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08.01.24 Management of Dry Eye Syndrome

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Summary

Description

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 individuals to seek ophthalmologic care. Dry eye disease (DED) is a multifactorial disease of the ocular surface with loss of homeostasis of the tear film and ocular symptoms. DED is also known as keratoconjunctivitis sicca, dry eye syndrome (DES), and dysfunctional tear syndrome. There are various purposed diagnostic tests (i.e., near-infrared dual imaging, tear film imaging) and treatment options (i.e., autologous eye drops, intense pulsed light, intraductal probing, intranasal neurostimulation, thermal pulsation/electrothermal heat systems) for dry eye syndrome.

Summary of Evidence

Thermal/Electrothermal Pulsation Systems

For individuals who have dry eye symptoms consistent with meibomian gland dysfunction (MGD) who receive eyelid thermal/electrothermal 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/electrothermal 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. Another systematic review of multiple therapies for MGD found similar efficacy between thermal pulsation devices and comparator treatments. Since the publication of the systematic reviews, 2 industry-sponsored RCTs examining eyelid thermal/electrothermal 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 5US 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/electrothermal pulsation system with topical cyclosporine 0.05% (CsA) in 345 participants across 19 clinics in 11 US states. The trial found significant tear break-up time improvements in both groups, with TearCare showing greater enhancement, and notable Ocular Surface Disease Index 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 long-term follow-up found that efficacy was maintained in 134 patients at 24 months without need for retreatment, but 32 patients required additional treatment with TearCare. 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/ electrothermal pulsation therapy. These trials should include adequate masking, standardized testing methodologies (eg, evidence-based controls), 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.

Other Dry Eye Syndrome Treatments/Testing

For individuals who suffer from dry eye syndrome (DES) who receive other treatments for dry eye (i.e., simultaneous reflective and transilluminated light) or interferometry of meibomian glands, tear film imaging (e.g., LipiView Ocular Surface Interferometer), autologous eye drops (e.g., autologous serum tears), intense pulsed light (e.g.,IPL), intraductal probing (e.g., Maskin Device), intranasal neurostimulation (e.g., TrueTear, iTEAR100), thermal pulsation/electrothermal heat systems to include but not limited to the iLux thermal pulsation system, LipiFlow thermal pulsation system, Systane iLux2 thermal pulsation system, TearCare system) the evidence includes systematic reviews, meta-analyses and randomized controlled trials (RCTs). Relevant outcomes are symptoms, morbid events, and functional outcomes. While study results of other treatments for DES caused by meibomian gland dysfunction (MGD) may be promising, further multi-center RCTs with a larger sample and treatment comparison

groups are needed to assess long-term effectiveness and safety using standardized questionnaires to measure participant-reported outcomes and objective clinical tests as well as objective biomarkers, when applicable. In the case of autologous eye drops Pan et. al. 2017, found inconsistent benefits in populations with DES of various etiologies. Results did not indicate IPL is superior to the current standard of care such as MGX and there is uncertainty in outcomes like meibomian gland orifice plugging as well as adverse events. The evidence is insufficient to determine the technology results in an improvement in the net health outcomes.

Additional Information

None

OBJECTIVE

The objective of this evidence review is to determine whether individuals with dry eye syndrome utilizes the following diagnostic tests and/or treatments improves the net health outcomes.

- Diagnostic Tests (i.e., near-infrared dual imaging, tear film imaging); or
- Treatments (i.e., autologous eye drops, intense pulsed light (e.g., IPL), intraductal probing, intranasal neurostimulation, thermal pulsation/electrothermal heat systems)

PRIOR APPROVAL

Not applicable.

POLICY

The diagnosis/treatment of dry eye syndrome (DES) including but not limited to the following tests and/or therapies is considered **investigational**, because the evidence is insufficient to determine that the technology results in an improvement in the net health outcomes:

- Autologous eye drops (e.g., autologous serum tears)
- Imaging studies using near-infrared dual imaging (i.e., LipiScan Dynamic Meibomian Imager) or interferometry of meibomian glands (0507T)
- Intense Pulsed Light (e.g., IPL)
- Intraductal probing (e.g., Maskin Device) (68810 or 68811)
- Intranasal Neurostimulation (e.g., TrueTear, iTEAR100)
- Tear film imaging (e.g., LipiView Ocular Surface Interferometer) (0330T)
- Thermal Pulsation/electrothermal heat systems to include but not limited to:
    - iLux Thermal Pulsation System
    - LipiFlow Thermal Pulsation System (0207T)
    - Systane iLux2 Thermal Pulsation System
    - TearCare System (0563T)

POLICY GUIDELINES

Coding

See the Codes table for details.

