Local Coverage Determination (LCD): Amniotic Membrane- Sutureless Placement on the Ocular Surface (L36237)

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Contractor Information

<table>
<thead>
<tr>
<th>Contractor Name</th>
<th>Contract Type</th>
<th>Contract Number</th>
<th>Jurisdiction(s)</th>
<th>State(s)</th>
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<td>First Coast Service Options, Inc.</td>
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LCD Information

Document Information

- LCD ID: L36237
- Original Effective Date: For services performed on or after 10/01/2015
- Revision Effective Date: For services performed on or after 10/13/2016
- Revision Ending Date: N/A
- Retirement Date: N/A
- Notice Period Start Date: N/A
- Notice Period End Date: N/A

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CMS National Coverage Policy Language quoted from CMS National Coverage Determination (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

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

CMS National Coverage Policy Title XVIII of the Social Security Act (SSA), §1862(a)(1)(A), states that no Medicare payment shall be made for items or services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Title XVIII of the Social Security Act, §1833(e). Prohibits Medicare payment for any claim lacking the necessary documentation to process the claim

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

Human amniotic membrane is a unique collagenous membrane derived from the innermost submucosa of the placenta. It consists of a collagen-rich thick basement membrane and an avascular stroma. Amniotic tissue has been used in a variety of surgical procedures to cover a defect on the surface of the eye and facilitate wound healing as well as decreasing inflammation. Some defects are created by the surgical excision of lesions or necrotic tissue while others result from injury, infection or degeneration. The usefulness of amniotic membrane has been attributed to its anti-inflammatory, anti-fibrotic, anti-vascularization, and anti-scarring effects and also to its ability to enhance epithelial healing.

Amnion can be prepared for implantation a number of ways. Heat- or air-dried amniotic membrane loses some of its biologic properties and is not ideal for ocular surface rehabilitation. The tissue can be lyophilized (freeze-dried), which induces minimal change in its properties. Amnion can be preserved in cold glycerol and cryopreserved and stored frozen at -80 degrees. The cryopreservation method allows for greater retention of the membrane’s structural, physiological and biochemical properties responsible for its dramatic healing and easier handling intraoperatively.

This LCD addresses limited indications of the sutureless form of amniotic membrane used as a biological corneal bandage.

Amniotic membrane transplant for ocular conditions will be considered medically reasonable and necessary for the following indications:

- Failure of standard therapy for severe ophthalmological conditions demonstrated by ocular surface cell damage or failure and/or underlying inflammation, scarring, or ulceration of the underlying stroma.
- There may be circumstances where there is a severe condition requiring acute treatment with amniotic membrane such as chemical, thermal or radiation injuries, or Stevens Johnson Syndrome, or limbal stem cell failure.
- Band keratopathy after treatment with other therapy such as surgery, topical medications, bandage contact lens, or patching.
- Bullous keratopathy associated with an epithelial defect.
• Scleral melting.
• Corneal ulcer following initiation of anti-infective therapy and demonstration of clinical response for the purpose of healing the persistent epithelial defect.
• Chemical burns of the ocular surface.
• Conjunctival defects after treatment with other therapy such as surgery or topical medications.
• Corneal melting.
• Limbal Stem Cell Deficiency.
• Recurrent Corneal Erosions after treatment failure with other therapy such as bandage contact lens, patching, and topical medications.

**LIMITATIONS:**

• Amniotic membrane must be cleared by, or registered with, the U.S. Food and Drug Administration (FDA) for sutureless application of the eye.
• Application for dry eye syndrome is noncovered, given no demonstrated impact on long term outcome.
• Cogan’s Dystrophy is noncovered unless associated with corneal epithelial removal.

**Following Surgery / Within Global Period:** Use of amniotic membrane within the postoperative period of a prior surgery, not requiring a return to the operating room, and not pre-planned, is subject to the principles for global surgery defined in Medicare Claims Processing Manual, Chapter 12, §40, and will not be reimbursed separately.

**Notice:** This LCD imposes diagnosis limitations that support diagnosis to procedure code automated denials. However, services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

As published in CMS IOM 100-08, Section 13.5.1, in order to be covered under Medicare, a service shall be reasonable and necessary. When appropriate, contractors shall describe the circumstances under which the proposed LCD for the service is considered reasonable and necessary under Section 1862(a)(1)(A). **Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:**

• Safe and effective;
• Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, that meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
• Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
  
  o Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition or to improve the function of a malformed body member;
  o Furnished in a setting appropriate to the patient's medical needs and condition;
  o Ordered and furnished by qualified personnel;
  o One that meets, but does not exceed, the patient's medical needs; and
  o At least as beneficial as an existing and available medically appropriate alternative.

