Policy Statement

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

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

Policy Guidelines

There is a CPT category III code specific to eyelid thermal pulsation therapy:
- **0207T**: Evacuation of meibomian glands, automated, using heat and intermittent pressure, unilateral

There is also a CPT category III code for tear film imaging (e.g., LipiView Ocular Surface Interferometer), which is being marketed for use with this treatment:
- **0330T**: Tear film imaging, unilateral or bilateral, with interpretation and report

The following category III code may be used in conjunction with the LipiScan Thermal Pulsation System:
- **0507T**: Near-infrared dual imaging (i.e., simultaneous reflective and trans-illuminated light) of meibomian glands, unilateral or bilateral, with interpretation and report

Description

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

Related Policies

- N/A

Benefit Application

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

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

In 2011, the LipiFlow® Thermal Pulsation System (TearScience; assigned the generic name of eyelid thermal pulsation system) was cleared by the U.S. Food and Drug Administration (FDA). The FDA classified the LipiFlow® System as class II (special controls) to provide a “reasonable assurance of safety and effectiveness” of the device. The LipiFlow® System was identified by the FDA “as an electrically powered device intended for use in the application of localized heat and pressure therapy to the eyelids. The device is used in adult patients with chronic cystic conditions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye.” FDA product code: ORZ

Rationale

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. DES is considered a significant public health problem. It is estimated to affect between 14% and 33% of the population worldwide. The prevalence of DES increases with age, especially in postmenopausal women. It is estimated that DES affects more than 7 million Americans older than 40 years of age, and approximately 1 to 4.3 million Americans between 65 and 84 years of age. Prevention and treatment of DES are expected to be of greater importance as the population ages.

Treatment

Current treatment options for Meibomian gland dysfunction include physical expression to relieve the obstruction, administration of heat (warm compresses) to the eyelids to 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. These treatment options, however, have shown limited clinical efficacy. 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. While the symptoms of DES often improve with treatment, the disease usually is not curable and may lead to substantial patient and physician frustration. Dry eyes can be a cause of visual morbidity and may compromise results of corneal, cataract, and refractive surgery. Inadequate treatment of DES may result in increased ocular discomfort, blurred vision, reduced quality of life, and decreased productivity.

Literature Review

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

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

Dry Eye Syndrome
Clinical Context and Therapy Purpose
The purpose of eyelid thermal pulsation in patients who have dry eye syndrome 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 is individuals with dry eye syndrome. Dry eye syndrome is often classified into the aqueous-deficient subtype or the evaporative subtype, although classification is not mutually exclusive. Dry eye syndrome is a multifactorial disease of the ocular surface that may require a combination approach to treatment. Meibomian gland dysfunction (MGD), characterized by changes in gland secretion with or without concomitant gland obstruction, is recognized as the most common cause of evaporative dry eye and may also play a role in aqueous-deficient dry eye.

Interventions
The therapy being considered is eyelid thermal pulsation. The LipiFlow Thermal Pulsation System is 1 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 dry eye syndrome: standard treatment with warm compresses and eyelid massage. Current treatment options for MGD include physical expression to relieve the obstruction, administration of heat (warm compresses) to the eyelids to liquefy solidified meibomian gland contents, eyelid scrubs to relieve external meibomian gland orifice blockage, and medications (e.g., antibiotics, topical corticosteroids) to mitigate infection and inflammation of the eyelids.

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

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 include 4 RCTs and 1 nonrandomized comparative study of the LipiFlow System (Table 1). 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). 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. 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. 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 gland 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 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). 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 with 25 patients using warm compresses and lid massage. At 4 and 12 weeks, between-group outcomes were similar for symptom change, change in meibomian gland force evaluator, and tear break-up time. At 12 weeks, change in Schirmer test scores also did not differ significantly between groups.

Four other studies have evaluated long-term outcomes for some trial subjects who had undergone LipiFlow treatment. The study by Greiner (2013) evaluated 18 of 30 subjects from 1 site of the Lane trial (described above). 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. 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. 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). 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**

<table>
<thead>
<tr>
<th>Study</th>
<th>Active</th>
<th>Comparator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar-May 2009</td>
<td>control 70</td>
<td>Daily warm compress for 2 wk</td>
</tr>
<tr>
<td>Germany NR 2012-2013</td>
<td>control 20</td>
<td>Twice daily lid warming and massage</td>
</tr>
<tr>
<td>Singapore 1 Feb-Mar 2013</td>
<td>control 25</td>
<td>Twice daily lid warm compresses and massage</td>
</tr>
<tr>
<td>U.S. 9 Feb-Oct 2012</td>
<td>control 99</td>
<td>Twice daily warm compress and eyelid hygiene control therapy for 3 mo</td>
</tr>
<tr>
<td>Tauber (2020)</td>
<td>LipiFlow 50</td>
<td>Single LipiFlow treatment</td>
</tr>
<tr>
<td>U.S. 1 Sept 2017-Aug 2018</td>
<td>control 50</td>
<td>Twice daily lifitegrast ophthalmic solution 5%</td>
</tr>
</tbody>
</table>

NR: not reported.

