L36232: Medicare Part A/B local coverage determination (LCD) comment summary

LCD Number

L36232

Contractor Name

First Coast Service Options, Inc.

Contractor Numbers

09101 – Florida
09201 – Puerto Rico/Virgin Islands
09102 – Florida
09202 – Puerto Rico
09302 – Virgin Islands

Contractor Type

MAC Part A/B

LCD Title

Diagnostic Evaluation and Medical Management of Moderate-Severe Dry Eye Disease (DED)

AMA CPT Copyright Statement

Start Date of Comment Period:

06/12/2015

End Date of Comment Period:

07/27/2015

Comments received:

Tear osmolarity test Current Procedural Terminology (*CPT*®) code 83861

Comment #1: Several comments, as well as supporting literature, were received in support of tear testing for osmolarity (*CPT*® code 83861-microfluidic analysis).

- **New modality:** Tear osmolarity testing represents one of the major advances in our field and has offered an innovative, practical, and cost-effective way to help test for dry eye disease. The draft LCD denying coverage of tear osmolarity testing will result in the elimination of a valuable diagnostic modality for dry eye disease, which represents one of the most common conditions encountered by eye care practitioners. It is also important to note that new modalities of tear testing, including tear osmolarity, are continuing to improve and evolve. This denial could have a significantly negative impact on research and technology in this field, which will undoubtedly hinder further developments on diagnostic devices (and potentially therapeutic agents) for dry eye and other conditions where tear osmolarity testing may apply.
- **Diagnosis confirmation:** The significance of this accurate convenient office based measurement on the diagnosis and management of DED is profound. The tear osmolarity testing has the ability to separate out the difference between dry eye disease and inflammatory ocular surface disease, and patient-induced irritation due to chronic rubbing of the eyes. In addition to confirming the precise diagnosis, the severity of disease can be established and the clinician can prescribe treatment based upon objective information. Obviously patient symptoms are an important part of clinical decision making; however, an objective measurement of the primary pathophysiologic disturbance provides the clinician with a better tool to care for the patient. The denial of this coverage will have an adverse outcome on the quality care of patients with dry eye disease.
- **Sensitivity and specificity:** The central role of elevated tear osmolarity in the pathophysiology of dry eye is well supported in the clinical literature. Although there are other ways to diagnose and monitor DED, the sensitivity and specificity of tear osmolarity testing is higher than any other tests available. Tear osmolarity testing exceeds the accuracy of Schirmer testing, staining, and tear film break-up time (TFBUT), all recommended in the draft LCD. Schirmer testing is highly variable and

subject to false negative scores and does not identify the evaporative form of dry eye which is the more common variant of dry eye disease. These older methods are relatively subjective and can be somewhat unreliable because of variability in the methodology or irritation associated with the test. Multiple peer reviewed publications have shown that elevated tear film osmolarity, variable tear film osmolarity, and/or asymmetric tear film osmolarity are observed in dry eye disease. In addition to being a definite improvement over these older testing methods, osmolarity testing can better stratify dry eye into mild, moderate, and severe disease states. This will provide for more efficient treatment plans and help evaluate patient response to treatment. In summary, tear film osmolarity is an important test with the highest sensitivity and specificity of all the dry eye tests in use today.

- **Clinical guidelines:** The Sjögren's Syndrome Foundation (SSF) clinical guidelines for the management of Sjögren's Disease identify and recommend tear testing beyond simply the Schirmer test, TFBUT, and ocular surface staining and look towards newer methods that detect the disease earlier and thus allow for a quicker referral to a rheumatologist for systemic therapy. The conclusions of the guidelines with respect to tear testing, including the tear osmolarity test, found that osmolarity testing was both medically necessary and helped select the proper therapy, since therapy is largely based upon the severity of the disease, something that symptoms alone are quite poor at determining.
- **Increased use and reimbursement:** Evidence supporting the benefit of the tear osmolarity test is the increased use by eye care specialists. The difference in reimbursement and cost of supplies does not cover the technician's or the physician's time required to perform the test.
- **Quantitative value:** Tear osmolarity testing reduces the number of office visits required to determine the correct diagnosis, gives doctors a quantitative value to determine if the treatment plan is working, and improves the patient's quality of life. The ability to provide a quantitative assessment of treatment progress to patients is beneficial for the clinician and the patient. Providing patients with a number serves as a target or goal and encourages treatment adherence or shows whether alternative treatments are warranted. Based on peer reviewed literature recommendations for the frequency of testing is as follows, with the ultimate goal of osmolarity returning to normal, usually following a three to six month course of treatment: baseline, one month to monitor efficacy, three months to establish if osmolarity has returned to normal or if osmolarity is not reduced, and six months to establish if osmolarity is returned to normal or reduced.
- **Definition DED:** The 2007 Report of the International Dry Eye WorkShop (DEWS) is an encyclopedic review of dry eye disease and is frequently cited as an important peer-reviewed reference on this condition. It is pertinent that one of the defining conditions of dry eye, tear film osmolarity, is precisely the tear test that the draft LCD deems "not medically necessary." The clinical definition of dry eye disease as presented by the DEWS 2007 report includes "increased osmolarity".