**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.
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.

CPT/HCPCS Codes

**Group 1 Paragraph:** N/A

**Group 1 Codes:**
65778 PLACEMENT OF AMNIOTIC MEMBRANE ON THE OCULAR SURFACE; WITHOUT SUTURES

ICD-10 Codes that Support Medical Necessity

**Group 1 Paragraph:** N/A

<table>
<thead>
<tr>
<th>ICD-10 Codes</th>
<th>Description</th>
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<tr>
<td>H04.131 -</td>
<td>Lacrimal cyst, right lacrimal gland - Lacrimal cyst, unspecified lacrimal gland</td>
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<td>H04.139</td>
<td></td>
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<tr>
<td>H15.89 - H15.9</td>
<td>Other disorders of sclera - Unspecified disorder of sclera</td>
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<tr>
<td>H16.001 -</td>
<td>Unspecified corneal ulcer, right eye - Perforated corneal ulcer, unspecified eye</td>
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<td>H16.079</td>
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<tr>
<td>H16.121 -</td>
<td>Filamentary keratitis, right eye - Filamentary keratitis, unspecified eye</td>
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<td>H16.129</td>
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<td>H16.231 -</td>
<td>Neurotrophic keratoconjunctivitis, right eye - Neurotrophic keratoconjunctivitis, unspecified eye</td>
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<td>H16.239</td>
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<td>H18.10 - H18.13</td>
<td>Bulous keratopathy, unspecified eye - Bulous keratopathy, bilateral</td>
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<td>H18.421 -</td>
<td>Band keratopathy, right eye - Band keratopathy, unspecified eye</td>
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<td>H18.831 -</td>
<td>Recurrent erosion of cornea, right eye - Recurrent erosion of cornea, unspecified eye</td>
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<td>H18.839</td>
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<td>H18.891 -</td>
<td>Other specified disorders of cornea, right eye - Other specified disorders of cornea, unspecified eye</td>
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<tr>
<td>L51.0</td>
<td>Nonbullous erythema multiforme</td>
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<td>L51.1</td>
<td>Stevens-Johnson syndrome</td>
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<td>L51.3</td>
<td>Stevens-Johnson syndrome-toxic epidermal necrolysis overlap syndrome</td>
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<td>L51.9</td>
<td>Erythema multiforme, unspecified</td>
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<td>T26.00XA -</td>
<td>Burn of unspecified eyelid and periocular area, initial encounter - Corrosion of left eye and adnexa, part unspecified, sequela</td>
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<td>T26.92XS</td>
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ICD-10 Codes that DO NOT Support Medical Necessity N/A

**ICD-10 Additional Information** Back to Top

**General Information**

Associated Information

**Documentation Requirements**

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Medical record documentation (e.g., office/progress notes, history and physical, procedure notes) must indicate
the medical necessity for performing this service. When the documentation does not meet the criteria for the
service rendered or the documentation does not establish the medical necessity for the services, such services
will be denied as not reasonable and necessary.

The procedure indicated in this LCD will be considered medically reasonable and necessary only when furnished
by a qualified optometrist or ophthalmologist.

*Effective April 1, 1987, a doctor of optometry is considered a physician with respect to all services the
optometrist is authorized to perform under State law or regulation. To be covered under Medicare, the services
must be medically reasonable and necessary for the diagnosis or treatment of illness or injury, and must meet all
applicable coverage requirements.*

**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.

One placement per eye is expected in an episode of care. More than one will be subject to prepayment review
and possible denial.

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**

- Aetna Clinical Policy Bulletin: Corneal Graft with Amniotic Membrane Transplantation or Limbal Stem Cell
  Transplantation, number 0293. Available at: http://www.aetna.com/cpb/medical/data/200_299/0293.html (Last

- AmeriHealth Caritas; Clinical Policy Title: Therapeutic Contact Lenses; Clinical Policy Number: 10.02.01. Available
  at: https://www.amerihealthnortheast.com/pdf/provider/resources/clinical/policies/therapeutic-contact-lenses.pdf

  Bacterial Keratitis; American Academy of Ophthalmology; 2013. Available at: http://one.aao.org/preferred-

  Corneal Edema and Opacification; American Academy of Ophthalmology; 2013. Available at:
  http://one.aao.org/preferred-practice-pattern/corneal-edema-opacification-ppp 2013 (Last accessed January 23,
  2015).

  Eye Syndrome. San; American Academy of Ophthalmology; 2013. Available at: http://one.aao.org/preferred-

- BlueCross BlueShield of Kansas City; Policy: Amniotic Membrane Transplantation 2006. Available at:
  http://medicalpolicy.bluekc.com/MedPolicyLibrary/Surgery/Standard%20Surgery/02-14_7_Amniotic_Membrane-

- Cigna Healthcare Coverage Position: Amniotic Membrane Transplant for the Treatment of Ocular, coverage


- Jeng, B. Treating the Nonhealing Epithelial Defect. Cataract & Refractive Surgery Today Europe, Sept. 2011; 25-
  28.

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**Revision History Information**

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<th>Revision History Explanation</th>
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<td>10/13/2016</td>
<td>R2</td>
<td>Explanation of Revision: The LCD was revised under the “Limitations” section of the LCD to clarify language that amniotic membrane for suterless application of the eye must be cleared by, or registered with, the U.S. Food and Drug Administration (FDA). The effective date of this revision is based on date of service.</td>
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<td>04/06/2016</td>
<td>R1</td>
<td>Explanation of Revision: The LCD was revised to incorporate additional diagnosis code ranges per a reconsideration request. ICD-10-CM diagnosis code ranges H16.121 – H16.129 (Filamentary keratitis) and H16.231 – H16.239 (Neurotrophic keratoconjunctivitis) were added to the “ICD-10 Codes that Support Medical Necessity” section of the LCD. The effective date of this revision is based on date of service.</td>
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**Associated Documents**

Attachments [Coding guidelines effec 10/1/15 (PDF - 72 KB)]

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