FEP 9.03.29 Eyelid Thermal Pulsation for the Treatment of Dry Eye Syndrome

Effective Date: July 15, 2018

Related Policies: None

Eyelid Thermal Pulsation for the Treatment of Dry Eye Syndrome

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.

FDA 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) (K093937).[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.

POLICY STATEMENT

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

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

For individuals who have dry eye symptoms consistent with meibomian gland dysfunction who receive eyelid thermal pulsation, the evidence includes 3 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 the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

In 2013, the American Academy of Ophthalmology published preferred practice patterns guidelines on dry eye syndrome.[3] A number of treatment options were recommended. The use of thermal pulsation treatment devices was not mentioned.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

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POLICY HISTORY

Date	Action	Description
June 2013	New Policy	
June 2014	Update Policy	Policy updated with literature review, references 9-11 added. The policy statement is unchanged.
June 2015	Update Policy	Policy updated with literature review, Rationale revised: references 10-11 added; policy statement unchanged.
September 2016	Update Policy	Policy updated with literature review, reference 8 added. Policy statement unchanged.
June 2018	Update Policy	Policy updated with literature review through January 8, 2018; no references added. Policy statement unchanged except “not medically necessary” corrected to “investigational” due to FDA Class II status.