Medical Policy: 
Amniotic Membrane Transplantation for Ocular Reconstruction (Commercial)

<table>
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<tr>
<th>POLICY NUMBER</th>
<th>LAST REVIEW DATE</th>
<th>APPROVED BY</th>
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<tr>
<td>MG.MM.SU.49C</td>
<td>04/10/2020</td>
<td>MPC (Medical Policy Committee)</td>
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**IMPORTANT NOTE ABOUT THIS MEDICAL POLICY:**

Property of ConnectiCare, Inc. All rights reserved. The treating physician or primary care provider must submit to ConnectiCare, Inc. the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, ConnectiCare will not be able to properly review the request for prior authorization. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. The clinical review criteria expressed below reflects how ConnectiCare determines whether certain services or supplies are medically necessary. ConnectiCare established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). ConnectiCare, Inc. expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. Each benefit plan defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by ConnectiCare, as some plans exclude coverage for services or supplies that ConnectiCare considers medically necessary. If there is a discrepancy between this guideline and a member's benefits plan, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of the State of CT and/or the Federal Government. Coverage may also differ for our Medicare members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including including National Coverage Determinations (NCD), Local Coverage Determinations (LCD) and/or Local Medical Review Policies (LMRP). All coding and web site links are accurate at time of publication.

**Definitions**

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<th><strong>Amniotic membrane transplantation (AMT)</strong></th>
<th>Consists of the permanent implantation of a human amniotic membrane product classified by the FDA as a Human Cell and Tissue-based Product (HCT/P) derived from Donated Human Tissue. It is intended for ocular wound repair and healing.</th>
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<td><strong>Corneal epithelial device (E.g., PROKERA®)</strong></td>
<td>Consists of a plastic ophthalmic conformer, which incorporates a cryopreserved amniotic membrane to retain the natural biological properties of the membrane. It is intended for use in eyes in which ocular surface cells have been damaged, or underlying stroma is inflamed or scarred. The device is temporarily overlaid on the ocular surface remaining in the eye for up to 30 days or until the surface has healed or the membrane has dissolved.</td>
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| Limbal deficiency | Hypofunction or total loss of stem cells |

Guideline
Members with limbal deficiency who are refractory to conventional treatment are eligible for coverage of AMT for ocular surface reconstruction as follows:

A. **Stem cell loss (total)** — in one eye secondary to any:
   a. Chemical / thermal ocular surface injuries
   b. Contact lens-induced keratopathy or toxic effects from lens-cleaning solutions
   c. Multiple surgeries or cryotherapies to limbal region
   d. Stevens-Johnson syndrome

B. **Stem cell hypofunction** — in one or both eyes secondary to any:
   a. Aniridia (hereditary)
   b. Bullous keratopathy
   c. Chronic limbitis
   d. Keratitis associated with multiple endocrine deficiency (hereditary)
   e. Neurotrophic keratopathy (neuronal or ischemic)
   f. Peripheral corneal ulcerative keratitis
   g. Pterygium and pseudopterygium

C. Conjunctival reconstruction/revision of scars and symblepharon
D. Corneal ulcers/thinning perforation/persistent corneal epithelial defect

Note: ConnectiCare considers corneal bandaging with PROKERA® to be a clinically appropriate step component within a step protocol prior to transplant. The bandage is indicated for conditions in which ocular surface cells have been damaged, or underlying stroma is inflamed and scarred. The preferred practice recommendation, according to the American Academy of Ophthalmology, is a step protocol beginning with topical agents, emulsions, gels/ointments with progression to systemic antiinflammatory medications (e.g., corticosteroids) as the severity of the dry eye increases.

Exclusions and Limitations:
The plan does not consider AMT or the use of corneal-epithelial devices to be medically necessary for the treatment of dry eye syndrome.

Amniotic membrane must be cleared by, or registered with, the U.S. Food and Drug Administration (FDA) for sutureless application of the eye (e.g., corneal bandage).

Applicable Coding
*To access the codes, please download the policy to your computer, and click on the paperclip icon within the policy*

| Applicable CPT and Diagnosis Codes |
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References


Specialty-matched clinical peer review.

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Revision history

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<tr>
<td>04/10/2020</td>
<td>• Added persistent corneal epithelial defect as a covered indication</td>
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<tr>
<td>03/09/2018</td>
<td>• added that the Prokera corneal bandage is covered</td>
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