Medical Policy

Automated Evacuation of the Meibomian Glands

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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 Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. 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. 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. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance and Providence Plan Partners as applicable (referred to individually as "Company" and collectively as "Companies").

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☒ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP 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.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

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

Link to Evidence Summary

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

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.[1] MGD occurs when these glands are not secreting enough oil, often due to the gland becoming 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."[1] 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."[2] 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.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

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.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

<u>Systematic Reviews</u>

- In 2022, Hayes conducted a comparative effectiveness review assessing the safety and efficacy of thermal pulsation for the treatment of chronic dry eye syndrome and meibomian gland dysfunction.[3] In total, 9 studies, including 6 RCTs and 3 prospective comparative cohort studies evaluating thermal pulsation therapy were included for review. Sample sizes across studies ranged from 25 to 200 patients, with follow-up recorded between 2 weeks and 3 months. Across studies, thermal pulsation therapy was similar to or better than standard warm compresses self-administered at home for improving symptoms. No studies indicated whether statistically significant

improvements represented clinically meaningful differences. Limitations included small treatment groups, partial or no blinding, incomplete reporting of demographics, significant differences between treatment groups at baseline, assessment of only 1 outcome (1 study), loss to follow-up, and relatively short follow-up. Evidence was also insufficient to establish definitive patient selection criteria for thermal pulsation therapy. Hayes concluded that evidence, though large in size, was low in quality due to the limited evidence for the comparative effectiveness of thermal pulsation therapy relative to active comparators other than warm compress therapy (e.g., oral or topical therapies), and uncertainty regarding the durability of treatment benefit for thermal pulsation therapy. Hayes ultimately assigned a "C" rating (potential but unproven benefit.)

- In 2021, Hu and colleagues conducted a systematic review and meta-analysis assessing the safety and efficacy of a vectored thermal pulsation system (Lipiflow®) in the treatment of meibomian gland dysfunction (MGD).[4] Systematically searching the literature through December 2020, investigators identified 10 RCTs (n=761). In the comparison of Lipiflow® treatment and lid hygiene, the subgroup with inconsistent units of randomization and analysis showed that the Lipiflow® treatment brought slight improvement in corneal fluorescein staining (mean difference (MD), - 0.42; 95% CI, - 0.75 to - 0.1), significant improvements in ocular surface disease index (OSDI) score (MD, - 7.4; 95% CI, - 11.06 to - 3.74), Standard Patient Evaluation of Eye Dryness (SPEED) score (MD, - 2.7; 95% CI, - 3.95 to - 1.45), meibomian glands yielding liquid secretion (MGYLS) (MD, 1.3; 95% CI, 0.78 to 1.82), and meibomian glands yielding secretion score (MGYSS) (MD, 4.09; 95% CI, 1.18 to 6.99). Meanwhile, significant improvements were detected in OSDI score, SPEED score, MGYLS, and MGYSS with patients who received Lipiflow® treatment compared with those who received nontreatment. The adverse events were comparable in the two control groups. Investigators concluded that while Lipiflow® treatment can improve the subjective and objective outcomes of MGD and does not increase the incidence of adverse events, additional well-designed, large-scale RCTs are required to establish the treatment's long-term efficacy.

- In 2019, Pang and colleagues conducted a systematic review and meta-analysis evaluating the safety and efficacy of vectored thermal pulsation (VTP) and warm compress treatments (WCT) in meibomian gland dysfunction.[5] Independent investigators systematically searched the literature through July 2018, identified eligible studies, assessed study quality, extracted data and pooled results. In total, 4 trials assessing 385 patients were included for review. The primary outcome was meibomian gland function determined using the meibomian gland evaluator or other methods. The secondary outcomes were the tear breakup time (TBUT) in seconds, Schirmer test, tear osmolarity, lipid layer thickness (LLT), Standard Patient Evaluation for Eye Dryness (SPEED), and the improvement of subjective symptoms as assessed using the Ocular Surface Disease Index (OSDI). Significantly greater improvement was observed in meibomian gland function, tear breakup time, and Standard Patient Evaluation for Eye Dryness at 2 to 4 weeks in the VTP group than in the WCT group. A significantly greater decrease in Ocular Surface Disease Index was observed at 2 to 4 weeks and 3 months in the VTPT group than in the WCT group. No statistically significant differences were seen for VTP versus warm compress treatment. Investigators concluded that a single 12-minute VTPT was more efficacious than traditional WCT in treating meibomian gland dysfunction. Limitations included the lack of long-term follow-up, multiple control groups and a heterogeneous patient group.

- In 2018, ECRI conducted an evidence review assessing the safety and efficacy of LipiFlow Thermal Pulsation System (TearScience, Inc.) for treating dry eye syndrome.[6] Available evidence from controlled trials suggests LipiFlow treatment works for at least 12 months to relieve dry eye symptoms and improve gland function in many patients with meibomian gland dysfunction (MGD). One SR (eight full published studies and 23 conference abstracts) reported on meibomian gland function symptom improvement, osmolarity, tear break-up time (TBUT), and lipid layer thickness (LLT). Four RCTs (n = 30, n = 200, n = 25, n = 55) compared a single 12-minute LipiFlow treatment to a variety of controls (i.e., no treatment, antibiotic treatment, daily warm compress and eyelid hygiene, MeiboPatch) and reported on symptom relief and other disease measures, including the number of functioning meibomian glands, meibomian gland secretion, TBUT, and SPEED scores (standard patient evaluation for eye dryness). Two prospective nonrandomized controlled trials (n = 29, n =50) compared a single 12-minute LipiFlow treatment with warm compress and no treatment and reported SPEED scores, ocular surface disease index, a modified SANDE (symptom assessment in dry eye) questionnaire, and other measures, including LLT, partial blink ratio, and TBUT. The SR and several RCTs have authors who are either employed by and/or are consultants of the device manufacturer. Data from the nonrandomized controlled trials may not be generalizable because they were conducted in different countries whose health systems and clinical practices may vary. Additionally, many of the studies have a single-center focus, which may also affect their generalizability. ECRI concluded that multicenter, independent RCTs that provide longer-term data would be useful to confirm results of the manufacturer-sponsored trials and compare long-term LipiFlow efficacy to pharmacologic therapies, warm compress, and other similarly functioning devices in patient groups of different disease severity.

<u>Randomized Controlled Trials (RCT)</u>

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.[7] 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 ($P<0.0001$)."[7] 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).[8] 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."[8]

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.[9-16] 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

American Academy of Ophthalmology (AAO)

The 2018 Preferred Practice Pattern guideline of the AAO lists thermal pulsation therapy (e.g., LipiFlow) as a second-stage option for treatment of dry eye disease (AAO-Dry Eye Syndrome).[17] No specific evidence was cited supporting this recommendation.

EVIDENCE 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 evidence-based clinical practice guidelines were identified which address the automated evacuation of meibomian glands.

BILLING GUIDELINES AND CODING

If CPT code 0330T is billed in conjunction with 0207T then it will deny as investigational.

CODES*		
CPT	0207T	Evacuation of meibomian glands, automated, using heat and intermittent pressure, unilateral
	0330T	Tear film imaging, 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

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
1/2024	Annual update. Policy name change. Change in denial type from “investigational” to “not medically necessary.”