD) change from baseline
LipiFlow	7.3 (9.3)	0.69 (4.6)		-2.1 (5.3)
Controls	4.7 (10.1)	0.06 (3.7)		-1.5 (5.6)
p	.05	.26		.60
Meng et al. (2023) (28)	At 3 mo Mean (SD)	At 3 mo Mean (SD)		At 3 mo Mean (SD)
LipiFlow	12.8 (3.9)	5.6 (2.2)		3.8 (1.5)
Controls	10.7 (3.1)	4.0 (1.9)		6.6 (2.8)
p	<.01	.01		<.01

Mo: month; MGS: meibomian gland secretion; NR: not reported; NS: not significant; PRVSQ: Patient-Reported Visual Symptom Questionnaire; OSDI: Ocular Surface Disease Index; SD: standard deviation; SPEED: Standard Patient Evaluation for Eye Dryness; TBUT: tear break-up time; VAS: visual analog scale.

[a] The Meibomian Gland Evaluator device was developed by TearScience to evaluate gland secretion through gland expression to determine if meibomian glands are blocked.

[b] Practice parameters from the American Academy of Ophthalmology (2013) have indicated that a tear break-up time of <10 s is considered abnormal. (10) Note that Zhao et al. (2016) is reported in percent not seconds.

[c] The 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. (16)
[d] The SPEED questionnaire is a self-reported measure of the frequency and severity of dryness, grittiness, scratchiness, soreness, irritation, burning, watering, and eye fatigue within 3 months of examination. It was developed by TearScience and validated in a 2013 study funded by TearScience. (17) In this validation study, the mean SPEED score of symptomatic subjects was 21.0 and the mean of asymptomatic subjects was 6.25.
[e] Eye discomfort was reported using a visual analog scale from 0 to 100 mm. Symptoms were reported on a scale of 0 to 3 (0, none/absent; 1, mild; 2, moderate; and 3, severe) and included burning, stinging, foreign body sensation, dryness, pain/soreness, and photophobia. (22)
[f] Tear lipid layer thickness was measured using the LipiView (Johnson & Johnson Vision/TearScience) device, which uses noise canceling technology to measure the submicron thickness of the lipid layer. Authors did not provide the unit of measure for this outcome. (22)

Table 3B. Summary of Key Results of Randomized Controlled Trials of LipiFlow

Study	Symptoms	Visual acuity	Schirmer Test, mm	Tear lipid layer thickness[f]
Lane et al. (2012) (19)				
LipiFlow				
Controls				
p				
Finis et al. (2014) (20)				
LipiFlow				
Controls				
p				
Blackie et al. (2016) (21)				
LipiFlow				
Controls				
p				
Blackie et al. (2018) (23)				
LipiFlow				
Controls				
p				
Tauber (2020) (22)	Eye discomfort[e] Change from baseline to day 42, mean (SD)			Change from baseline to day 42, mean (SD)

LipiFlow	-0.48 (0.96)			1.25 (15.69)
Controls	-1.05 (0.79)			-3.67 (21.12)
p	.0340			NR
Kasetsuwan et al. (2020) (24)			At 6 mo Change from baseline, mean (95% CI)	At 6 mo Change from baseline, mean (95% CI)
LipiFlow			-1.2 (-2.3 to -0.04)	2.7 (0.1 to 5.2)
Controls			1.3 (-.2 to 2.8)	Unclear
p			NS	.68
Park et al. (2021) (25)				At 3 mo Mean (SD)
LipiFlow				87.4 (21.4)
Controls				86.2 (13.6)
p				.75
Mencucci et al. (2023) (26)			At 1 mo Mean (SD)	
LipiFlow			12.6 (5.9)	
Controls			11.2 (6.1)	
p			.42	
Matossian et al. 2023) (27)	At 3 mo Bothersome ocular symptoms (PRVSQ)	At 3 mo Mean logMAR (SD) monocular uncorrected distance visual acuity		
LipiFlow	Halos, 7 days: 59% Multiple/ double vision, 7 days: 26%	0.08 (0.15)		
Controls	Halos, 7 days: 79% Multiple/ double vision, 7 days: 9%	0.07 (0.13)		
p	Halos, 7 days:.02 Multiple/ double	.42		

	vision, 7 days: .06			
Meng et al. (2023) (28)				At 3 mo Mean (SD)
LipiFlow				81.9 (17.6)
Controls				69.3 (13.8)
p				NR

Mm: millimeter; mo: month; CI: confidence interval; MGS: meibomian gland secretion; NR: not reported; NS: not significant; PRVSQ: Patient-Reported Visual Symptom Questionnaire; OSDI: Ocular Surface Disease Index; SD: standard deviation; SPEED: Standard Patient Evaluation for Eye Dryness; TBUT: tear break-up time; VAS: visual analog scale.