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. Based on data from 2013, an estimated 16.4 million Americans have dry eye syndrome. The prevalence of dry eye syndrome increases with age, especially in postmenopausal women. For both sexes, prevalence is more than 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.

In a 2022 meta-analysis of 3 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 years and older, and 8% among those aged 68 years and older. Prevention and treatment of dry eye syndrome are expected to be of greater importance as the population ages.

Risk Factors

Risk factors for DES include:

- Advanced age
- Contact lens wear
- Decreased corneal sensation
- Environments which increase tear evaporation (e.g., windy, smoky, dry, or low humidity)
- Genotypical XX individuals
- Hormonal changes primarily due to decreased androgens
- Nutritional deficiencies (e.g., vitamin A deficiency)
- Ocular medications especially those containing preservatives
- Ophthalmic surgery (especially corneal refractive surgery)
- Systemic diseases (e.g., diabetes mellitus, Parkinson disease, Sjorgren's syndrome)
- Systemic medications including amiodarone, antihistamines, anticholinergics, estrogen, isotretinoin, selective serotonin receptor antagonists, and nicotinic acid

Dry eye syndrome (DES), particularly when severe, can have a significant impact on visual acuity, daily activities, social and physical functioning, and workplace productivity.

DES has a complex and multifactorial etiology. The tear film of the eye consists of aqueous, mucous, and lipid components. A healthy tear film relies on a synergistic interaction of the lacrimal glands, eyelids, and ocular surface, which together comprise the lacrimal functional unit. Dysfunction of any component in the lacrimal functional unit can lead to DES.

DES has been classified into two general groups: decreased tear production (resulting in aqueous deficient DES) and abnormal meibomian gland physiology (resulting in evaporative DES). However, it is now believed that both mechanisms are present in most patients, although one may be predominant. For all individuals, tear film hyperosmolarity and subsequent ocular surface inflammation lead to the variety of symptoms and signs associated with DES.

Symptoms in DES result from activation of sensory nerves of the ocular surface, either due to tear hyperosmolarity, the presence of inflammatory mediators, or hypersensitivity of the sensory nerves.

Causes

- Decreased tear production: Impaired lacrimal tear production can be caused by any form of lacrimal gland destruction or dysfunction. The reduced volume of aqueous fluid leads to hyperosmolarity of the tear film and subsequently the ocular surface, which incites inflammation of the ocular surface cells.

- Deficiency of aqueous tear production can be subclassified into two subtypes:
    - Sjogren's syndrome**:** Sjogren's syndrome is a chronic autoimmune inflammatory disorder characterized by diminished lacrimal and salivary gland function with resultant dryness of the eyes and mouth. The onset of Sjögren's syndrome is rare after age 65 years.
    - Dry eye syndrome not due to Sjogren's syndrome – This syndrome refers to patients with aqueous tear-deficient DES involving lacrimal dysfunction without associated systemic findings. The most common form is age-related DES in which it is believed that there is lacrimal ductal obstruction over time, leading to decreased lacrimal gland function. Lacrimal gland obstruction can also be due to conjunctival scarring conditions such as trachoma, pemphigoid, vitamin deficiency, post-viral syndromes, and ocular burns. This syndrome can also be caused by lacrimal gland infiltration due to sarcoidosis, lymphoma, graft versus host disease, and episcleritis. Other causes include contact lens use, which is associated with reduced corneal sensitivity and subsequent reduced reflex sensory tear secretion, and diabetes mellitus.

- Increased evaporative loss: Excessive water loss from the ocular surface leads to tear film instability and a cycle of tear hyperosmolarity and lacrimal functional unit inflammation. Increased tear evaporation is most commonly caused by meibomian gland dysfunction, also known as posterior blepharitis, in which the accessory lacrimal glands responsible for the lipid component of the tear film are dysfunctional. In a normally functioning eye, the nature of the mucin allows even spreading of the tear film to form a membrane, and the lipid layer provides a barrier to minimize evaporation of tears. Abnormalities of the lipid layer are associated with a higher rate of tear film evaporation. Structural abnormalities of eyelid position or decreased blink function also increase evaporation of the tear film by increasing the area or the time of tear film exposure. Lastly, topical medicated or preserved eye drop use, chronic contact lens wear, and ocular allergy syndromes can cause ocular surface irritation and increased tear film evaporation.

