Protocol

Eyelid Thermal Pulsation for the Treatment of Dry Eye Syndrome

(90329)

Medical Benefit		**Effective Date**: 08/01/20	**Next Review Date**: 05/21
Preauthorization	No	**Review Dates**: 05/20	

This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With dry eye symptoms consistent with meibomian gland dysfunction	Interventions of interest are: • Eyelid thermal pulsation	Comparators of interest are: • Standard treatment with warm compresses and eyelid massage	Relevant outcomes include: • Symptoms • Morbid events • Functional outcomes

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.

SUMMARY OF EVIDENCE

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

POLICY

Eyelid thermal pulsation therapy, including imaging in conjunction with this therapy, to treat dry eye syndrome is considered **investigational**.

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.[1,2] 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[1] and approximately one to 4.3 million Americans between 65 and 84 years of age.[3] 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.[4,5] 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.[5] 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.

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).[6] 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 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.

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Fiscella RG. Understanding dry eye disease: a managed care perspective. Am J Manag Care. Dec 2011; 17(Suppl 16):S432-439. PMID 22435675
2. The definition and classification of dry eye disease: report of the Definition and Classification Subcommittee of the International Dry Eye WorkShop (2007). Ocul Surf. Apr 2007;5(2):75-92. PMID 17508116
3. American Academy of Ophthalmology Cornea/External Disease Panel. Preferred Practice Pattern Guidlines. Dry Eye Syndrome. San Francisco, CA: American Academy of Ophthalmology; 2013.
4. Nichols KK, Foulks GN, Bron AJ, et al. The international workshop on meibomian gland dysfunction: executive summary. Invest Ophthalmol Vis Sci. Mar 2011;52(4):1922-1929. PMID 21450913
5. Blackie CA, Korb DR, Knop E, et al. Nonobvious obstructive meibomian gland dysfunction. Cornea. Dec 2010; 29(12):1333-1345. PMID 20847669
6. Medical devices; ophthalmic devices; classification of the eyelid thermal pulsation system. Final rule. Fed Regist. Aug 19 2011;76(161):51876-51878. PMID 21894651
7. Lane SS, DuBiner HB, Epstein RJ, et al. A new system, the LipiFlow, for the treatment of meibomian gland dysfunction. Cornea. Apr 2012;31(4):396-404. PMID 22222996
8. Finis D, Hayajneh J, Konig C, et al. Evaluation of an automated thermodynamic treatment (LipiFlow(R)) system for meibomian gland dysfunction: a prospective, randomized, observer-masked trial. Ocul Surf. Apr 2014;12(2):146-154. PMID 24725326
9. Blackie CA, Coleman CA, Holland EJ. The sustained effect (12 months) of a single-dose vectored thermal pulsation procedure for meibomian gland dysfunction and evaporative dry eye. Clin Ophthalmol. Jul 26 2016;10:1385-1396. PMID 27555745
10. Zhao Y, Veerappan A, Yeo S, et al. Clinical trial of thermal pulsation (Lipiflow) in meibomian gland dysfunction with preteatment meibography. Eye Contact Lens. Nov 2016;42(6):339-346. PMID 26825281
11. Greiner JV. Long-term (12-month) improvement in meibomian gland function and reduced dry eye symptoms with a single thermal pulsation treatment. Clin Experiment Ophthalmol. Aug 2013;41(6):524-530. PMID 23145471
12. Finis D, Konig C, Hayajneh J, et al. Six-month effects of a thermodynamic treatment for MGD and implications of meibomian gland atrophy. Cornea. Dec 2014;33(12):1265-1270. PMID 25321941
13. Greiner JV. Effects of a single thermal pulsation system treatment on meibomian gland function and dry eye symptoms. Eye Contact Lens. Mar 2016;42(2):99-107. PMID 26222095
14. Miller KL, Walt JG, Mink DR, et al. Minimal clinically important difference for the Ocular Surface Disease Index. Arch Ophthalmol. Jan 2010;128(1):94-101. PMID 20065224
15. Ngo W, Situ P, Keir N, et al. Psychometric properties and validation of the Standard Patient Evaluation of Eye Dryness questionnaire. Cornea. Sep 2013;32(9):1204-1210. PMID 23846405