MEDICAL POLICY

Eye: Automated Evacuation of Meibomian Glands

Effective Date: 7/1/2020

Technology Assessment Committee Approved Date: 9/12; 10/13; 9/14; 9/15; 5/16

Medical Policy Committee Approved Date: 7/17; 1/18; 2/18; 8/19; 11/19; 7/2020; 8/2020

Medical Officer Date

See Policy CPT CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

The automated evacuation of meibomian glands using heat and intermittent pressure (i.e., Lipiflow® Thermal Pulsation System) is considered investigational and is not covered as a treatment of any condition, including, but not limited to, meibomian gland dysfunction and dry eye disease.

Link to Policy Summary

BILLING GUIDELINES

If CPT code 0330T is billed in conjunction with 0207T then it will deny as investigational for all lines of business.
MEDICAL POLICY
Eye: Automated Evacuation of Meibomian Glands

CPT CODES

<table>
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<tr>
<th>All Lines of Business</th>
<th>Not Covered</th>
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<tbody>
<tr>
<td>0207T Evacuation of meibomian glands, automated, using heat and intermittent pressure, unilateral</td>
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<tr>
<td>0563T Evacuation of meibomian glands, using heat delivered through wearable, open-eye eyelid treatment devices and manual gland expression, bilateral</td>
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DESCRIPTION

Meibomian Gland Dysfunction (MGD)

Meibomian glands are tiny glands which line the edges of the eyelids and secret oil that coat the surface of the eye to keep them from drying out. MGD occurs when these glands are not secreting enough oil, often due to the gland getting plugged, or when the oil secreted is of poor quality. “In the early stages, patients are often asymptomatic, but if left untreated, MGD can cause or exacerbate dry eye symptoms and eyelid inflammation.” Chronically clogged meibomian glands can lead to permanent changes in the tear film and dry eyes. Treatment includes eyelid hygiene practices (cleaning off the dead skin, oil, and bacteria build up), warm compress, massage, and omega-3 fatty acid supplements.

Automated Evacuation of Meibomian Glands

The automated evacuation of meibomian glands (i.e., LipiFlow® Thermal Pulsation System) is an, “in-office procedure for patients with chronic cystic conditions of the eyelids to provide controlled heat to the inner eyelid surface, close to the location of the meibomian glands, and intermittent pressure to the outer eyelid to facilitate release of lipid from the cystic meibomian glands.” The device includes a sterile, single-use eyepiece that is inserted around the patient’s eyelids. The eyepiece is attached to a physician-controlled console, which adjusts the heat and pressure delivered to the eyelid.

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the automated evacuation of meibomian glands (i.e., LipiFlow Thermal Pulsation System) as a treatment for meibomian gland dysfunction and dry eye disease. Below is a summary of the available evidence identified through November of 2017.

Systematic Reviews

No systematic reviews were identified which evaluated the automated evacuation of meibomian glands.
Randomized Controlled Trials (RCT)

- In 2016, Blackie et al. conducted a prospective, multicenter, open-label RCT to evaluate the sustained effect (12 months) of a single-dose vectored thermal pulsation procedure for meibomian gland dysfunction and dry eye. A total of 200 patients (400 eyes) were randomized to receive a single vectored thermal pulsation (VTP) treatment or twice-daily, 3-month, conventional warm compress (control group). At 3 months, the control patients were crossed over to VTP treatment (crossover group). The outcomes of effectiveness, meibomian gland secretion (MGS), and dry eye symptoms were evaluated at baseline, 1, 3, 6, 9, and 12 months.

The treatment group had greater mean improvement in MGS and dry eye symptoms compared to the control group at 3 months. “At 12 months, 86% of the treatment group had received only one VTP treatment, and sustained a mean improvement in MGS from 6.4±3.7 (baseline) to 17.3±9.1 (P<0.0001) and dry eye symptoms from 44.1±20.4 to 21.6±21.3 (P<0.0001); 89% of the crossover group had received only one VTP treatment with sustained mean improvement in MGS from 6.3±3.6 to 18.4±11.1 (P<0.0001) and dry eye symptoms from 49.1±21.0 to 24.0±23.2 (P<0.0001).” A statistically significant association between greater mean improvement in MGS and less severe baseline MGS and shorter duration of time between diagnosis and treatment was also identified.

