

TearLab Tear Osmolarity Billing Guidance

This guide addresses billing recommendations for CPT® 83861, “Microfluidic analysis utilizing an integrated collection and analysis device, tear osmolarity”, a covered service by CMS Medicare under the Clinical Laboratory Fee Schedule. CLIA Certification is required to perform and bill laboratory tests.

Billing Codes and Modifiers

• CMS Medicare Part B

- 2018 allowable - \$22.48 per test (\$44.96 per patient) – no deductible or patient co-payment applies
- Code CPT 83861 as one unit of service with LT/RT and QW modifiers on two lines, once for each eye tested:
 - 83861 QW RT (1 unit)
 - 83861 QW LT (1 unit)
- Include ordering physicians individual NPI number (NOT group NPI) in Box 17
- Check “No” on Box 20
- Include CLIA license number in Box 23

CPT 83861 has universal coverage under CMS Part B Medicare. Claim denials from CMS are usually due to errors in coding or transmission of pertinent information by billing software. If any denial is received for CPT 83861 contact the TearLab Reimbursement Support Center promptly at rsc@tearlab.com for assistance.

• Commercial Third Party, Medicare Advantage Part C and Medicaid

Reimbursement, coding and coverage policies will vary by carrier, provider contract and patient benefit plan. Contact the TearLab Reimbursement Support Center at rsc@tearlab.com for payer specific billing guidance.

Diagnostic Codes

Medical necessity rules are met when a patient presents with a sign or symptom of dry eye as determined by the clinician, which should be documented in the patient’s medical record. Codes commonly used for coding dry eye diagnosis and/or dry eye symptoms, as referenced in the clinical literature, are available on the “ICD-10 Coding for Dry Eye” brochure, available on the TearLab website.

Currently CMS has no National Coverage Determinations (NCD) that define diagnosis codes to bill for CPT 83861 tear osmolarity test, so a decision to perform a test based on signs or symptoms of dry eye is up to the physician. Always ensure that all the items listed below in “Documenting a Laboratory Test” are included in the patient record to meet medical necessity guidelines.

Documenting a Laboratory Test

Medicare has several documentation requirements for laboratory tests such as tear osmolarity, which must be noted in the patient chart or Electronic Health Record (EHR).

1. The sign or symptom of disease that prompted the ordering of the test
2. A notation in the medical record that a “tear osmolarity test was ordered” with “tear osmolarity” specifically identified
3. The numerical tear osmolarity test results and indication if the results were normal or abnormal
4. Treatment/Management Plan - the medical action taken as a result of the tear osmolarity test, and referencing the test results in the plan.
5. Managing clinician’s signature at the end of the record indicating that everything in the record that day was reviewed and confirmed as medically necessary

Note that Medicare and most commercial payers do not cover screening tests, thus a sign or symptom of dry eye, or a previously diagnosed but “unstable” dry eye under management, must be properly documented prior to submitting a claim for reimbursement for a tear osmolarity test.

What if the tear osmolarity test is normal?

If the tear osmolarity test result is normal and dry eye is “ruled out”, code for the final or confirmed diagnosis, and “*the symptoms that prompted ordering the test may also be reported as additional diagnosis if they are not fully explained or related to the confirmed diagnosis*”. (ref: CMS Program Memorandum AB-01-144, Sept 26, 2001).

CMS coverage rules for laboratory tests state, “*The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test*”. (ref: Fed Reg Vol 66, No 226, Nov 23, 2001)

How often can I perform a tear osmolarity test?

Medical necessity as determined by the clinician determines how often a tear osmolarity test may be performed and must accompany proper documentation consisting of either a current sign or symptom of disease, or a patient under therapy that is being managed for a previously diagnosed but “unstable” dry eye. Testing a patient with a prior history of dry eye without current signs or symptoms of disease would likely be considered a “screening” test.

All items noted in “Documenting a Laboratory Test” must be included in the patient medical record to ensure proper support for multiple testing.

Are there Global Period exclusions?

No, laboratory tests do not apply to “global period” exclusions for procedures such as the 10-day global period for punctal occlusion and 90-day post-operative global exclusion for cataract surgery. (ref: Medicare Claims Processing Manual -Chapter 12, Section 40.1)

TearLab requests that the office billing department NOT spend time to resolve billing issues for CPT 83861, and instead contact the TearLab Reimbursement Support Center, under a Business Associate Agreement. Remittance Advisements or EOBs indicating billing or payment problems should be faxed to TearLab at the following HIPAA secure number - (858) 812-0540 - promptly upon receipt. TearLab will review the denial for you and determine the reason for denial and best method to resolve - rsc@tearlab.com

Disclaimer: The above information is current as of January 2016, and was obtained from third-party sources and is subject to change without notice as a result of changes in reimbursement laws, regulations, rules, policies, and payment amounts. All content is informational only, general in nature, and does not cover all situations or all payers' rules and policies. This content is not intended to instruct hospitals and/or physicians on how to use or bill for healthcare procedures, including new technologies outside of Medicare national guidelines. A determination of medical necessity is a prerequisite that TearLab Corporation assumes will have been made prior to assigning codes or requesting payments.

Under Federal and State law, it is the individual provider's responsibility to determine appropriate coding, charges and claims for a particular service. Policies regarding appropriate coding and payment levels can vary greatly from payer to payer and change over time. TearLab Corporation recommends that providers contact their own regional payers to determine appropriate coding and charge or payment levels.

If you are a provider participating in a clinical trial, we recommend you contact your payers, including Medicare/Medicaid and private insurers, to verify correct coverage and reimbursement policies for investigational devices.

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