Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 3/1/24**
(See policy history boxes for previous effective dates)

Title: Eyelid Thermal Pulsation and Interferometric Color Assessment of the Tear Film for the Diagnosis and Treatment of Dry Eye Syndrome

Description/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.[1,2] Based on data from 2013, an estimated 16.4 million Americans have dry eye syndrome.[2] The prevalence of dry eye syndrome increases with age, especially in postmenopausal women. For both sexes, prevalence is more than 3 times higher in individuals 50 years of age or older compared to those 18 to 49 years of age. Meibomian gland dysfunction (MGD) is considered to be the most common cause of dry eye syndrome.[3] The prevention and treatment of dry eye syndrome is expected to be of greater importance as the population ages.

Treatment

Current treatment options for MGD include physical expression to relieve the obstruction, administration of heat (warm compresses) to the eyelids to potentially liquefy solidified meibomian gland (MG) contents, eyelid scrubs to relieve external meibomian gland orifice blockage, and medications (e.g., antibiotics, topical corticosteroids) to mitigate infection and inflammation of the eyelids.[4,5] These treatment options however have shown limited clinical efficacy. Physical expression, for example, can be very painful given the significant amount of force needed to express obstructed glands. Warm compress therapy can be both time-consuming and labor intensive, and there is limited evidence that medications can relieve MGD.[5] While the symptoms of dry eye syndrome often improve with treatment, the disease usually is not curable and may lead to substantial patient and physician frustration. Dry eyes can be a cause of visual morbidity and may compromise results of corneal, cataract, and

refractive surgery. Inadequate treatment of DED may result in increased ocular discomfort, blurred vision, reduced quality of life, and decreased productivity.

Regulatory Status:

The LipiFlow® System (assigned the generic name of eyelid thermal pulsation system) was cleared by the Food and Drug Administration (FDA) in June 2011.[6] The FDA classified the LipiFlow® System into class II (special controls) in order to provide a "reasonable assurance of safety and effectiveness" of the device. The LipiFlow® System is identified by the FDA as a "Battery-operated, handheld device that the physician uses in an in-office procedure to control the application of warmth and massage to the eyelids. The handheld device connects to a single-use disposable unit made of biocompatible polycarbonate and silicone that is inserted around the patient's eyelids. The device provides controlled warmth to the inner eyelid surface, close to the location of the meibomian glands, and intermittent massage to the outer eyelid surface to facilitate release of lipid from the cystic meibomian glands." All 3 devices are indicated for "the application of localized heat and pressure therapy in adult patients with Meibomian Gland Dysfunction (MGD), which is associated with evaporative dry eye." The Systane® iLux2® system is also indicated "to capture/store digital images and video of the meibomian glands."

Additionally FDA-cleared eyelid thermal pulsation systems include, but are not limited to, the TearCare® System (Sight Sciences, Inc., K213045, December 2021). The TearCare® System is indicated 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."

Product Code: ORZ

Medical Policy Statement

Eyelid thermal pulsation for the treatment of dry eye syndrome and interferometric color assessment of the tear film by specular reflection is experimental/investigational. They have not been scientifically demonstrated to improve patient clinical outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

0207T 0330T 0563T

Rationale

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 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 Purpose

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

The question addressed in this evidence review is: Does the use of eyelid thermal pulsation improve the net health outcome in patients with dry eye syndrome?

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

Populations

The relevant population(s) of interest are patients with DES. DES is often classified into the aqueous-deficient subtype or the evaporative subtype, although classification is not mutually exclusive. DES 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 treatment being considered is the use of 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; 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, change in disease status, functional outcomes and quality of life.

Follow-up of at least 6 months would be desirable to assess outcomes.

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

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

Review of Evidence

Randomized Controlled Trials

Comparative studies of eyelid thermal pulsation for the treatment of dry eye syndrome includes two randomized controlled trials (RCTs) and one nonrandomized comparative study of the LipiFlow® System (see Table 1). In the multicenter RCT by Lane et al, controls crossed over to treatment after 2 weeks; therefore, only the 2-week follow-up is available (see Table 2).[7] 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 meibomian gland dysfunction.

An RCT by Finis et al (2014), which reported 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.[8] 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 meibomian gland function and dry eye symptoms.[9] 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 (MGS) score (higher scores reflect less dysfunction) (see 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 MGS score. 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 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).[17.] 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 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).

