Local Coverage Determination (LCD): Diagnostic Evaluation and Medical Management of Moderate- Severe Dry Eye Disease (DED) (L36232)

Contractor Information

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<tr>
<th>Contractor Name</th>
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LCD Information

Document Information

**LCD ID**
L36232

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

**Proposed LCD in Comment Period**
N/A

**Source Proposed LCD**
DL36232

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11/22/15

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Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:

CMS Online Manual System, Pub 100-02, Medicare Benefit Policy Manual, Chapter 15-Covered Medical and Other Health Services, section 30.4 - Optometrist's Services

CMS Online Manual System, Pub 100-08, Medicare Program Integrity Manual, Chapter 13-Local Coverage Determinations, section 13.5.1 - Reasonable and Necessary Provisions in LCDs

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Background

Dry eye disease (DED) is divided into two groups: 1) aqueous-deficient, and 2) evaporative. Dry eye is a common and often chronic and progressive problem, particularly in older adults, but not exclusively associated with age.

Dry eye (also known as dry eye syndrome (DES), dysfunctional tear syndrome (DTS), keratoconjunctivitis sicca, xerophthalmia, xerosis, or sicca syndrome) is a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability with potential damage to the ocular surface. It is often accompanied by increased osmolarity of the tear film and inflammation of the ocular surface. DED can occur alone or in conjunction with inflammatory disorders or immunologic disorders such as rheumatoid arthritis, systemic lupus erythematosus, Sjogren's syndrome and other diagnosed or suspected disorders such as celiac disease or vitamin deficiency. It is a frequent side effect manifestation of certain pharmaceuticals and allergies. DED can also result from mechanical issues such as exposure keratopathy, nodular keratopathy or postsurgical changes. Additionally, there are systemic disorders such as hormonal changes that may cause dry eyes.

DED is commonly (but not always) associated with symptoms which include: dryness, redness, burning, reflex tearing, itching, foreign body sensation, grittiness, stinging, soreness, photophobia, and pain. In cases of corneal neuropathy resulting from DED, symptoms may be lessened or missing. In some severe cases, the ocular discomfort becomes marked and visual acuity may be reduced or distorted with resulting limitations in activities of daily living. Exacerbating factors such as systemic medications that decrease tear production (e.g., diuretics, antihistamines, and anticholinergics), topical medications, contact lens wear or environmental conditions that increase tear evaporation may lead to an acute increase in the severity of symptoms.
Elimination of such factors often leads to marked improvement.

Diagnostic testing

The initial evaluation of a patient who presents with a history or symptoms suggestive of DED should include those features of the eye exam relevant to dry eye, as well as evaluating patient history to determine the presence of any general health problems, medications taken, or environmental factors that may be contributing to the dry eye problem. Ocular surface diseases, systemic or local inflammatory diseases, or surgeries that produce symptoms similar to those associated with dry eye should be identified. Corneal sensation should also be assessed when neuropathy is suspected.

There are several dry eye questionnaires that assess patient symptoms. Many have been statistically validated as effective instruments to screen for dry eyes. The Ocular Surface Disease Index (OSDI), the Standard Patient Evaluation of Eye Dryness (SPEED) and the 5-Item Dry Eye Questionnaire (DEQ-5) questionnaires are valid and reliable instruments for measuring the severity of dry eye disease. The OSDI analyzes patient responses across three different subscales: vision-related function, ocular symptoms, and environmental triggers. The OSDI has good to excellent reliability, validity, sensitivity, and specificity for the overall questionnaire and each subscale. The OSDI is effective in discriminating between normal, mild to moderate, and severe DED as defined by both physician's assessment and a composite disease severity score. The DEQ-5, the sum of scores for frequency and intensity of dryness late in the day and discomfort plus frequency of watery eyes, effectively discriminated across self-assessed severity ratings and between patients with dry eye diagnoses. The SPEED questionnaire was shown to be a repeatable and valid instrument for measurement of dry eye symptoms. The SPEED score also correlated significantly with ocular surface staining and clinical measures of meibomian gland function. Along with other clinical and subjective measures of DED, these questionnaires provide a quantifiable assessment of dry eye symptom frequency and the impact of these symptoms on vision-related functioning.

