ScoutPro™ Osmolarity System by Bausch + Lomb

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: $22.48 per test ($44.96 per patient)

- No deductible or patient co-payment applies
- Code CPT 83861 as one unit of service with QW modifiers followed by LT/RT on two lines, once for each eye:

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE	17a.		18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY
Dr. John Smith	17b. NPI	1234567890	FROM TO
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)			20. OUTSIDE LAB? YES [X] NO $ CHARGES
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.			22. RESUBMISSION CODE ORIGINAL REF. NO.
A. H53.141 B. H53.142 C. D. E. F. G. H. I. J. K. L.			23. PRIOR AUTHORIZATION NUMBER 10D2345678

24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER			E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
09	01	22	09	01	22	11		83861	QW	RT		A	40 00	1		NPI	1234567890
09	01	22	09	01	22	11		83861	QW	LT		B	40 00	1		NPI	1234567890

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 Bausch + Lomb for details on specific payers and 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.

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. Furthermore, ICD-10-CM official guidelines indicate that, "*codes that describe the symptoms and signs, as opposed to diagnoses, are acceptable for reporting purposes when a related definitive diagnosis has not been established (confirmed) by the provider.*"[1]

CMS coverage rules for laboratory tests state, "*If a person is tested to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom, this is considered a diagnostic test, not a screening test.*"[2] In these cases, the sign or symptom should be used to explain the reason for the test.[2]

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.[3]

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR SCOUTPRO OSMOLARITY SYSTEM

INDICATIONS: The ScoutPro Osmolarity System is an automated device intended to quantitatively measure the osmolarity of human tears to aid in the diagnosis of dry eye disease, in patients suspected of having dry eye disease in conjunction with other methods of clinical evaluation.

CONTRAINDICATIONS: Do not collect tear fluid from a patient within two hours of medicinal eye drop use or use of topical medications. Do not collect or store tear fluid samples for transport or testing at a later time. Do not collect tear fluid after ocular surface staining. Do not collect tear fluid within 15 minutes of use of anesthetic or mydriatic (dilating) eye drops or after other invasive ocular diagnostic testing. Do not collect tear fluid within 15 minutes after a slit lamp examination. Do not collect tear fluid within 15 minutes from a patient who has been crying.

The ScoutPro Osmolarity System (ScoutPro) is a CLIA Waived test system for human tears. Each laboratory or testing site using the ScoutPro must have a CLIA Certificate of Waiver before starting testing.

The ScoutPro is designed for stability, reliability, and safety, and it has been developed, manufactured, and marketed under a quality management system certified to ISO 13485 (2012).

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

ATTENTION: This is not all you need to know. Please refer to the User Manual for a complete listing of indications, contraindications, precautions, and use information.

REFERENCES: 1. ICD-10-CM Official Guidelines for Coding and Reporting. FY 2022 – Updated April 1, 2022. **2.** Medicare Claims Processing Manual. Chapter 16 – Laboratory Services. Revision 12443 issued January 04, 2024. **3.** Medicare Claims Processing Manual. Chapter 12 – Physician/Nonphysician Practitioners. Revision 13012 issued December 19, 2024.

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