[a] The Meibomian Gland Evaluator device was developed by TearScience to evaluate gland secretion through gland expression to determine if meibomian glands are blocked.

[b] Practice parameters from the American Academy of Ophthalmology (2013) have indicated that a tear break-up time of <10 s is considered abnormal. (10) Note that Zhao et al. (2016) is reported in percent not seconds.

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[d] The SPEED questionnaire is a self-reported measure of the frequency and severity of dryness, grittiness, scratchiness, soreness, irritation, burning, watering, and eye fatigue within 3 months of examination. It was developed by TearScience and validated in a 2013 study funded by TearScience. (17) In this validation study, the mean SPEED score of symptomatic subjects was 21.0 and the mean of asymptomatic subjects was 6.25.

[e] Eye discomfort was reported using a visual analog scale from 0 to 100 mm. Symptoms were reported on a scale of 0 to 3 (0, none/absent; 1, mild; 2, moderate; and 3, severe) and included burning, stinging, foreign body sensation, dryness, pain/soreness, and photophobia. (22)

[f] Tear lipid layer thickness was measured using the LipiView (Johnson & Johnson Vision/TearScience) device, which uses noise canceling technology to measure the submicron thickness of the lipid layer. Authors did not provide the unit of measure for this outcome. (22)

Table 4. Study Relevance Limitations of Randomized Controlled Trials of LipiFlow

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Lane et al. (2012) (19)			2: control group did not include massage along with the warm compress	5: clinically significant difference not pre-specified	1, 2: only 2 weeks of follow-up
Finis et al. (2014) (20)				3, 6: clinical significance not supported for the	

				primary outcome	
Blackie et al. (2016) (21)			2: control group did not include massage along with the warm compress	3, 6: clinical significance not supported for the primary outcome	
Blackie et al. (2018) (23)		3: LipiFlow group received eyelid margin cleaning	2, 3: Control group did not receive eyelid margin cleaning	3: unclear how harms data were collected 5: clinically significant difference not specified	
Tauber (2020) (22)	4: patients with MGD with inflammation included			4, 5: unclear if co-primary outcomes were validated measures	
Kasetsuwan et al. (2020) (24)	1: Unclear whether participants had chronic disease or whether they had tried previous treatments 5: Not representative of U.S. population diversity			3: unclear how harms data were collected 5: clinically significant difference not specified	
Park et al. (2021) (25)	1. Included a mix of patients with existing MGD (treatment population) and those without (prevention population) 1: Unclear whether participants had chronic disease or whether they had tried previous treatments			3: unclear how harms data were collected	

	5: Not representative of U.S. population diversity				
Mencucci et al. (2023) (26)	1: Unclear whether participants had chronic disease or whether they had tried previous treatments 5: Racial/ ethnic study characteristics not provided			3: unclear how harms data were collected 5: clinically significant difference not specified	1: Follow-up of 1 mo
Matossian et al. (2023) (27)	1: Unclear whether participants had chronic disease or whether they had tried previous treatments		2. No treatment in control group	3: unclear how harms data were collected	
Meng et al. (2023) (28)	1: Unclear whether participants had chronic disease or whether they had tried previous treatments 5: Not representative of U.S. population diversity			3: unclear how harms data were collected 5: clinically significant difference not specified 7: no clear statement regarding what the primary outcome was or whether it was pre-specified	

MGD: meibomian gland disfunction; mo: month; U.S.: United States. The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use; 5: Enrolled study populations do not reflect relevant diversity; 6: Other.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest; 5: Other.

[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5: Other.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported; 7: Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 8: Other.