Symptoms

Most individuals will present with symptoms of chronic eye irritation associated with mild to moderate discomfort. However, there is considerable variability in patient-reported symptoms and clinically measurable signs over time, as well as a recognized lack of correlation between these signs and symptoms. Common eye complaints include:

- Blurred vision
- Burning sensation
- Dryness
- General irritation
- Gritty sensation
- Light sensitivity
- Paradoxical excessive testing
- Red eyes

Questionnaires

Due to the variability of findings on clinical evaluation of dry eye syndrome (DES), some clinicians base their assessment of DES on the results of validated questionnaires. These can also be used for monitoring DES and can be useful for standardizing the identification and classification of DES.

Available questionnaires used specifically for the evaluation of DES symptoms include:

- Dry Eye Questionnaire (DEQ-5) – Five-item questionnaire reduced from the Dry Eye Questionnaire and validated to determine DES symptom severity.
- Impact of Dry Eye on Everyday Life (IDEEL) – Fifty-seven questions in three modules validated in patients with DES.
- Ocular Surface Disease Index (OSDI) – Twelve-item questionnaire validated in patients with DES. The OSDI can be useful clinically, particularly in patients with more severe symptoms, to monitor the response to therapy and variability in symptoms over time.
- Salisbury Eye Evaluation Questionnaire (SEE) – Six-item questionnaire used in self-reported, population-based prevalence surveys to determine visual impairment among older adult subjects.

Diagnosis

The diagnosis of dry eye syndrome (DES) is based on characteristic patient symptoms and supporting findings on the physical examination, both of which can vary considerably in intensity over time and under different environmental conditions.

There is no single diagnostic test or set of tests to confirm or rule out DES. Examples of methods often used to evaluate ocular surface include, but are not limited to:

- Meibography: Is the imaging and study of the morphology (structure and function) of meibomian glands. Near-infrared dual imaging uses reflective and transilluminated light purportedly to improve meibography techniques (i.e., reduce time and discomfort) and enhance results. The LipiScan is one example of biography device. The LipiView II is an example of a meibography device capable of ocular surface interferometry involving a three- mode ophthalmic camera for imaging the lipid layer of the tear film, meibomian glands, ocular surface, and eyelids. In the ocular imaging mode, the device captures high resolution images or video of the ocular surface or eyelids. The lipid imaging- mode uses white light interferometry to provider a video color assessment of the tear film distribution over the cornea during blinking. The gland imaging mode relies on near-infrared illumination reflected by the meibomian glands to obtain an image. The evidence is insufficient is insufficient to determine that the technology results in an improvement in the net health outcome.

Treatment

Current treatment for DES is aimed at improving symptoms by increasing or supplementing tear production, slowing tear evaporation, reducing tear resorption, or reducing ocular surface inflammation. First line treatments for dry eye syndrome may include the following:

- Amelioration of eyelid abnormalities including blepharitis
- Application of warm compresses to soften secretions in obstructed meibomian gland excretory ducts
- Discontinuation of systemic or ocular medications that can contribute to dryness, if possible
- Environmental coping strategies
- Tear supplementation

These treatment options, however, have shown limited clinical efficacy, and often require a trial-and-error approach. While the symptoms of dry eye syndrome often improve with treatment, the disease usually is not curable and may lead to substantial individual and physician frustration. Dry eyes can be a cause of

visual morbidity and may compromise results of corneal, cataract, and refractive surgery. Inadequate treatment of dry eye syndrome may result in increased ocular discomfort, blurred vision, reduced quality of life, and decreased productivity.

Autologous Eye Drops (e.g., Autologous Serum Tears)

Autologous eye drops (autologous serum tears) have been proposed for dry eye syndrome (DES) and are made by mixing the individual's serum with other substances.

Electrothermal Heat (e.g., TearCare System)

The TearCare® system is intended as an alternative to warm compresses to reduce dry eye syndrome (DES) symptoms caused by meibomian gland blockages. The system comprises four components: a smart hub to control thermal energy emission, a charger for the hub, two pairs of single-use thermal emitters (SmartLid™ devices), and a single use, blunt-tipped, tweezer-like device (Clearance Assistant™).