Observational Trials

The nonrandomized trial by Zhao et al (2016) compared 25 patients undergoing a single LipiFlow® treatment to 25 patients using warm compresses and lid massage.[10] At 4 weeks and 12 weeks, outcomes were similar between groups for symptom change, change in Meibomian Gland Evaluator assessment, and tear break-up time. At 12 weeks, change in the Schirmer test also did not differ significantly between groups. Thus, of the three trials, only the Lane study, which followed patients for 2 weeks, showed positive findings for most outcomes.

Four other studies have evaluated long-term outcomes for some of the trial subjects who underwent LipiFlow® treatment. The study by Greiner (2013)[11] evaluated 18 of 30 subjects from one site of the RCT of Lane.[7] 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 at 6 months after LipiFlow® treatment.[12] 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.[13] 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).[18] 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.

Table 1. Summary of Key Characteristics of Comparative Studies

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	*Comparator*
Lane et al (2012)[7]	U.S.	9	Mar-May 2009	69 LipiFlow· 70 control	Single LipiFlow treatment	Daily warm compress for 2 wk
Finis et al (2014)[8]	Germany	NR	Apr 2012-Jun 2013	20 LipiFlow· 20 control	Single LipiFlow treatment	Twice daily lid warming and massage
Zhao et al (2016)[10]	Singapore	1	Feb 2012-Mar 2013	25 LipiFlow· 25 control	Single LipiFlow treatment	Twice daily lid warm compresses and massage
Blackie et al (2016)[9]	U.S.	9	Feb-Oct 2012	101 LipiFlow· 99 control	Single LipiFlow treatment	Twice daily warm compress and eyelid hygiene control therapy for 3 mo
Tauber (2020)[17]	U.S.	1	Sept 2017-Aug 2018	50 LipiFlow· 50 control	Single LipiFlow treatment	Twice daily lifitegrast ophthalmic solution 5%

NR: not reported.

Table 2. Summary of Key Results of Comparative Studies

Study	MGS Score[a]	TBUT, s[b]	OSDI Score[c]	SPEED Score[d]	Symptom Score, %	Schirmer Test, mm	Eye discomfort[e] change from baseline to day 42, mean (SD)	Tear lipid layer thickness[f] change from baseline to day 42, mean (SD)
Lane et al (2012)[7]								
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				
Finis et al (2014)[8]								
LipiFlow	3.0	2.0	11.6	2.3				

Controls	2.5	0.2	0.1	1.2				
p	NS	NS	0.029	NS				
Zhao et al (2016)[10,]								
LipiFlow		89.2%			-30.5%	1.0		
Controls		63.0%			-15.9%	-3.95		
p		0.625				0.55		
Blackie et al (2016)[9,]								
LipiFlow	11.6		-23.4					
Controls	4.5		-17.8					
p	<0.001		0.007					
Tauber (2020)[17,]								
LipiFlow							-0.48 (0.96)	1.25 (15.69)
Controls							-1.05 (0.79)	-3.67 (21.12)
p							0.0340	NR

MGS: meibomian gland secretion; NR: not reported; NS: not significant; OSDI: Ocular Surface Disease Index; SD: standard deviation; SPEED: Standard Patient Evaluation for Eye Dryness; TBUT: tear break-up time.
[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.[6,] 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.[17,]
[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.[18,] 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.[11,]
[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.[11,]

Table 3. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Lane et al (2012)[7,]			2; control group did not include massage along with the warm compress	5; clinical significant difference not prespecified	1, 2; only 2 weeks of follow-up

Finis et al (2014)[8,]				3, 6; clinical significance not supported for the primary outcome	
Zhao et al (2016)[10,]					
Blackie et al (2016)[9,]			2; control group did not include massage along with the warm compress	3, 6; clinical significance not supported for the primary outcome	
Tauber (2020)[17,]	4; patients with MGD with inflammation included			4, 5; unclear if co- primary outcomes were validated measures	

MGD: meibomian gland disfunction.
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.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[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.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 4. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Lane et al (2012)[7,]	3	1, 2, 3			1, 2	
Finis et al (2014)[8,]	3	1; investigator blinded only		1, 6; reasons for drop out not described		
Zhao et al (2016)[10,]	1	1, 2, 3				
Blackie et al (2016)[9,]	3	1, 2, 3	1	1; reasons for drop out not described	1, 2	

Tauber (2020)[17]	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	

The evidence limitations stated in this table are those notable in the current 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.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[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).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[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.