Table 5. Study Design and Conduct Limitations of Randomized Controlled Trials of LipiFlow

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Lane et al. (2012) (19)	3	1, 2, 3			1, 2	
Finis et al. (2014) (20)	3	1: Investigator blinded only		1, 6: reasons for drop out not described		
Blackie et al. (2016) (21)	3	1, 2, 3	1	1: reasons for drop out not described	1, 2	
Blackie et al. (2018); (23)		1, 2, 3: Open-label			1, 3: Assumptions for power calculations not given	
Tauber (2020) (22)	3	1: Investigator blinded only	1	1: attrition in the control group	3: the sample size was not based on formal statistical calculations or clinical assumptions	
Kasetsu-wan et al. (2020) (24)		1: Participants not blinded; outcomes assessors were masked		1: 12/60 originally randomized were lost to follow-up due to: 'inconvenience or health problems unrelated to the ocular disease' 2: No sensitivity analyses for missing data	3: Justification for powered difference not given	

				6: No ITT analyses		
Park et al. (2021); (25)		1, 2, 3: Open-label		1: 23% of control participants lost to follow-up (did not have surgery or did not complete study visits) 2: No sensitivity analyses for missing data 6: No ITT analysis	3: Justification for powered difference not given	
Mencucci et al. (2023); (26)		1, 2, 3: Open-label		2. No description of study flow or missing data	3: Justification for powered difference not given	
Matossian et al. (2023); (27)		1, 2, 3: Open-label				
Meng et al. (2023) (28)		1: Participants not blinded; outcome assessors were masked	1. No report of registration		1, 2, 3: No description of sample size/power calculations	2: Unclear whether analyses accounted for multiple eyes per participant

The evidence limitations stated in this table are those notable in the current literature review; this is not a comprehensive gaps assessment.

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5: Other.

[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician; 4: Other.

[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4: Other.

[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7: Other.

[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4: Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5: Other.

Nonrandomized Comparative Trials and Observational Studies

Nonrandomized trials have been conducted but do not provide longer follow-up or inclusion of populations or outcomes of interest beyond what is available from RCTs and will not be discussed further.

Four other studies have evaluated long-term outcomes for some trial subjects who had undergone LipiFlow treatment. The study by Greiner (2013) (29) evaluated 18 of 30 subjects from 1 site of the Lane trial (described above). (19) Several outcomes remained significantly improved from baseline, but the improvements were of lower magnitude at 1 year than at 1 month. Finis et al. (2014) evaluated 26 patients 6 months after LipiFlow treatment. (30) Several outcome measures remained improved 6 months after treatment. Another study of 20 patients conducted by Greiner (2016) found that most outcomes remained significantly improved up to 3 years relative to baseline. (31) Lastly, a retrospective cohort study by Hura et al. (2020) compared dry eye disease markers and meibomian gland imaging between patients who had undergone LipiFlow treatment (n=30) versus those who declined LipiFlow treatment (n=13). (32) At 1 year, visible meibomian gland structure, tear break-up time, corneal staining, and meibomian gland evaluation scores all showed sustained improvements in the treatment group over the control. On the other hand, Standard Patient Evaluation for Eye Dryness scores and tear osmolarity did not show a sustained improvement 1-year post-therapy.

ECRI

In 2024, ECRI examined all available literature specific to TearCare for the treatment of dry eyes and considers the evidence as “favorable.” (39) Overall, the evidence demonstrates TearCare is safe, improves symptoms of dry eye disease due to meibomian gland dysfunction, and appears to work as well as or better than the LipiFlow thermal device, cyclosporine ophthalmic emulsion, and warm compresses based on the evidence from RCTS and before-and after studies. How TearCare compares with LipiFlow or cyclosporin containing eyedrops is assessed in 1 RCT each, and additional studies are needed to form conclusions. In addition, ECRI noted available studies have several limitations. The pilot RCT is a high risk for bias due to single center focus and small size. Individuals assigned to the TearCare group had more severe meibomian gland dysfunction at baseline than individuals assigned to the warm compress condition; this additional risk of bias would favor the control condition. The larger, multicenter RCT did not blind individuals to treatment allocation because masking was not possible for comparisons with cyclosporin ophthalmic emulsion and LipiFlow, which renders outcomes reported in these studies as a high risk of bias. The before-and-after studies are also at a high risk of bias due to 2 or more of the following: single center focus, retrospective design, and lack of independent control group. In 1 before-and-after study, individuals who required retreatment for dry eye disease were censored from the study group. The need for retreatment

would be an appropriate outcome to document. The remaining evidence gaps are largely around comparative effectiveness and the need for additional studies to verify existing study findings.