An optometrist or ophthalmologist delivers the TearCare® treatment during an office visit. The clinician applies the SmartLid devices to the individual's upper and lower eyelids over the meibomian glands and activates the hub. The connected emitters heat the eyelids to 41°C to 45°C for 12 minutes. During treatment, individuals keep their eyes open and blink normally; blinking is intended to help clear meibomian gland obstructions and re-lubricate eyes. After removing emitters, the clinician applies a drop of 0.5% tetracaine to each eye and expresses any remaining meibomian gland blockages from the individual's eyelids using the Clearance Assistant.

Intraductal Probing (e.g., Maskin Device)

Intra-ductal probing is performed using local or topical anesthetic and introduces a thin stainless-steel wire probe into the meibomian gland orifices to forcefully expel any obstructing material and restore patency.

Intense Pulsed Light (IPL)

Intense Pulsed Light (IPL) therapy delivers bursts of light at specific wavelengths. The light energy is converted to heat. IPL therapy has been suggested as a treatment for dry eye syndrome (DES).

Intranasal Neurostimulation (e.g., TrueTear and iTEAR100)

TrueTear is a handheld stimulator with a prolonged hydrogel-containing disposable tip with a reusable cover. The tip provides the contact for conducting the stimulation current, produced by the base unit, to the target site inside the nasal passages. The device is inserted into the nostrils where a tingling sensation is felt. The stimulation intensity is adjustable, and the device automatically turns off after one minute. The process purports to stimulate a nerve that innervates the lacrimal glands, causing tear production. The device has a usage limit of 30 minutes in a 24 - hour period and the disposable tip should be discarded after 24 hours.

Thermal Pulsation System

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.

Regulatory Status

Regulatory Status Autologous serum eye drops are a blood product and are not regulated by the United States Food and Drug Administration.

Several devices been approved by the U.S. Food and Drug Administration (FDA) for marketing through the 510(k) process which are approved to be used to aid in the diagnosis or treatment of dry eyes. *The tables below are not intended to be all-inclusive.*

Table 1. Diagnostic Tests

Diagnostic Tests			
Device/Test	**Manufacturer**	**Approval Year/Number**	**Information**
LipiScan	TearScience Inc, Morrisville NC	2018/ K182506	It is indicated for "use by a physician in adult patients to capture, archive, manipulate and store digital images of the meibomian glands." The device does not provide a diagnosis.
LipiView II Ocular Surface Interferometer	TearScience Inc	2015/K152869	It is indicated "for use by a physician in adult patients to capture, archive, manipulate and store digital images of the tear film, meibomian glands, ocular surface and eyelids." LipiView II, like its predicate LipiView, perform the same principal functions of ocular imaging and for specular observations of the tear film using white light interferometry. Neither device provides a diagnosis.

Table 2: Therapies

Therapies			
Device/Test	**Manufacturer / Location**	**Approval Year/Number**	**Information**
iLux® System	Tear Film Innovations, Inc. / San Diego, CA [a]	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."

Therapies			
Device/Test	**Manufacturer / Location**	**Approval Year/Number**	**Information**
iTEAR100	Olympic Ophthalmics	2022/K213623	This device type is a non-implantable device intended to increase tear production via mechanical stimulation via a battery-operated handheld electromechanical actuator with a vibratory tip, and software controller. The device activates tear production through stimulation of the nasolacrimal reflex. Stimulation mechanically activates external nasal nerve and initiates the nasolacrimal reflex, resulting in tear secretion. To produce the intended effect, the vibratory tip of the device should be applied to the lateral aspect of the nose for several seconds.
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."
Systane® iLux2®	Tear Film Innovations, Inc. / Carlsbad, CA [a]	2020/K200400	"For the application of localized heat and pressure therapy in adult individuals with meibomian gland dysfunction (MGD), which is associated with evaporative dry eye, and to capture/store digital images and video of the meibomian glands"

Therapies			
Device/Test	**Manufacturer / Location**	**Approval Year/Number**	**Information**
TearCare® System	Sight Sciences, Inc. / 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, Inc. / 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.'
TrueTear Intranasal Tear Neurostimulator	Allergan	2020/K193589	This device type is intended to temporarily increase tear production using neurostimulation to improve dry eye symptoms. The intranasal electrostimulation device for dry eye symptoms is a handheld device with two electroconductive tips that are inserted into the nasal cavity during neurostimulation. The disposable tips are made of rigid biocompatible USP Class VI plastic and the conductive tips are made of silicone hydrogel. Additional hardware components include a reusable base, charging station, and cover. The base has two buttons that allow the user to select the

			stimulation level (device is locked from use after a predetermined amount of stimulation has been triggered). The device is powered by a rechargeable battery.

*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.