Contractor response: Thank you for your comments and supporting literature. The contractor agrees that testing for tear osmolarity may be a useful diagnostic test for DED when used in conjunction with other methods of diagnostic testing. Therefore, the LCD will be revised to include limited indications, documentation requirements, and utilization guidelines for tear osmolarity testing (*CPT*® code 83861).

Though stakeholders for both emerging diagnostic tests (both tear osmolarity test *CPT*® code 83861 and MMP-9 protein *CPT*® code 83516) addressed in this LCD for DED have adequate support given analytical and clinical validity, the clinical utility-the likelihood that the test, (by implementing an intervention), will result in improved health outcome, has not been well established in the Medicare population. If future peer reviewed literature suggests alternative approaches to the evaluation of moderate to severe DED, these tests will be evaluated for added limitations or non-coverage. As clearly outlined in the LCD – test results must be used for individual patient treatment decisions as a predictive marker (patient likely to respond to a given therapy). And testing of patients without signs or symptoms is screening and not a covered service.

Comment #2: Tear osmolarity testing has utility in dry eye patients that are asymptomatic and are hesitant to start treatment. For the dry eye patient who has no complaints yet has significant signs on the ocular exam, osmolarity provides the skeptical patient with objective proof that the disease exists, much like a blood pressure measurement does in a hypertensive patient. One may make the argument that since blood pressure is not reimbursed; the same should apply to osmolarity testing. A sphygmomanometer is purchased once and is used thousands of times over, but osmolarity involves a disposable one time use microchip so the analogy cannot be made.

It is important to conduct tear film osmolarity assessments at the initial assessment in order to determine a baseline reading and to observe the patient's response to treatment as the osmolarity decreases and the tear film stabilizes. Negative tear film osmolarity assessments can also be effective in assisting in the diagnosis of patients who do not have dry eye disease. Because of the overlap in the signs and symptoms of numerous diseases affecting the ocular surface, negative results of diagnostic tests (normal tear film osmolarity) can direct a clinician to consider evaluating patients for other ocular conditions (e.g., ocular allergy, contact lens intolerance, medicamentosa) that may not be as easily obtained with the older assessment tool.

Contractor response: The scope of the Medicare benefit requires the beneficiary to have signs and symptoms of disease. Coverage of tear osmolarity testing on the initial visit absent signs and symptoms of DED is considered screening and is statutorily excluded from coverage. However, as stated in contractor response to Comment #1, the contractor agrees that testing for tear osmolarity may be a useful diagnostic test for DED when used in conjunction with other methods of diagnostic testing. The LCD will be revised to include the limited indications, documentation requirements, and utilization guidelines for tear osmolarity testing (*CPT*® code 83861), including criteria for tear osmolarity testing on the initial visit prior to any ocular surface altering tests (e.g. Schirmer test, vital dye staining, TFBUT, etc.).

Comment #3: Several comments received concerning the statement “Testing of mild DED is not clinically useful because these patients cannot be differentiated from normal patients, and the resultant therapeutic intervention does not vary (e.g., tear supplementation, tear retention, tear stimulation, etc.).”

- The treatments for mild dry eye disease, including artificial tear supplementation, are different than for patients with normal eyes, who require no treatment. Dry eye disease is a progressive condition, often with devastating consequences, and to deny treatment to patients in the early stages of this disease makes little sense and is contrary to good and accepted medical practice. I cannot imagine denying treatment or appropriate diagnostic testing to patients with “mild diabetes" because their measured blood glucose levels may not be as dramatically elevated in the early stages of the disease. I would respectfully request at this time that First Coast establish coverage for tear osmolarity testing when used for the diagnosis and treatment of patients exhibiting signs and/or symptoms of dry eye disease, without limitation.
- The statement ignores current medical evidence that tear osmolarity testing in conjunction with a comprehensive clinical evaluation can, in fact, effectively differentiate normal from mild dry eye. It is clear that patients with mild dry eye can be differentiated from normal patients if modern tear osmolarity testing is employed. In addition, treatment does exist for mild dry eye based on severity evaluation. Furthermore, since normal patients are not treated for dry eye, the statement is not accurate. In addition, a policy ignoring patients presenting with mild “dry eye” complaints, who in fact do not have dry eye disease, but another ocular surface disease would disenfranchise those patients from appropriate and necessary medical care. If this limitation remains all patients with mild dry eye symptoms will be treated as if they had mild dry eye, regardless of the actual pathology present.
- Patients with mild dry eye have lesser or intermittent symptoms characteristic of ocular dryness and examination findings are lesser in degree than those patients with moderate or severe disease. Tear film osmolarity is an important test with the highest sensitivity and specificity of all the dry eye tests in use today. It helps in differentiating normal, mild, moderate, and severe dry eye patients thus guiding treatment. I strongly support Medicare coverage for this test for patients with mild, moderate, and severe dry eye disease.