There are several commonly used objective tests for documenting and assessing the severity of DED including: (1) the Schirmer test, (2) vital dye staining of the ocular surface (e.g., fluorescein, Rose Bengal, lissamine green), (3) tear film break-up time (TFBUT), (4) slit lamp evaluation with particular attention to conjunctiva and cornea, (5) tear meniscus height, and (6) assessment of eyelid and meibomian glands. All are usually performed by ophthalmologists or optometrists in an office setting and are part of the evaluation and management of DED.

- Tear production may be measured by the Schirmer test by inserting a small piece of filter paper in the lateral third of the lower eyelid and measuring the extent of wetting in a prescribed amount of time (typically 5 minutes) either with or without topical anesthesia. Findings are typically similar in both eyes.
- Damage to the conjunctiva and corneal epithelial cells may be assessed by ocular surface staining with several dyes (e.g. Rose Bengal, lissamine green, or fluorescein dyes), demonstrating areas of injury when viewed with appropriate light source under the slit lamp biomicroscope.
- TFBUT provides a global assessment of the function of the lacrimal functional unit on the ocular surface. The test is performed by measuring breakup time after instillation of fluorescein. Break-up times less than 10 seconds are considered abnormal.
- Tear meniscus height is typically 1.0 mm or greater and less than that height is considered abnormal.
- Slit lamp evaluation allows for an assessment of the conjunctiva, eyelids and cornea.

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.).

When used in conjunction with other methods of clinical evaluation, measuring the osmolarity of human tears has been shown to aid in the diagnosis of DED in patients suspected of having DED. A commercial device has become available for clinicians use. Several studies using this device have demonstrated an increase in tear osmolarity in patients with aqueous tear deficiency or evaporative dry eye and it has been approved by the Food and Drug Administration (FDA) for the use as a point-of-care laboratory test to diagnose dry eye.

Similar projections have been made for the qualitative measurement of multiple analytes, including MMP-9/Gelatinase B (e.g., InflammaDry®) and associated enzymes or markers of systemic disease processes (rheumatoid arthritis, celiac disease, vitamin deficiencies). MMP-9, an important metalloproteinase associated with ocular surface disease, is a proteolytic enzyme produced by stressed epithelial cells on the ocular surface in dry eye disease. Elevated MMP-9 levels are highly correlated with clinical exam findings in patients with mild to severe DED. Patients who have elevated MMP-9 in their tears are more likely to respond to anti-inflammatory therapy such as cyclosporine. Patients without elevated MMP-9 are much more likely to benefit from supportive management with artificial tears or punctal occlusion. The MMP-9 test is considered reasonable
Management

Treatments for dry eyes aim to restore or maintain the normal quantity and quality of tears in the eye to minimize dryness and related causative factors that are amenable to treatment. Tear replacement is frequently unsuccessful when used as the sole treatment if additional causative factors are not concomitantly addressed. Specific treatment recommendations depend on severity and cause. The sequence and combination of therapies should be determined on the basis of the patient’s needs and the treating ophthalmologist’s or optometrist’s medical judgment.

The American Academy of Ophthalmology (AAO) recommends the following conservative interventions for dry-eye disease:

- Elimination of exacerbating medications where feasible
- Ocular environmental interventions (computer work site interventions, household allergens exposure)
- Aqueous tear enhancement with topical agents or external means
- Treatment of contributing ocular factors (e.g. blepharitis or meibomianitis)
- Correction of identified lid abnormality
- Medications (anti-inflammatory agents [e.g. topical cyclosporine and corticosteroids] and systemic omega-3 fatty acids)

Cyclosporine ophthalmic emulsion has been approved by the FDA to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Cyclosporine emulsion is thought to act as a partial immunomodulator.