Eyelid thermal pulsation systems (FDA product code: ORZ)

RATIONALE

This evidence review was created in September 2016 and has been updated regularly with searches of the PubMed database. The most recent literature update was conducted through April 2026.

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/Test Purpose

The purpose of therapy 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 review.

Populations

The relevant population of interest is individuals with dry eye syndrome (DES). DES 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 testing/therapy being considered are near-infrared dual imaging (i.e., simultaneous reflective and transilluminated light) or interferometry of meibomian glands, tear film imaging (e.g., LipiView Ocular Surface Interferometer), autologous eye drops (e.g., autologous serum tears), intense pulsed light (e.g., IPL), intraductal probing (e.g., Maskin Device), intranasal neurostimulation (e.g., TrueTear, iTEAR100), thermal pulsation/electrothermal heat systems to include but not limited to the iLux thermal pulsation system, LipiFlow thermal pulsation system, Systane iLux2 thermal pulsation system, TearCare system.

Comparators

The following practices are currently being used to diagnose dry eye syndrome (DES): patient symptoms and physical exam findings which may include:

- Conjunctival injection, usually symmetric in both eyes.
- Breakdown of ocular surface, and corneal scarring.
- Excessive reflex tearing from irritation due to dryness, which can paradoxically be a sign of DED.
- Blepharitis, often visible as erythematous or irritated eyelid edges.
- Malposition of the eyelids (inward or outward turning, also called entropion and ectropion, respectively).
- Reduced blink rate. Normal blink rate varies by environment and activity but is generally in the range of 5 to 26 blinks per minute.
- Visual impairment, with visual acuity assessed in each eye separately. This should include evaluation as to whether acuity improves with increased blink rate or use of lubricating eye drops.

The following practices are currently being used to treat dry eye syndrome (DES): standard treatment with warm compresses and eyelid massage. Current treatment options for meibomian gland dysfunction (MGD) include physical expression to relieve the obstruction, administration of heat (warm compresses) to the eyelids to liquefy solidified meibomian gland content, 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 s is considered abnormal.

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 to7.3 for mild or moderate disease. The overall OSDI score defines the ocular surface as normal (0 to12 points) or as having mild (13 to22 points), moderate (23 to32 points), or severe (33 to100 points) disease.

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. 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 8 glands are expressed, then the score range is 0 to (8 x 3) = 24.

Study Selection Criteria

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.

Thermal/Electrothermal Pulsation

Systematic Reviews

In December 2019 Hayes completed a Health Technology Assessment which was last updated May 2023 on thermal pulsation for chronic dry eye syndrome and meibomian gland disfunction. Hayes rated thermal pulsation therapy, also known as vectored thermal pulsation (VTP) therapy, as a treatment for chronic dry eye and meibomian gland dysfunction in adults a C. A C rating according to Hayes indicates, “potential but unproven benefit. Some published evidence suggests that safety and impact on health outcomes are at least comparable to standard treatment/testing. However, substantial uncertainty remains about safety and/or impact on health outcomes because of poor-quality studies, sparse data, conflicting study results, and/or other concerns.”

In April 2026 Hayes completed a Health Technology Assessment on TearCare (Sight Sciences) for the treatment of chronic eye syndrome and meibomian gland dysfunction. This review evaluated 7 studies, including 4 RCT’s (as reported in 7 publications) [Ayres 2023/2024, Hovanesian 2025, Gupta 2022, Holland 2022, and Badawi 2018/2019]. Hayes rated TearCare, an in-office eyelid heating therapy, as a treatment of chronic dry eye syndrome and meibomian gland dysfunction in adults a B. A B rating according to Hayes indicates, "some proven benefit. Published evidence indicates that safety and impact on health outcomes are at least comparable to standard treatment/testing. However, there are outstanding questions regarding long-term safety and impact on health outcomes, clinical indications, contraindications, optimal treatment/testing parameters, and/or effects in different patient subpopulations." The Hayes Technology Assessment concluded that "Uncertainty remains regarding the durability of the treatment effect due to limited follow-up beyond 6 months.”

Ben Ephraim Noyman et al (2025) conducted a systematic review of 45 studies that compared device-based MDG treatment to conservative therapy. Of the 45 studies, 9 evaluated LipiFlow, 2 evaluated iLux, and 2 evaluated TearCare. For TBUT, none of the thermal pulsation devices had a significant effect compared to conservative treatment. Similarly, none of the MGD symptom scores were significantly different between thermal pulsation devices and conservative treatment. Regarding TearCare, however, these findings are inconsistent with the more recent 2026 Hayes review. This is likely due to the fact that the Ben Ephraim Noyman systematic review did not include the largest and most recent trial (e.g., Ayres

et al. 2023/2024 and Hovanesian et al. 2025), which may limit the completeness and applicability of its conclusions.