Tear Film Imaging (e.g., LipiView Ocular Surface Interferometer)

In 2014, Finis et al. acknowledged that the quantitative measurement of the tear film LLT is a relatively new and promising method. (33) However, it has not been investigated whether there is a diurnal or a day-to-day variability and whether certain factors are confounding the measurement of the LLT. In this small study in 3 different experimental settings, 10 subjects without known sicca syndrome were examined at 3 different timepoints on one day, on 3 different days and before and after therapeutic expression of the meibomian gland(s). As a comparison, the parameters tear film break-up time, tear meniscus height (tm), diagnostic expression of the meibomian gland(s) and subjective symptoms, determined using the OSDI questionnaire, were measured. The results of the study showed a smaller variation of the LLT measurements during the day and from day to day compared to the tear film BUT. The expression of the meibomian gland(s) significantly increased the LLT. There was a correlation between the baseline values of tear film BUT and the LLT. The authors concluded that these findings showed that the LLT, measured with the LipiView interferometer, appears to be a relatively constant parameter over time. In addition, the expression of the MG(s) could be identified as a potential confounding factor. In this study these investigators included only healthy subjects without known sicca syndrome; These findings need to be validated in dry eye patients.

In 2016, Dohlman and colleagues noted that dry eye disease is a complex, multifactorial condition that is challenging to diagnose and monitor clinically. (34) Currently, diagnosis consists largely of self-reported symptom questionnaires and a collection of clinical tests as no gold standard exists. As the dry eye field is progressing, new assessment methods have been developed. Dry eye disease is now known to be characterized by tear hyperosmolarity and ocular surface inflammation. There is now a variety of imaging modalities that have shown promise in their ability to identify patients with dry eye disease by assessing tear film dimensions and tear film instability. The authors noted that there is a significant need for the development of tear film assessments for accurate diagnosis and monitoring of dry eye. There are several new devices and techniques that have shown promise in their ability help clinicians manage patients.

In 2017, Ji et al. (35) investigated the clinical utility of automated values obtained by keratography and LipiView when evaluating non-Sjögren dry eye syndrome (NSDES) with MGD. Sixty-four patients (64 eyes) diagnosed with NSDES with MGD were enrolled. All eyes were evaluated using the OSDI, fluorescence staining score, tear film breakup time, Schirmer test, and MGD grade. Noninvasive keratography average tear film breakup time (NIKBUTav), tear meniscus height (TMHk), MG dropout grade, and LLT using interferometry were measured. Among automated indexes, NIKBUTav and the MG dropout grade significantly correlated with the OSDI, as did all conventional indicators, except the Schirmer score. TMHk had significant correlation with the Schirmer score, the staining score, TBUT, and NIKBUTav, but not any MGD

indicator, even the meibomian gland dropout grade. NIKBUTav showed significant correlations with all clinical parameters and other automated values, except the Schirmer score and LLT. The MG dropout grade highly correlated with all indexes except TMHk. LLT was significantly associated with tear film breakup time, MGD grade, and MG dropout grade, although it was not related to patient symptoms. The authors concluded that automated noninvasive measurements using an advanced corneal topographer and LLT measured with an ocular surface interferometer can be alternatives to conventional methods to evaluate tear conditions on the ocular surface; the former device can provide information about conformational MG changes in NSDES with MGD. According to the authors, a limitation of this study was that they included dry eye limited to NSDES with MGD. Therefore, caution should be exercised when applying the present results to the general patient population with dry eye.