When medical therapy is not effective or contraindicated, punctal occlusion may be accomplished by inserting lacrimal punctal plugs into the punctal orifice to decrease tear clearance and increase retention of the tear film by blocking the outflow of tears to the nasolacrimal system.

The diagnostic occlusion of lacrimal puncta by collagen plugs (temporary/dissolvable within 1-2 weeks) is generally used to predetermine if there is any epiphora or excessive moisture with occlusion and as a limited trial as to whether increasing the retention of the tear film reduces the patient’s dry eye symptoms and, subsequently, whether a longer duration temporary/dissolvable (4-6 months) or more permanent punctal occlusion may benefit the patient. These collagen plugs dissolve within one to two weeks. If a trial of temporary punctal occlusion proves successful, semi-permanent/non-dissolvable or slowly dissolvable occlusion is usually considered. Silicone or thermal labile polymer plugs (semi-permanent/non-dissolvable) or collagen plugs that dissolve over an extended time (4-6 months) period are therapeutic and are generally considered useful after the diagnostic occlusion has been performed. After the silicone plugs are inserted, the patient intermittently returns to the physician to insure the integrity of the plugs and to determine if additional measures are necessary given the progressive nature of the disease.

While the choice of initially using collagen (temporary/dissolvable) or silicone (semi-permanent/non-dissolvable) is left to the clinician’s discretion, the semi-permanent plugs afford a trial of punctal closure, and may better serve to delineate candidates for permanent closure (e.g., via thermal cautery). Long term (greater than 90 days), slowly dissolvable punctal plugs may be an appropriate treatment for patients for whom silicone punctal plugs are contraindicated. Serial application of temporary plugs serves no useful clinical purpose.

Punctal occlusion and/or tarsorrhaphy (to reduce the evaporative surface area of the ocular surface) are indicated in cases of DED that are refractory to conservative management. Surgical punctal occlusion (occlusive punctoplasty) may be achieved by cautery, electrodesiccation, simple excision, or argon laser surgery. In its position statement, the AAO affirmed its earlier conclusion that the preferred surgical methods of permanent punctal occlusion are electrodesiccation or thermal cautery, and that laser punctal occlusion should be discouraged because it is less effective and more expensive than other methods.

Indications

Note: It is not the intent of this LCD to endorse any product or manufacturer. Alternative products may be equally therapeutic and will be considered such upon FDA approval.

The evaluation of DED does not depend on a single clinical sign, or symptoms alone, or the patient’s medical history, but a combination of all of these elements. Frequently mild DED cannot be differentiated from normal
patients. More often is the case; only moderate to severe DED can be distinguished from mild DED or normal patients. The treatment of moderate to severe DED depends on the severity of the disease, and not exclusively on symptoms.

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, for the following:

- Tear testing for immunoassay analysis (MMP-9) performed on patients who present with symptoms suggestive of DED identified by a comprehensive eye exam relevant to dry eye and detailed personal history. The test results are used as a predictive marker (identifies a patient likely to respond to a given therapy).

Testing of tear osmolarity in patients with a clinical diagnosis of dry eye as determined in conjunction with other methods of diagnostic testing (e.g., Schirmer test, vital dye staining of the ocular surface, TFBUT, slit lamp evaluation with particular attention to conjunctiva and cornea, tear meniscus height, and assessment of eyelid and meibomian glands) is considered medically reasonable and necessary to aid in the diagnosis of moderate to severe DED. Tear osmolarity also aids in the assessment of disease severity as well as monitoring the effectiveness of therapy by a reduction or stabilization of hyperosmolarity. Tear osmolarity test results can be altered by a number of external factors if performed prior to test such as prior eye drop usage, punctal occlusion, and ophthalmic diagnostic exams (e.g., tonometry, slit lamp examination, ocular surface staining, etc.). These factors should be eliminated prior to testing. When tear osmolarity testing is performed on an initial visit prior to any ocular surface altering tests (e.g., Schirmer test, vital dye staining, TFBUT, etc.), it would be considered reasonable and necessary when there is a high clinical suspicion of moderate to severe dry eye disease as suggested by an OSDI score of 18, a SPEED test score of 12 or a DEQ-5 test score of >6.