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. 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, 6 took place in the USA, 3 in China, 2 in Thailand, 1 in France, and 1 in Italy. Eight trials were single-center, 4 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 5 trials, a thermostatic device in another 5, an oral intervention in 1 trial, and topical dry eye medications in another. Additionally, 1 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 5 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). 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. Eight studies were rated as providing level I evidence (well-designed and well-conducted RTCs 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/electrothermal 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. 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 with LipiFlow. The TMA cohort underwent 3 treatment sessions 2 weeks apart, while the thermal pulsation 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 thermal pulsation, at Week 4 and Week 12, respectively. Notably, the change in TBUT for TMA was proven to be non-inferior to thermal pulsation (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 (, Sight Sciences) in comparison to topical cyclosporine 0.05% (CsA) for addressing dry eye disease in adults. The trial enlisted 345 participants (172 in the TearCare 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 TearCare 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 TearCare 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.

Ayres et al (2024) published phase 2 results of the SAHARA study (a 6-month extension of SAHARA), which involved a single dose of TearCare in patients who had previously received CsA for 6 months (n=322 eyes). After crossover to TearCare, TBUT improved to 6.6 ± 3.2 seconds at 3 months and 6.1 ± 2.8 seconds at 6 months (both p<.001 vs. baseline). There was no improvement in ODSI scores at 3 months, but there was a significant change in ODSI scores at 6 months (p<.0001 vs. baseline).

Hovanesian et al (2025) published results of phase 3 of the SAHARA study (long-term follow-up). A total of 166 patients were followed for 24 months. Retreatment with TearCare was allowed if TBUT decreased to within 2 seconds of baseline and if OSDI scores increased by 15 points from the prior visit; 32 patients

required additional treatment at a median time of 8 months. Improvements from baseline in all efficacy parameters was maintained until 24 months in the remaining 134 patients.

Observational Studies

Four observational studies have assessed the long-term outcomes of subjects who underwent LipiFlow treatment. Greiner et al (2013) evaluated 18 (of 30) participants from a single site of the Lane (2012) RCT (cited in the Tao systematic review above), 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. Greiner et al (2016) study of 20 patients found that most outcomes remained significantly improved up to 3 years compared to baseline. 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). 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.

Section Summary: Thermal/Electrothermal Pulsation System

The majority of the RCTs reported greater efficacy with LipiFlow compared to standard warm compress therapy. Eyelid hygiene and improvements were generally seen in both objective metrics of MGD and in patient-reported symptoms for up to 3 months. Limited longer-term follow-up is available. The RCTs have evaluated only the LipiFlow system 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. Observational studies have shown sustained treatment effects for most outcomes up to 3 years. The method for collecting adverse events in the studies was unclear but no serious adverse events were reported in any studies.

Other Dry Eye Treatments/Testing

Wellmark did not identify any RCTs or systematic reviews that meet our trial design criteria for **i**ntraductal **p**robing (e.g., Maskin Device), intranasal neurostimulation (e.g., TrueTear and iTEAR100), near-infrared dual imaging for the treatment of dry eye syndrome outcomes of interest, such as symptoms, morbid events, and functional outcomes.

Autologous Serum Tears

Systematic Reviews

In February 2018 Hayes completed a Health Technology Assessment which was last updated June 2020 on autologous serum eye drops for the treatment of dry eye disease. Hayes rated the use of 20% autologous serum eye drops as a treatment for dry eye disease (DED) in adults a C. A C rating according to Hayes indicates, “potential but unproven benefit. Some published evidence suggests that safety and impact on health outcomes are at least comparable to standard treatment/testing/ However, substantial uncertainty remains about safety and/or impact on health outcomes because of poor-quality studies, sparse data, conflicting study results, and/or other concerns.” For the use of 50% autologous serum eye drops for the treatment of dry eye disease in adults Hayes rates this therapy a D^2. A D^2 rating reflects “insufficient evidence evaluating the safety and efficacy of 50% ASED. This Rating also reflects a very-low-quality body of evidence limited chiefly by 2 studies with small sample sizes, limited follow-up periods, and conflicting findings.”

