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

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Contractor Information

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<th>CONTRACTOR NAME</th>
<th>CONTRACT TYPE</th>
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LCD Information

Document Information

**LCD ID**
L36237

**LCD Title**
Amniotic Membrane- Sutureless Placement on the Ocular Surface

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

**Source Proposed LCD**
N/A

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CMS National Coverage Policy

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for Amniotic Membrane-Sutureless Placement on the Ocular Surface Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for Amniotic Membrane-Sutureless Placement on the Ocular Surface and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site.

Internet Only Manual (IOM) Citations:

- CMS IOM Publication 100-02, Medicare Benefit Policy Manual,
  - Chapter 15, Section 30.4 Optometrist’s Services
- CMS IOM Publication 100-04, Medicare Claims Processing Manual,
  - Chapter 12, Section 40 Surgeons and Global Surgery
- CMS IOM Publication 100-08, Medicare Program Integrity Manual,
  - Chapter 13, Section 13.5.4 Reasonable and Necessary Provision in an LCD

Social Security Act (Title XVIII) Standard References:
Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.

Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.

Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.

Federal Register References:

N/A

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

History/Background and/or General Information

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.

Covered Indications

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.
- The procedure will be considered medically reasonable and necessary only when furnished by a qualified optometrist or ophthalmologist.
- One placement per eye is expected in an episode of care. More than one will be subject to prepayment review and possible denial.

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 and will not be reimbursed separately. Please refer to CMS IOM Publication 100-04, Medicare Claims Processing Manual, Chapter 12, Section 40 Surgeons and Global Surgery.

As published in the CMS IOM Publication 100-08, Medicare Program Integrity Manual, Chapter 13, Section 13.5.4, an item or service may be covered by a contractor LCD if it is reasonable and necessary under the Social Security Act Section 1862 (a)(1)(A). Contractors shall determine and describe the circumstances under which the item or service is considered reasonable and necessary.

Summary of Evidence

N/A

Analysis of Evidence
(Rationale for Determination)

N/A

General Information

Associated Information
Documentation Requirements

Please refer to the Local Coverage Article: Billing and Coding: Amniotic Membrane-Sutureless Placement on the Ocular Surface (A57679) for documentation requirements that apply to the reasonable and necessary provisions outlined in this LCD.

Utilization Guidelines

Please refer to the Local Coverage Article: Billing and Coding: Amniotic Membrane-Sutureless Placement on the Ocular Surface (A57679) for utilization guidelines that apply to the reasonable and necessary provisions outlined in this LCD.

Sources of Information

1. Aetna Clinical Policy Bulletin: Corneal Graft with Amniotic Membrane Transplantation or Limbal Stem Cell Transplantation, number 0293.
2. AmeriHealth Caritas; Clinical Policy Title: Therapeutic Contact Lenses; Clinical Policy Number: 10.02.01.

Bibliography

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## Revision History Information

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<th>REVISION HISTORY DATE</th>
<th>REVISION HISTORY NUMBER</th>
<th>REVISION HISTORY EXPLANATION</th>
<th>REASON(S) FOR CHANGE</th>
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| 01/08/2019            | R3                      | Revision Number: 3  
Publication: November 2019 Connection  
LCR A/B2019-075 | • Other (Revision based on CR 10901) |
|                       |                         | Explanation of Revision: Based on Change Request (CR)  
10901, the LCD was revised to remove all billing and coding and all language not related to reasonable and necessary provisions (“Bill Type Codes,” “Revenue Codes,” “CPT/HCPCS Codes,” “ICD-10 Codes that Support Medical Necessity,”  
“Documentation Requirements” and “Utilization Guidelines” sections of the LCD) and place them into a newly created billing and coding article. During the process of moving the ICD-10-CM diagnosis codes to the billing and coding article, the ICD-10-CM diagnosis code ranges were broken out and listed individually. In addition, the Social Security Act and IOM reference sections were updated. The effective date of this revision is for claims processed on or after January 8, 2019, for dates of service on or after October 3, 2018.  
At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination and therefore not all the fields included on the LCD are applicable as noted in this LCD. | |
| 10/13/2016            | R2                      | Revision Number: 2  
Publication: October 2016 Connection  
LCR A/B2016-104 | • Provider Education/Guidance |
|                       |                         | 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. | |
| 04/06/2016            | R1                      | Revision Number: 1  
Publication: March 2016 Connection  
LCR A/B2016-056 | • Revisions Due To ICD-10-CM Code Changes |
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.

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Associated Documents

Attachments
N/A

Related Local Coverage Documents

Article(s)
A57679 - Billing and Coding: Amniotic Membrane- Sutureless Placement on the Ocular Surface

Related National Coverage Documents

N/A

Public Version(s)

Updated on 11/21/2019 with effective dates 01/08/2019 - N/A
Updated on 10/18/2016 with effective dates 10/13/2016 - 01/07/2019
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

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Keywords

N/A