Lacrimal punctal plugs are considered medically reasonable and necessary for patients with the following:

- Symptomatic moderate or severe dry eyes that are not adequately treated by conservative interventions including a 2 or more week trial of artificial tears, ophthalmic cyclosporine where indicated, and adjustment to medications that may contribute to dry eye syndrome; and

- A diagnosis of aqueous tear deficiency confirmed by:

  One or more of the following diagnostic tests: tear break-up time (TBUT), Schirmer test, ocular surface dye staining pattern (Rose Bengal, fluorescein, or lissamine green); and

Slit-lamp biomicroscopic exam.

Punctoplasty by electrodessication or electrocautery is considered medically necessary for patients with the following:

- Symptomatic moderate or severe dry eyes that are not adequately treated by conservative interventions including a 2 or more week trial of artificial tears, ophthalmic cyclosporine where indicated, and adjustment to medications that may contribute to dry eye syndrome; and

- A diagnosis of aqueous tear deficiency confirmed by:

  One or more of the following diagnostic tests: tear break-up time (TBUT), Schirmer test, ocular surface dye staining pattern (Rose Bengal, sodium fluorescein, or lissamine green); and

Slit-lamp biomicroscopic exam

- A trial occlusion with nonpermanent punctal plugs should be considered first to screen for the potential development of epiphora (excessive tearing).

**Limitations**

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.).
Testing of DED performed in the absence of signs, symptoms, complaints, personal history of disease, or injury is not covered by Medicare.

Tear film imaging (e.g., the Tear Stability Analysis System) for evaluation of dry eyes or any other indications is considered not medically reasonable and necessary because its effectiveness has not been established.

Autologous serum tears for the treatment of dry eyes are considered not medically reasonable and necessary because its effectiveness has not been established.

The test results must be used for individual patient treatment decisions—as a predictive marker. Therefore, if individual therapy is not addressed the test is not covered.

The repeated use of temporary short-term (collagen) plugs for DED therapy has no proven value and is considered not reasonable and necessary.

Punctal occlusion procedures are considered not medically reasonable and necessary for the treatment of contact lens intolerance.

The use of the laser to occlude the tear duct opening is considered not medically reasonable and necessary because it has not been proven to be as effective as electrodessication or thermal cautery.

**Coding Information**

**Bill Type Codes:**

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

- 012x Hospital Inpatient (Medicare Part B only)
- 013x Hospital Outpatient
- 083x Ambulatory Surgery Center

**Revenue Codes:**

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

- 049X Ambulatory Surgical Care - General Classification
- 050X Outpatient Services - General Classification

**CPT/HCPCS Codes**

**Group 1 Paragraph:** N/A

**Group 1 Codes:**

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<tr>
<td>68760</td>
<td>CLOSURE OF THE LACRIMAL PUNCTUM; BY THERMOCAUTERIZATION, LIGATION, OR LASER SURGERY</td>
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<td>68761</td>
<td>CLOSURE OF THE LACRIMAL PUNCTUM; BY PLUG, EACH</td>
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<td>83516</td>
<td>IMMUNOASSAY FOR ANALYTE OTHER THAN INFECTIOUS AGENT ANTIBODY OR INFECTIOUS AGENT ANTIGEN; QUALITATIVE OR SEMIQUANTITATIVE, MULTIPLE STEP METHOD</td>
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<td>83861</td>
<td>MICROFLUIDIC ANALYSIS UTILIZING AN INTEGRATED COLLECTION AND ANALYSIS DEVICE, TEAR OSMOLARITY</td>
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**Group 2 Paragraph:** The following CPT codes are non-covered when used for the evaluation and treatment of dry eyes/Sicca Syndrome.
ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:
The following ICD-10 codes apply to 68760, 68761, and 83861.