Contractor response: The contractor will not change its current language. Patients with normal eyes and patients with mild DED could both have unspecific complaints of eye discomfort which would be treated similarly for the purpose of symptom relief.

Comment #4: Many ocular surface diseases have symptoms that mimic dry eye; “non-dry eye disease” must be ruled-out by objective and quantitative testing, including laboratory testing for tear osmolarity. A normal tear osmolarity test in the presentation of dry eye symptoms would indicate a “non-dry eye disease” and direct the clinician to look elsewhere for the cause of symptoms through additional clinical evaluation. In such a case, it would be inappropriate to code “dry eye” as the reason for ordering a tear osmolarity test, since dry eye is “ruled out” if the tear osmolarity is normal. CMS coding guidelines for clinical laboratory services states, “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.” We therefore request the following ICD-10 codes for dry eye symptomology, as defined by validated dry eye symptom questionnaires, including the Ocular Surface Disease Index (OSDI), the Standard Patient Evaluation of Eye Dryness Questionnaire (SPEED), and the 5-Item Dry Eye Questionnaire (DEQ-5), be included as dry eye symptom codes that support medical necessity.

H04.209-Epiphora, unspecified
H04.219-Epiphora due to excess lacrimation
H04.229-Epiohora due to insufficient drainage
H53.129-Transient visual loss
H53.141-Visual discomfort, right eye
H53.142-Visual discomfort, left eye
H53.149-Visual discomfort, unspecified
H53.8-Other visual disturbances

- Blurred vision
- Hazy vision
- Multiple visual images
- Reduced visual acuity
- Visual acuity reduced
- Visual disturbance, multiple images

H57.10-Ocular pain, unspecified eye
H57.11-Ocular pain, right eye
H57.12-Ocular pain, left eye
H57.13-Ocular pain, bilateral

Contractor response: Thank you for your comments. The LCD will be revised to include additional diagnosis for ocular pain. Once the draft LCD is finalized and becomes effective, an LCD reconsideration request may be submitted with clinical literature supporting further revision/modification to the LCD.

Comment #5: Comments received agreeing with the draft LCD.

- I agree with the policy. I suggest making it shorter but keep the same force and effect. The providers who care about it will know the information in the background, diagnostic testing, and management.

- I support the First Coast proposal to not cover the tear osmolarity test because it cannot guide therapeutic decision making and is associated with significant variability with testing. It cannot differentiate normal from mild or mild-moderate dry eye, which represents the majority of patients; therefore, it is not clinically useful.

Contractor response: Thank you for your comments and feedback. We received several comments supporting coverage of tear osmolarity in addition to literature that supported clinical utility of tear osmolarity testing for certain patients. Therefore, the contractor has decided to provide limited coverage of tear osmolarity.

MMP-9 protein *CPT*® code 83516

Comment #6: Several comments received disagreeing with the frequency of testing, once in a lifetime, for MMP-9 protein *CPT*® code 83516.

- It is insufficient to perform a single test in the lifetime of a patient and expect this to affect ongoing care over time. Repeat testing is required to decide whether or not to add an additional anti-inflammatory medication or pursue punctal occlusion or other conservative measures. The MMP-9 test is needed to measure the presence or absence of significant inflammation in the tear film. The level of inflammation is not constant and is impacted by environment. Surgery and medication changes a patient experiences. To optimize therapy, we recommend allowing a test of both eyes per visit and up to a maximum of three times annually per eye per patient for those who remain symptomatic despite therapeutic interventions.
- Both eyes should be tested with the MMP-9 test because dry eye may present asymmetrically (e.g. history of surgery, infection, trauma, monocular contact lens use, etc.) and its presentation is influenced by conditions that, among others, include corneal anesthesia, a potentially devastating problem that could lead to corneal scars, erosions, and even blindness.
- If only one eye were tested, it may be the uninflamed eye whilst the inflamed eye is misdiagnosed. Moreover, bilateral testing will clarify when only unilateral treatment is needed, in order to avoid bilateral multi-drug corticosteroid treatment or bilateral punctal occlusion.
- I propose First Coast allow at least eight tests per year and two tests on the same date of service. Dry eye is a dynamic multifactorial condition and therapeutic decisions are based on presence or absence of inflammation, including transitioning to maintenance anti-inflammatory treatment, modifying treatment from monotherapy to multi-drug therapy, or timing the decision to proceed with punctal occlusion.
- Instead of limiting the test to once in a lifetime, recommendation was received to add a limitation such as:

  After the initial diagnosis is made, which may require bilateral testing up to 3 times during the first year, First Coast expects MMP-9 test is not clinically useful when provided for continued eye disease more often than two tests per visit or more often than 4 tests in 12 months for symptomatic patients or patients tested prior to surgical intervention.

Contractor response: Thank you for your comment. The language in the "Utilization Guidelines" section will be revised to clarify that bilateral testing may be allowed and to allow limited additional follow-up testing to assess effects of therapy.

Comment #7: The term "comprehensive" in the proposed LCD suggests a 99215 or 99204 level E&M service may be required to qualify for a MMP-9 test. I recommend First Coast not require a specific level of E&M service in order to allow for a MMP-9 test.

Questionnaires are available to help practitioners more easily evaluate suspected DED. Patients who are known to have Sjögren's syndrome (SS) or Meibomian gland dysfunction (MGD) are more likely to have moderate or severe DED. Accordingly, a 99203 or 99213 level of service may provide sufficient information in order for the practitioner to accurately diagnose moderate DED to warrant a MMP-9 when needed.

Recommend changing the language as follows:

> *The MMP-9 test is considered reasonable and necessary to aid in the diagnosis of dry eye for patients who present with symptoms suggestive of dry eye identified by a sufficiently detailed history eye exam relevant to dry eye*

Contractor response: The contractor acknowledges that there are several dry eye questionnaires that have been statistically validated as effective instruments to screen for dry eyes and will incorporate language to the LCD recognizing their usefulness. Regarding the statement that MMP-9 test is reasonable and necessary when performed on patients who present with symptoms suggestive of dry eye identified by a comprehensive eye exam relevant to dry eye and detailed personal history. This statement is not suggesting a particular level of E&M. The level of E&M is based on the level of documentation of the history, the physical exam and the medical decision making. Without the documentation of the medical decision making, a level of E&M cannot be determined. Therefore, no changes will be made to the current language.

Comment #8: In order to address inappropriate preventive use of MMP-9 testing, a recommendation was received to point out that the test is not a benefit for a preventive or screening purpose. For example, restatement of a general rule:

> *MMP-9 test is not a benefit of Medicare unless the patient has signs or symptoms of DED. Use of a MMP-9 test for screening purposes is not covered.*

Contractor response: Thank you for your comment and suggestion. The LCD will be revised to include language clarifying, that "tests that are performed in the absence of signs, symptoms, complaints, personal history of disease, or injury are not covered by Medicare except when there is a statutory provision that explicitly covers tests for screening as described in the manual."

Comment #9: MMP-9 testing in symptomatic dry eye before cataract or refractive surgery is both medically necessary and reasonable as untreated dry eye would negatively affect the quality of preoperative measurements such as keratometry, biometry, and aberrometry. This can lead to lens power mistakes, up to 1-2 diopters of induced cylinder and errors in axis position.

Contractor response: Thank you for your comment. Testing for MMP-9 protein in human tears from patients suspected of having dry eye is considered medically reasonable and necessary to aid in the diagnosis of dry eye, in conjunction with other methods of clinical evaluation when performed on patients who present with symptoms suggestive of dry eye identified by a comprehensive eye exam relevant to dry eye and detailed personal history.

Comment #10: The code descriptor of 83516 is not specific to eye diseases. The code for MMP-9 properly may be reported for tests related to various conditions other than the eye. Therefore, a frequency limit is problematic. I propose First Coast allow at least two immunoassay analysis tests per year for other conditions when a beneficiary also requires MMP-9 tests for the eye.

Contractor response: Thank you for your comment. The intention of this policy is to provide the reasonable and necessary criteria for the diagnostic evaluation and medical management of DED, including when MMP-9 is used as a diagnostic test for DED. First Coast is aware the code descriptor for *CPT*® code 83516 is not specific to eye diseases. Therefore, *CPT*® code 83516 is not associated with a list of ICD-10 Codes that support medical necessity. Documentation should support the criteria outlined in the LCD. When services are performed in excess of established parameters, they may be subject to review for medical necessity.