SUMMARY OF EVIDENCE

For individuals who have dry eye symptoms consistent with meibomian gland dysfunction who receive eyelid thermal pulsation, the evidence includes 3 randomized controlled trials (RCTs), a nonrandomized comparison study, and longer-term follow-up of patients from RCTs and observational studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. The trials do not provide strong evidence of long-term efficacy. Two RCTs have demonstrated positive findings for most outcome measures over the short term (up to 3 months). Observational studies have shown sustained treatment effects for most outcomes up to 3 years. The nonrandomized study showed similar outcomes for eyelid thermal pulsation and standard treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome**.**

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov did not identify any ongoing or unpublished trials that would likely influence this review.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Academy of Ophthalmology (AAO)

In 2018, the American Academy of Ophthalmology updated preferred practice patterns guidelines on dry eye syndrome.[14] These guidelines list "In-office, physical heating and expression of the meibomian glands (including device-assisted therapies, such as LipiFlow, or intense pulse light treatment)" as 1 of several step-up treatments for patients who do not respond to conventional management, including the elimination of environmental factors and offending medications, dietary modifications, ocular lubricants, and lid hygiene and warm compresses.

In 2018, the American Academy of Ophthalmology updated preferred practice patterns guidelines on blepharitis.[3,] These guidelines cover the 3 clinical subcategories of blepharitis: staphylococcal, seborrheic, and meibomian gland dysfunction (posterior blepharitis specifically affects the meibomian glands). The following statements are made relevant to thermal pulsation treatment:

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

Government Regulations

National/Local:

There is no national or local coverage determination on this topic. However, there is an LCD, A56902, original effective date 8/29/2019, revision effective date 04/27/23 which lists category III services deemed to be reasonable and medically necessary. Codes 0207T, 0330T, and 0563T are not located on this list.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [BCBSA, formerly HCFA] are updated and/or revised periodically. Therefore, the most current BCBSA CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Measurement of Tear Osmolarity in the Assessment of Dry Eye Using a Point of Care Device

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References

1. Fiscella RG. Understanding dry eye disease: a managed care perspective. Am J Manag Care. Dec 2011;17 Suppl 16:S432-439. PMID 22435675
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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through September 25, 2023, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/10	5/13/10	4/20/10	Joint policy established
11/1/12	8/21/12	8/21/12	Routine maintenance; references updated.
11/1/13	8/20/13	9/3/13	Policy updated to mirror BCBSA; title changed from "Evacuation of Meibomian Glands, Automated" to "Thermal Pulsation and Interferometric Color Assessment of the Tear Film for the Diagnosis and Treatment of Dry Eye Syndrome." Added information regarding the LipiView and LipiFlow devices.
3/1/15	12/12/14	12/29/14	Routine maintenance. No significant changes, status unchanged. Updated rationale and references.
1/1/16	10/13/15	10/27/15	Routine maintenance.
11/1/16	8/16/16	8/16/16	Routine policy maintenance with updates to rationale and references.
11/1/17	8/15/17	8/15/17	Updated rationale section. Added references # 9 and 13. No change in policy status.
11/1/18	8/21/18	8/21/18	Routine policy update. No change in policy status.
11/1/19	8/20/19		Routine policy maintenance. No change in policy status.
3/1/20	12/17/19		Added code 0563T to policy as E/I.
3/1/21	12/15/20		Routine policy maintenance. No change in policy status.
3/1/22	12/14/21		Routine policy maintenance. No change in policy status.
3/1/23	12/20/22		Routine policy maintenance. No change in policy status. (ky)
3/1/24	12/19/23		Routine policy maintenance. No change in policy status. Vendor: N/A. (ky)

Next Review Date: 4th Qtr. 2024

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: EYELID THERMAL PULSATION AND INTERFEROMETRIC COLOR ASSESSMENT OF THE TEAR FILM FOR THE DIAGNOSIS AND TREATMENT OF DRY EYE SYNDROME

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

N/A