<table>
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<tr>
<th>ICD-10 Code</th>
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<td>H04.121 - H04.129</td>
<td>Dry eye syndrome of right lacrimal gland - Dry eye syndrome of unspecified lacrimal gland</td>
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<tr>
<td>H11.141 - H11.149</td>
<td>Conjunctival xerosis, unspecified, right eye - Conjunctival xerosis, unspecified, unspecified eye</td>
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<td>H16.221 - H16.229</td>
<td>Keratoconjunctivitis sicca, not specified as Sjogren's, right eye - Keratoconjunctivitis sicca, not specified as Sjogren's, unspecified eye</td>
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<td>H57.10 - H57.13</td>
<td>Ocular pain, unspecified eye - Ocular pain, bilateral</td>
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<td>M35.00</td>
<td>Sicca syndrome, unspecified</td>
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<td>M35.01</td>
<td>Sicca syndrome with keratoconjunctivitis</td>
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<td>M35.02</td>
<td>Sicca syndrome with lung involvement</td>
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<td>M35.03</td>
<td>Sicca syndrome with myopathy</td>
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<tr>
<td>M35.04</td>
<td>Sicca syndrome with tubulo-interstitial nephropathy</td>
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<td>M35.09</td>
<td>Sicca syndrome with other organ involvement</td>
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ICD-10 Codes that DO NOT Support Medical Necessity

Additional ICD-10 Information
N/A

General Information

Associated Information

Documentation Requirements

Medical record documentation of an eye examination and treatment for DED should include patient’s medical history, pertinent elements of the eye exam, associated diagnostic tests, diagnosis and/or impression, and treatment plan. The documentation must support the patient’s complaints normally associated with DED (e.g., dryness, redness, burning, reflex tearing, itching, foreign body sensation, grittiness, stinging, soreness, photophobia and pain) and the results of physical examination, including external examination and slit-lamp biomicroscopic exam (i.e. eyelids, conjunctiva, cornea, and tear meniscus height) and one or more of the following diagnostic tests: tear film break-up time test (TFBUT), Schirmer test, ocular surface dye staining pattern (Rose Bengal, fluorescein, or lissamine green), tear osmolarity.

For tear osmolarity testing performed on an initial visit prior to any ocular surface altering tests (eg, Schirmer test, vital dye staining, TFBUT, etc.) it would be expected the documentation of a composite disease severity score indicative of moderate to severe dry eye disease as suggested by an OSDI score of 18, a SPEED test score of 12 or a DEQ-5 test score of >6.

For lacrimal punctal plugs and punctoplasty, evidence of a trial period of artificial tears that proved unsuccessful in relieving the patient’s symptoms, preceding the decision to place the lacrimal punctal plugs or perform permanent punctal occlusion must be documented.

When applicable, documentation must include an operative or procedure report with description of medical
indications, anesthesia, surgical technique, affected anatomy, implanted device(s), and complications.

Documentation on follow-up visits after placement of the collagen or silicone plugs must indicate the status of the patient’s symptoms.

All documentation must be maintained in the patient’s medical record and made available to the contractor upon request.

An advanced beneficiary notice (ABN) is required for any items or services that do not meet the threshold for a reasonable and necessary (R&N) service under Medicare. Beneficiaries should be thoroughly educated about the benefits and risks of this item or service, in addition to the financial liability. Modifier GA must be used when physicians, practitioners, or suppliers want to indicate that they expect that Medicare will deny a service as not reasonable and necessary and they do have on file an ABN signed by the beneficiary. If such notice is not given, providers may not shift financial liability for such items or services to beneficiaries after a service is denied for R&N by Medicare. The ABN must be available to the contractor when requested.