Strengths of this study include the randomized controlled design, multicenter recruitment, and use of intention to treat analysis. The authors concluded that a single treatment with VTC delivers sustained improvement in meibomian gland function and dry eye symptoms over 12 months. However, the following methodological inadequacies limit the validity of this conclusion:

- Allowing patients to cross over from the control to treatment group (i.e., carryover effect)
- Short follow-up duration (3 months of randomized controlled design and 9 months crossover design)
- Lack of blinding
- Subjective primary outcome measures
- Significant conflict of interests due to the first and second authors being employees of the device manufacturer (TearScience, Inc.)

- In 2014, Finis and colleagues conducted a prospective, randomized, observer-masked trial to compare the effectiveness of a single LipiFlow® treatment with combined lid warming and massage in patients with meibomian gland dysfunction (MGD). A total of 40 patients were randomized to receive a single LipiFlow treatment or 3 months of twice-daily lid warming and massage (control group). The primary outcomes of interest, including improvement of subjective symptoms as assessed by the Ocular Surface Disease Index (OSDI) scores, were evaluated at 1 and 3 months.

A total of 31 patients completed the 3 month follow-up. At both 1 and 3 months follow-up, patients in the treatment group had a significant reduction in OSDI scores compared to the control group. Both groups showed a statistically significant improvement in expressible meibomian glands when compared to baseline, but this was not significant between the treatment and control groups. No other outcome measures showed a significant difference from baseline or between groups.
Strengths of this study include the randomized controlled design and use of intention to treat analysis. However, significant methodological limitations are present due to the small sample size, short follow-up period, lack of patient blinding, and high attrition. The authors concluded that LipiFlow® is at least as effective as 3-month, twice-daily lid warming and massage but, “the present study was observer-masked only, and therefore a placebo effect may have confounded any improvements in subjective symptoms and other parameters in both groups.”

Nonrandomized Studies

The evidence review also identified several nonrandomized studies evaluating automated evacuation of meibomian glands for the treatment of meibomian gland dysfunction and dry eye disease. Although these studies showed favorable results for the use of automated evacuation of meibomian glands, all are nonrandomized, uncontrolled studies, with a small sample size (n<50) and short follow-up period (0 months to 3 years). These significant methodological limitations do not permit meaningful conclusions regarding the long-term efficacy and safety of automated meibomian gland evacuation.

CLINICAL PRACTICE GUIDELINES

No clinical practice guidelines were identified which addressed the automated evacuation of meibomian glands (i.e., LipiFlow® Thermal Pulsation System) for the treatment of meibomian gland dysfunction or dry eye disease.

CENTERS FOR MEDICARE & MEDICAID

As of December 2017, no Centers for Medicare & Medicaid (CMS) coverage guidance was identified which addresses the automated evacuation of meibomian glands (i.e., LipiFlow® Thermal Pulsation System) for the treatment of meibomian gland dysfunction or dry eye disease.

POLICY SUMMARY

There is insufficient evidence to support the clinical utility or safety of automated evacuation of meibomian glands (i.e., LipiFlow® Thermal Pulsation System) for the treatment of dry eye disease or meibomian gland dysfunction. Further, high-quality studies are required to establish the safety and effectiveness of this treatment, as well as its superiority to the standard of care (e.g., warm compress). In addition, no clinical practice guidelines were identified which address the automated evacuation of meibomian glands.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to
determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days’ notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

U.S. Food and Drug Administration (FDA)

In 2011, the U.S. FDA approved the LipiFlow® Thermal Pulsation System under the 510(k) premarket notification process.2

Intended use:

The LipiFlow® Thermal Pulsation System is intended 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.

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

REFERENCES

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