

Reimbursement Policy

Evaluation of Dry Eyes

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I. Policy Description

Dry eye disease (dysfunctional tear syndrome, DED) is defined by the Dry Eye Workshop II as “a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles.”¹ Five to fifteen percent of the United States population suffers from dry eye disease, leaving a substantial burden on functional vision, general health status, and workplace productivity.²

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual’s benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the “Applicable State and Federal Regulations” section of this policy document.

- 1) For individuals suspected of having dry eye, testing of tear osmolarity **MEETS COVERAGE CRITERIA** in **any** of the following situations:
 - a) To help determine the severity of dry eye disease.
 - b) To monitor effectiveness of therapy.
- 2) For individuals suspected of having dry eye disease based on comprehensive eye examination, testing for MMP-9 protein in human tears **DOES NOT MEET COVERAGE CRITERIA**.
- 3) For individuals suspected of having dry eye disease, testing for lactoferrin and/or IgE **DOES NOT MEET COVERAGE CRITERIA**.

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual’s illness.

- 4) For individuals suspected of having dry eye disease, all other testing not discussed above **DOES NOT MEET COVERAGE CRITERIA**.

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III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: <https://www.cms.gov/medicare-coverage-database/search.aspx>. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

On December 3, 1993, the FDA approved the lactoferrin microassay system by Touch Scientific, Inc.³⁶ Lactoferrin diagnostic kits are commercially available options for tear film biomarkers.³

On May 14, 2009, the FDA approved the TearLab Osmolarity System created by Ocusense Inc. From the FDA site: this device is used “to measure the osmolality of human tears to aid in the diagnosis of patients with signs or symptoms of DED, in conjunction with other methods of clinical evaluation.”³⁷ In 2022, Ocusense Inc. rebranded as Trukera Medical and continues to manage the TearLab Osmolarity System.³⁸

On November 20, 2013, the FDA approved InflammDry created by Rapid Pathogen Screening Inc. From the FDA site: “InflammDry is a rapid, immunoassay test for the visual, qualitative in vitro detection of elevated levels of the MMP-9 protein in human tears from patients suspected of having dry eye to aid in the diagnosis of dry eye in conjunction with other methods of clinical evaluation. This test is intended for prescription use at point-of-care sites.”³⁹

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). As an LDT, the U. S. Food and Drug Administration has not approved or cleared this test; however, FDA clearance or approval is not currently required for clinical use.

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
82785	Gammaglobulin (immunoglobulin); IgE
83516	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method
83520	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified
83861	Microfluidic analysis utilizing an integrated collection and analysis device, tear

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Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

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