In a Cochrane review, Pan 2017, reported results of 4 RCT's of autologous serum tears (autologous eye drops) vs artificial tears for treatment of DED of various etiologies found inconsistent potential benefits. Wellmark has not found any more recent RCT's.

Intense Pulsed Light (IPL)

Systematic Reviews

In January 2020 Hayes completed a Health Technology Assessment which was last updated May 2023 on intense pulsed light therapy for dry eye disease. Hayes rated IPL therapy as a treatment for chronic dry eye disease (DED) and meibomian glad dysfunction in adult patients a C. A C rating according to Hayes indicates, "potential but unproven benefit. Some published evidence suggests that safety and impact on health outcomes are at least comparable to standard treatment/testing/ However, substantial uncertainty remains about safety and/or impact on health outcomes because of poor-quality studies, sparse data, conflicting study results, and/or other concerns."

In a Cochrane review Cotes et al. (2020) completed a review to evaluate the effectiveness and safety of intense pulsed light (IPL) for the management of dry eye disease resulting from meibomian glad dysfunction (MGD). Three RCTs were included with 114 adults enrolled. "Two studies used a paired-eye (inter-eye comparison) design to evaluate the effects of a sham (control) IPL treatment relative to an actual IPL treatment. One study randomized individual to either an IPL intervention combined with meibomian gland expression (MGX), or MGX alone (standard therapy)". Follow up between the studies ranged from 45 days-9 months. Two studies used a paired-eye design that suggested minimal to no reduction in symptoms with IPL when compared a sham ("mean difference (MD) -0.33 units, 95% confidence interval (CI) -2.56 to 1.89; $I^2 = 0\%$; 2 studies, 144 eyes"). The last was not pooled because it had unit-of-analysis error. This study detailed decrease in symptoms in the IPL group ("MD -4.60, 95% CI -6.72 to -2.48; 84 eyes"). The authors report uncertainty "about the effect of IPL on DES". Relevant clinical guidelines to dry eye disease are unclear so secondary outcomes were not assessable. Additionally, there is uncertainty regarding the effects on the meibomian gland orifice plugging as well as corneal sodium fluorescein staining while utilizing IPL. Majority of the trials did not report adverse advents; thus, the safety was unable to be determined for utilizing IPL as a treatment for MGD.

Tear Film Imaging (i.e., LipiView) & Near-Infrared Dual Imaging (i.e., LipiScan Dynamic Meibomian Imager)

For individuals who suffer from dry eye syndrome who receive tear film imaging (i.e., LipiView) or near-infrared dual imaging (i.e., LipiScan Dynamic Meibomian Imager) testing, there is a lack of direct evidence that treatment protocols would be changed and clinical benefits would be improved when these tests are used. The lack of demonstrated clinical utility of these tests is based on the following factors: (1) there is no or extremely limited published data addressing the test; and/or (2) it is unclear where in the clinical pathway the test fits (replacement, triage, add-on); and/or (3) it is unclear how the test leads to changes in management that would improve health outcomes and/or avoiding existing burdensome and invasive testing; and/or (4) thresholds for decision making have not been established; (5) and/or the outcome from the test result does not result in a clinically meaningful improvement relative to the outcomes(s) obtained without the test.

Section Summary: Other Dry Eye Treatments/Testing

Individuals who suffer from dry eye syndrome (DES) who receive other treatments/testing for dry eye syndrome (intraductal probing (e.g., Maskin Device), intense pulsed light (IPL), autologous eye drops, intranasal neurostimulation (e.g. TrueTear and iTEAR100), near-infrared dual imaging (i.e., simultaneous reflective and transilluminated light), tear film imaging (i.e., LipiView) or near-infrared dual imaging (i.e., LipiScan Dynamic Meibomian Imager) testing) have studies which may be promising. Further multi-center

RCTs with a larger sample and treatment comparison groups are needed to assess long-term effectiveness and safety using standardized questionnaires to measure participant-reported outcomes and objective clinical tests as well as objective biomarkers, when applicable. In the case of autologous eye drops Pan 2017, found inconsistent benefits in populations with DES of various etiologies. Results did not indicate IPL is superior to the current standard of care such as MGX and there is uncertainty in outcomes like meibomian gland orifice plugging as well as adverse events.

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 (AAO)

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

In 2018, the AAO updated preferred practice patterns guidelines on blepharitis. 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 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. First-line treatment includes eyelid hygiene, warm compresses, and ocular lubrication. Other second-line treatment options include topical secretagogues, topical immunomodulators (such as cyclosporine), liftegrast, and short-term topical antibiotics and/or corticosteroids (for blepharitis).