**Utilization Guidelines**

It is expected that these services would be performed as indicated by current medical literature and/or standards of practice. When services are performed in excess of established parameters, they may be subject to review for medical necessity.

For tear testing immunoassay analysis (MMP-9) only a single (bilateral-2units) diagnostic test will be allowed per eye that may require one additional follow-up test (bilateral-2units) within 6 months to assess the effectiveness of therapy. Repeating tear testing for immunoassay analysis (MMP-9) after a second test is not reasonable or medically necessary for one year from baseline and then only if changes in the signs and symptoms support the testing.

Tear osmolarity testing is initially useful to diagnose and assess moderate to severe DED. The higher the osmolarity, the more severe the dry eye is considered to be. Osmolarity values above 308 mOsm/L are indicative of dry eye disease. When the baseline test (bilateral-2units) is indicative of moderate to severe DED (e.g. osmolarity = 312 mOsm), it would be considered reasonable and necessary to repeat tear osmolarity testing (bilateral-2units) for assessment of the effectiveness of the therapeutic intervention, after a 6-week trial of therapy. Repeating the tear osmolarity test a second time (bilateral-2units) to determine stability of treatment is reasonable and medically necessary after 3 months or more of therapy to confirm the effectiveness of the therapeutic intervention. Further testing is not reasonable or medically necessary. Testing after the treatment series can be considered in one year if significant signs and symptoms support the testing.

Repeating tear osmolarity testing after an initial test result of <308 mOsm/L (normal) is not reasonable or medically necessary for one year from baseline and then only if changes in the signs and symptoms support the testing.

Repititive use of short-term or quick-dissolving (1-2 weeks) temporary lacrimal punctal plugs for treatment of dry eye disease would not be expected.

Replacement of silicone punctal plugs or other long-lasting plugs (4-6 months) is generally not medically necessary more frequently than every 6 months unless they spontaneously and/or inadvertently come out. In this case a single replacement will be allowed. If punctal plugs do not stay in place because of anatomical reasons, other forms of punctal occlusion should be considered.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare.

**Sources of Information and Basis for Decision**


Corcoran, K. Find the proper documentation requirements and reimbursement potential for diagnosing and treating dry eye syndrome. *Optometric Management.* (2005); Retrieved on April 5, 2007 from www.optometric.com (71542).


Rao SN. Topical cyclosporine 0.05% for the prevention of dry eye disease progression. *J Ocul Pharmacol Ther.* (2010); 26(2):157-64.

Roberts CW, Carniglia PE, Brazzo BG, Comparison of topical cyclosporine, punctal occlusion, and a combination


Stonecipher, K, Donnenfeld, E., and McDonald, M., Diagnosis and Treatment of Dry Eye Disease and Ocular Allergy. *Advanced Ocular Care.* (2012); 1-16.


### Revision History Information

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<th>Revision History Number</th>
<th>Revision History Explanation</th>
<th>Reason(s) for Change</th>
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<tr>
<td>11/22/2015</td>
<td>R1</td>
<td>Revision Number: Original Publication: October 2015 Connection LCR A/B 2015-012 This is a new LCD released for 45 day notice, corrections were made to this LCD 10/2/2015.</td>
<td>• Provider Education/Guidance</td>
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### Associated Documents

**Attachments**

N/A

**Related Local Coverage Documents**

**Article(s)**

A54680 - Diagnostic Evaluation and Medical Management of Moderate-Severe Dry Eye Disease (DED) - coding guidelines

A55805 - Response to Comments: Diagnostic Evaluation and Medical Management of Moderate-Severe Dry Eye
Disease (DED) LCD(s)
DL36232 - (MCD Archive Site)

**Related National Coverage Documents**
N/A

**Keywords**
N/A