TearLab Tear Osmolarity Billing Guidance

Florida
Puerto Rico
US Virgin Islands

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

Medicare Part B - Florida, Puerto Rico and US Virgin Islands

First Coast Service Options, the Medicare Area Contractor for this jurisdiction, has published a Local Coverage Determination (LCD - L36232) which deems tear osmolarity testing as medically necessary, and includes the following ICD-10 codes that must be used when billing for Medicare Part B patients. The First Coast LCD only applies to providers under its jurisdiction. For further information, please contact your TearLab representative or visit the CMS website at the following link: *http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx*

ICD-10 CODES	DESCRIPTION
H04.121 - H04.129	Dry eye syndrome of right lacrimal gland - Dry eye syndrome of unspecified lacrimal gland
H11.141 - H11.149	Conjunctival xerosis, unspecified, right eye - Conjunctival xerosis, unspecified, unspecified eye
H16.221 - H16.229	Keratoconjunctivitis sicca, not specified as Sjögren's, right eye- Keratoconjunctivitis sicca, not specified as Sjögren's, unspecified eye
H57.10 - H57.13	Ocular pain, unspecified eye - Ocular pain, bilateral
M35.00	Sicca syndrome, unspecified
M35.01	Sicca syndrome with keratoconjunctivitis
M35.02	Sicca sybdrome with lung involvement
M35.03	Sicca syndrome with myopathy
M35.04	Sicca syndrome with tubulo-interstitial nephropathy
M35.09	Sicca syndrome with other organ involvement

For non-Medicare Part B patients, medical necessity rules are met when a patient presents with a sign or symptom of dry eye as determined by the clinician. Refer to "ICD-10 Coding for Dry Eye" brochure, available on the TearLab website.

How often can I perform a tear osmolarity test?

Florida, Puerto Rico and US Virgin Islands - Medicare Part B

For providers in the above jurisdiction, the First Coast Service Option LCD limits the number of times a Medicare Part B patient may be tested annually to 3-bilateral tear osmolarity tests. An initial test of both eyes is justified if the patient presents with moderate to severe dry eye symptoms based on a validated dry eye questionnaire, i.e., the DEQ-5 with a score >6. If the initial test is 312 mOsm/L or greater in either eye, indicative of moderate to severe dry eye, a second test in each eye is considered medically necessary after 6-weeks to monitor the effect of therapy, and a third after 90-days to confirm if the disease has been stabilized. Repeating tear osmolarity testing after an initial test result <308 mOsm/L (normal) is not considered medically necessary by First Coast for one year from baseline, and then only if changes in signs and symptoms support the test. Contact your TearLab representative for additional information.

For non-Medicare Part B patients, 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.

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. The First Coast LCD requires the use of a validated dry eye symptom questionnaire. TearLab recommends the DEQ-5, which requires a symptom score >6 before the LCD will cover tear osmolarity testing.
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. The First Coast LCD requires a Tear Osmolarity test of 312 mOsm/L or greater, indicative of moderate to severe dry eye, for repeat testing to monitor therapy. This should be noted 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. See the above section for more information on First Coast LCD requirements.

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

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