In 2023, the AAO updated preferred practice pattern guidelines for blepharitis. 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 randomized controlled trials 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]"

In 2019 the American Academy of Ophthalmology released an Ophthalmic Technology Assessment on Autologous Serum-Based Eye Drops for Treatment of Ocular Surface Disease which concluded, “Although autologous serum-based tears may be effective in the treatment of severe dry eye and persistent epithelial defect, conclusions are limited owing to the absence of controlled trials.” This assessment was last reviewed for currency and maintained in 2024.

Tear Film & Ocular Surface Society

The Tear Film & Ocular Surface Society is an industry-sponsored international organization that hosts periodic workshops on the topic of dry eye syndrome. The management and therapy report of the latest dry eye workshop (DEWS) was published in 2025; the document includes a conflict of interest disclosure, but there is no description of the literature review methodology or system of evidence grading. For patients with a lipid-based dry eye etiology or with dry eye caused by meibomian gland dysfunction, the report concludes that the efficacy of lid heating devices is supported by randomized, placebo-controlled trials and are one of several treatment options. No recommendations are made for a preferred thermal pulsation device, but the report does comment on comparative efficacy. Regarding LipiFlow, non-industry sponsored studies have found that LipiFlow has similar efficacy as warm compresses and eyelid hygiene. Regarding iLux, the report states that it has statistically similar efficacy as LipiFlow. Regarding TearCare, a randomized study found similar efficacy between TearCare and LipiFlow overall, but patients with more severe symptoms did better with TearCare.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	0207T	Evacuation of meibomian glands, automated, using heat and intermittent pressure, unilateral (*may be utilized for LipiFlow Thermal Pulsation System*)
	0330T	Tear film imaging, unilateral or bilateral, with interpretation and report (*may be utilized for LipiView Ocular Surface Interferometer*)

Codes	Number	Description
	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 (*may be utilized for TearCare/TearCare MGX*)
	17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue (*may be utilized for Intense Pulsed Light (e.g., IPL)*
	67999	Unlisted procedure, eyelids (may be utilized for *iLux Thermal Pulsation System or Systane iLux2 Thermal Pulsation System*)
	68810	Probing of nasolacrimal duct, with or without irrigation (*may be utilized for Intraductal probing (e.g., Maskin Device)*
	68811	Probing of nasolacrimal duct, with or without irrigation; requiring general anesthesia (*may be utilized for Intraductal probing (e.g., Maskin Device)*
	68899	Unlisted procedure, lacrimal system (*may be utilized for Autologous eye drops (e.g., autologous serum tears*)
	92499	Unlisted ophthalmological service or procedure (*may be utilized for TrueTear, iTEAR100, iLux Thermal Pulsation System or Systane iLux2 Thermal Pulsation System*)
HCPCS		
	No code(s)	
Type of Service	Ophthalmology	
Place of Service	Outpatient	

POLICY HISTORY

Date	Reason	Action
May 2026	Annual Review	Policy Renewal
May 2025	Annual Review	Policy Renewal
May 2024	Annual Review	Policy Renewal

May 2023	Annual Review	Policy Revision
June 2022	Annual Review	Policy Revision
June 2021	Annual Review	Policy Revised
June 2020	Annual Review	Policy Revised
September 2019	Annual Review	Policy Revised
September 2018	Annual Review	Policy Revised
September 2017	Annual Review	Policy Revised
September 2016		New Policy

Appendix

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

Study	Ben Ephraim Noyman (2025)	Pucker (2024)[a]	Tao (2023)
Baumann (2014)		●	
Blackie (2016)			●
Blackie (2018)			●
Booranapong (2020)	●	●	
Finis (2014)			●
Gupta (2022)	●	●	
Hagen (2018)		●	
He (2018)	●		
Holland (2022)	●	●	
Kasetsuwan (2020)	●	●	●
Lane (2012)	●		●
Li (2022)		●	
Matossian (2023)	●		
Mencucci (2023)	●	●	●

Meng (2023)	●	●	
Park (2021)	●		●
Schlatter (2023)	●		
Tauber (2020a)	●	●	
Tauber (2020b)		●	
Wesley (2022)	●	●	
Zhao (2021)			●

[a] Excluded from this table were two trials included in the Pucker (2024) systematic review as both trials were published in other languages (Baumann, 2014 in French; He, 2018 in Chinese).

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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