In 2019, Lee et al. (36) compared the LLT using the LipiView ocular surface interferometer between the eye treated with glaucoma medication and untreated normal eye in the unilateral glaucoma patients and evaluated the effect of topical glaucoma medication on the LLT parameters in glaucoma eyes. The 30 participants in this cross-sectional comparative study were unilateral glaucoma patients treated with topical glaucoma medications for more than 12 months. Three LLT parameters (average, minimum, and maximum) obtained by the LipiView were compared between the glaucomatous eye and normal eye. The factors associated with LLT parameters in the eyes treated with glaucoma medication were investigated with multiple regression analysis. Lipid layer average, minimum, and maximum were 64.83 ±16.50, 51.63 ±16.73, and 82.53 ±20.62 in glaucomatous eyes, 77.26 ±17.81, 62.83 ±20.99, and 86.13 ±15.42 in normal eyes. Lipid layer average and minimum were significantly thinner than those in normal eyes ($p < 0.001$, $p < 0.001$, respectively). Longer duration of glaucoma eye drops, and a greater number of glaucoma medications were associated with the lower LLT average ($\beta = -0.456$, $p < 0.001$, $\beta = -8.517$, $p = 0.003$, respectively), and increasing glaucoma medications have a significant correlation with lower LLT minimum in glaucoma eyes ($\beta = -8.814$, $P = 0.026$). The authors concluded that patients with long-term glaucoma medications need to be assessed for LLT parameters to objectively evaluate their ocular surface health. According to the authors, the findings of this study are subject to the following limitations. First, the sample size of patients with unilateral glaucoma was relatively small because the prevalence of unilateral glaucoma treated with topical glaucoma medication in the affected eye only is much less than the prevalence of bilateral glaucoma. Also, the present study did not compare the parameters in the LipiView interferometer with other measurements including tear break-up time, OSDI, or tear osmolarity for OSDI. According to the authors, further study is needed for evaluating the correlations between conventional measurements in OSDI and LipiView interferometers.

In 2020, Lee et al. (37) evaluated the clinical accuracy and utility of the Antares topographer in the diagnosis of dry eye disease. Thirty-three consecutive patients underwent analyses of their non-invasive first tear-film break-up time, tear meniscus height and meibography with the Antares topographer. The meibography with the LipiView scan was conducted. Slitlamp examinations were done for assessments of meibomian glands and fluorescein tear-film break-up time. Schirmer 1 test was done. The OSDI scores were graded. Thirty-three eyes of 33

patients (mean age 61.5 ±10.6 years, range 37.5-76.4 years, 27.3% males) completed the study. According to the Antares measurements, the non-invasive first tear-film break-up time of the patient population was 5.0 ±3.4 seconds on average (1.1-15.0 seconds), and the tear meniscus height was 0.2 ±0.1 mm at center (0.1-0.5 mm). The average OSDI score was 22.4 ±16.6 points (0.0-79.5 points). When correlations were calculated, significant correlations were found between the non-invasive first tear-film break-up time from the Antares topographer and film break-up time ($r = 0.538$, $p = .001$), and between MG dropout from the Antares topographer and that from the LipiView interferometer ($r = 0.446$, $p = .009$). Antares non-invasive first tear-film break-up time and film break-up time agreed with one another (95% limits of agreement -5.04 ±6.37, $p = .198$) as were the infrared images from the Antares topographer and those from the LipiView interferometer (95% limits of agreement -0.25 ±0.35, $p = .073$). The authors concluded that the Antares topographer is useful in the diagnosis of dry eye disease. Among its outputs, the non-invasive first tear-film break-up time and MG dropout most closely correlated with currently accepted modes of diagnosis. The authors indicated that concurrent clinical examinations are recommended for clinical follow-up. While this study reports correlations, it does not test diagnostic performance or clinical utility of tear film imaging.

Near Infrared Dual Imaging (e.g., LipiScan Dynamic Meibomian Imager)
No RCTs were identified that support the use of near infrared dual imaging (e.g., LipiScan Dynamic Meibomian Imager).

UpToDate
An UpToDate review in 2022 on “Blepharitis” (38) does not mention near-infrared dual imaging as a management tool.

Currently, there is a lack of evidence regarding the effectiveness of near-infrared dual imaging in the diagnosis and management of patients with meibomian gland dysfunction or blepharitis. Furthermore, professional society guidelines are lacking regarding near-infrared dual imaging of meibomian glands.