**Table 2. Summary of Key Results of Comparative Studies**

<table>
<thead>
<tr>
<th>Study</th>
<th>MGS Score</th>
<th>TBUT (s)</th>
<th>OSDI Score</th>
<th>SPEED Score</th>
<th>Symptom Score (%)</th>
<th>Schirmer Test (mm)</th>
<th>Eye discomfort change from baseline to day 42, mean (SD)</th>
<th>Tear lipid layer thickness change from baseline to day 42, mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lane et al (2012)</td>
<td>LipiFlow</td>
<td>7.9</td>
<td>1.5</td>
<td>14.7</td>
<td>6.2</td>
<td></td>
<td>&lt;0.00 &lt;0.00 &lt;0.00 &lt;0.00</td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>0.5</td>
<td>0.1</td>
<td>8.1</td>
<td>3.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>p</td>
<td>&lt;0.00</td>
<td>&lt;0.00</td>
<td>&lt;0.00</td>
<td>&lt;0.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Finis et al (2014)</td>
<td>LipiFlow</td>
<td>3.0</td>
<td>2.0</td>
<td>11.6</td>
<td>2.3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>2.5</td>
<td>0.2</td>
<td>0.1</td>
<td>1.2</td>
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<td></td>
<td></td>
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<tr>
<td>p</td>
<td>NS</td>
<td>NS</td>
<td>0.029</td>
<td>NS</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Zhao et al (2016)</td>
<td>LipiFlow</td>
<td>89.2%</td>
<td>-30.5%</td>
<td>1.0</td>
<td></td>
<td></td>
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<tr>
<td>Control</td>
<td>63.0%</td>
<td>-15.9%</td>
<td>-3.95</td>
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</table>
Eyelid Thermal Pulsation for the Treatment of Dry Eye Syndrome

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Duration of Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lane et al (2012)</td>
<td>2; control group did not include massage along with the warm compress</td>
<td>5; clinical significant difference not prespecified</td>
<td>1, 2; only 2 weeks of follow-up</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Finis et al (2014)</td>
<td>3, 6; clinical significance not supported for the primary outcome</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Zhao et al (2016)</td>
<td>2; control group did not include massage along with the warm compress</td>
<td>3, 6; clinical significance not supported for the primary outcome</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blackie et al (2016)</td>
<td>4; patients with MGD</td>
<td></td>
<td>4, 5; unclear if co-primary outcomes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MGD: meibomian gland dysfunction.

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

- 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).
- Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
- 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 MGD who receive eyelid thermal pulsation, the evidence includes 4 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.

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

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

American Academy of Ophthalmology
In 2018, the American Academy of Ophthalmology 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 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. 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."

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

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

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in January 2021 did not identify any ongoing or unpublished trials that would likely influence this review.

References


Documentation for Clinical Review

- No records required
Coding

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

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

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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<tr>
<td>CPT®</td>
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<td>HCPCS</td>
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Policy History

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

<table>
<thead>
<tr>
<th>Effective Date</th>
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<tbody>
<tr>
<td>06/30/2015</td>
<td>BCBSA Medical Policy adoption</td>
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<td>06/01/2016</td>
<td>Policy revision without position change</td>
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<td>04/01/2017</td>
<td>Policy revision without position change</td>
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<tr>
<td>05/01/2018</td>
<td>Policy revision without position change Coding update</td>
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<tr>
<td>05/01/2020</td>
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</tr>
<tr>
<td>05/01/2021</td>
<td>Annual review. No change to policy statement. Literature review updated.</td>
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</table>

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member’s illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.
**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements (as applicable to your plan)**

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

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

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.
**POLICY STATEMENT**
(No changes)

<table>
<thead>
<tr>
<th>BEFORE</th>
<th>AFTER</th>
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<tr>
<td>Eyelid Thermal Pulsation for the Treatment of Dry Eye Syndrome 9.03.29</td>
<td>Eyelid Thermal Pulsation for the Treatment of Dry Eye Syndrome 9.03.29</td>
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<td><strong>Policy Statement:</strong> Eyelid thermal pulsation therapy to treat dry eye syndrome is considered <strong>investigational.</strong></td>
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