Summary of Evidence
For individuals who have dry eye symptoms (DES) consistent with meibomian gland dysfunction (MGD) who receive eyelid thermal pulsation, the evidence includes randomized controlled trials (RCTs), nonrandomized comparison studies, and longer-term follow-up of patients from RCTs and observational studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. The RCTs have evaluated both the LipiFlow and the TearCare system. Study populations have been predominately White or Asian. The duration of MGD and previous treatments for MGD were unclear in the study populations. The majority of the RCTs have reported greater efficacy with LipiFlow compared to standard warm compress therapy and eyelid hygiene and improvements were generally seen in both objective metrics of MGD and in patient-reported symptoms. The method for collecting adverse events in the studies was unclear but no serious adverse events were reported in any studies. Observational studies have shown sustained treatment effects for most outcomes up to 3 years. The evidence is

insufficient to determine that the technology results in an improvement in the net health outcome. Additional long-term RCTs with larger sample sizes are needed.

For individuals who have dry eye symptoms who receive tear film imaging (e.g., LipiView Ocular Surface Interferometer), the evidence includes small, nonrandomized studies, comparative studies, and review articles. Currently, the evidence is insufficient to determine the effects of this technology on health outcomes. Additional randomized controlled trials (RCTs) with large sample sizes are needed.

For individuals who have dry eye symptoms who receive near infrared dual imaging (e.g., LipiScan Dynamic Meibomian Imager), there are no randomized controlled trials (RCTs) to support the use of this technology on health outcomes. Additional RCTs with large sample sizes are needed to determine the effects of this technology on health outcomes.

Practice Guidelines and Position Statements

American Academy of Ophthalmology

In 2018, the American Academy of Ophthalmology updated preferred practice pattern guidelines on dry eye syndrome. (10) 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. This guideline does not address tear film imaging.

In 2023, the American Academy of Ophthalmology updated preferred practice pattern 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 or superiority of any of these treatments over another."

Ongoing and Unpublished Clinical Trials

Some currently ongoing or unpublished trials that might influence this policy are listed in Table 6.

Table 6. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date

Ongoing			
NCT05162261	A Randomized, Masked (Evaluator), Controlled, Prospective Study Evaluating the Effectiveness and Safety of the Tixel® Medical Device, Versus LipiFlow® in the Treatment of Meibomian Gland Dysfunction	110	Sep 2024
Unpublished			
NCT03055832	Randomized Comparison Between iLux™ and LipiFlow® in the Treatment of Meibomian Gland Dysfunction	142	Jul 2017
NCT03502447	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	17	Jan 2019
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
NCT03956225	Comparison Between iLux and LipiFlow in the Treatment of Meibomian Gland Dysfunction (MGD): A 12-month, Multicenter Study	299	Oct 2020

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	0207T, 0330T, 0507T, 0563T
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/31/2025	Document became inactive.
12/01/2024	Document updated with literature review. The following change was made in Coverage: Added the TearCare® System as an example of eyelid thermal pulsation therapy. Added references 4, 6, 7, 15-18, 23-28, 39; some updated, others removed.
08/15/2023	Reviewed. No changes.
12/01/2022	Document updated with literature review. Coverage unchanged. Added references 1-3, 11-14, 18, 23, 27-29.
08/01/2021	Reviewed. No changes.
09/01/2020	CPT codes updated.
07/15/2020	Document updated with literature review. The following changes were made to Coverage: 1) Separated statement on eyelid thermal pulsation therapy (e.g., Lipiflow® Thermal Pulsation System) and tear fil imaging (e.g., LipiVieww II® Ocular Surface Interferometer) into two separate statements; and 2) Added statement on near infrared dual imaging (e.g., LipiScan™

	Dynamic Meibomian Imager) as experimental, investigational and/or unproven. Added references 4-6, 10, 18-20, and 23. Title changed from "Eyelid Thermal Pulsation Therapy".
07/15/2018	Document updated with literature review. Coverage unchanged. Added references 9, 13. Document title change from: Eyelid Thermal Pulsation Therapy for Dry Eye Syndrome.
07/15/2017	Reviewed. No changes.
07/15/2016	Document updated with literature review. Coverage unchanged.
07/01/2015	Reviewed. No changes.
07/15/2014	Document updated with literature review. Coverage unchanged.
11/01/2013	New medical document. Eyelid thermal pulsation therapy (which may include the use of the LipiView® for diagnosis and/or the LipiFlow® for treatment) is considered experimental, investigational, and unproven for all indications including but not limited to dry eye syndrome.