UTILIZATION REVIEW CRITERIA

Corneal Graft w/ Amniotic Membrane iCare Criteria #654.00

Amniotic Membrane Placement – CPT CODE: 65778, 65779, 65780, 65781, 65782

Coverage Criteria:
Amniotic membrane transplantation will be considered medically necessary for ocular surface reconstruction for the following conditions when primary and secondary treatment options have failed (which do not respond to conservative therapy):

- 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
- Chemical/thermal injuries of the ocular surface associated with or without an epithelial defect
- Contact lens-induced keratopathy or toxic effects from lens-cleaning solutions associated with or without an epithelial defect
- Corneal limbal dermoid
- Multiple surgeries or cryotherapies to the limbal region
- Stevens-Johnson syndrome
- Hypofunction of stem cells in Aniridia (hereditary)
- Bullous keratopathy associated with an epithelial defect
- Chronic limbitis
- Keratitis associated with multiple endocrine deficiency (hereditary)
- Neurotrophic keratopathy (neuronal or ischemic)
- Peripheral corneal ulcerative keratitis (including Mooren's ulcer)
- Pterygium (primary and recurrent) and pseudopterygium (including 1-day post-op corneal defect)
- Corneal ulcer
- Conjunctivochalasis
- Band keratopathy
- Persistent non-KCS (non-dry eye syndrome) corneal epithelial defects
- Corneal melting
- Recurrent corneal erosions after treatment failure with other therapy such as bandage contact lens, patching, and topical medications

Amniotic Membrane-Derived Grafts Include:

- AmbioDisk, AmnioGraft, Artacent Ocular, and Prokera.

Additional Specifications for Pterygium Only:

- Frontal photographs are required and must be original prints, not slides or faxes and be perpendicular to the plane of the camera (i.e., not tilted).
- Documentation indicates visually significant induced astigmatism.
- Documentation and photos demonstrate the pterygium threatening involvement of visual axis.

Additional Specifications for Corneal Ulcer Only:

- Amniotic membrane transplant will be considered medically necessary for the treatment of corneal ulcer after initiation of anti-infective therapy and demonstration of clinical response for the purpose of healing the persistent epithelial defect.

Limitations:

- Amniotic membrane must be cleared by, or registered with, the U.S. Food and Drug Administration (FDA) for sutured or 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.
- Application for glaucoma is noncovered, given the use of amniotic membrane-derived products has not yet become widely accepted as standard practice. A wide array of other less invasive treatment options is currently available which provide significant relief to this population.
- Amniotic membrane transplantation for the treatment of conjunctivochalasis will be considered medically necessary when conservative therapies (ex. artificial tears, antibiotic/steroid eye drops) have failed.
- 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.

Coding Information:

CPT codes covered if coverage criteria are met:

Code	Code Description
65778	Placement of amniotic membrane on the ocular surface; without sutures
65779	Placement of amniotic membrane on the ocular surface; single layer, sutured
65780	Ocular surface reconstruction: amniotic membrane transplantation, multiple layers (not covered for double-layer amniotic membrane transplantation)
65781	Limbal stem cell allograft (ex. cadaveric or living donor)
65782	Limbal conjunctival autograft (includes obtaining graft)

ICD-10 codes covered if coverage criteria are met:

Code	Code Description
D31.10 – D31.12	Benign neoplasm of cornea (dermoid)
H04.13 – H04.139	Lacrimal cyst
H11.001 – H11.069	Pterygium of eye
H11.811 – H11.829	Pseudopterygium and conjunctivochalasis (conjunctival tube erosion)
H15.89 – H15.9	Other disorders of sclera
H16.001 – H16.079	Corneal ulcer
H16.121 – H16.129	Filamentary keratitis
H16.231 – H16.239	Neurotrophic keratoconjunctivitis
H18.10 – H18.13	Bullous keratopathy
H18.40 – H18.49	Corneal degeneration LCD mentions only H18.421-429 for Band keratopathy
H18.50 – H18.59	Hereditary corneal dystrophies
H18.821 – H18.829	Corneal disorder due to contact lens
H18.831 – H18.839	Recurrent erosion of cornea
H18.891 – H18.899	Other specified disorders of cornea
L51.0	Non-bullous erythema multiforme
L51.1	Stevens-Johnson syndrome

L51.3	Stevens-Johnson syndrome – toxic epidermal necrolysis overlap syndrome
L51.9	Erythema multiforme
Q13.1	Absence of iris
T26.00x+ - T26.92x+	Burns and corrosion confined to eye and adnexa

Documentation Requirements:

- All documentation must be maintained in the patient's medical record and made available upon request. *The provider has a responsibility to maintain a record for possible post payment review.*
- Every page of the record must be legible and include appropriate patient identification information (ex. complete name, date of birth, dates of service[s]).
- The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
- The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
- Office notes supplying documentation of complaints or symptomatology for visual disturbances and the effect on activities of daily living.
- Diagnostic test results.
- Documentation of risk, benefits, and alternatives having been explained to the patient and/or the patient's legal guardian.
- Documentation of informed consent to complete the procedure must be obtained from the patient and/or the patient's legal guardian.

Definition and Background:

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.

Sources:

Portions of the criteria herein may have been adopted in whole or in part from Local Coverage Determinations as provided by the applicable fiscal intermediary and/or criteria from certain health plan partners.

- American Academy of Ophthalmology. Cornea Edema and Opacification Preferred Practice Pattern®. San Francisco, CA: AAO; 2023.
- First Coast Service Options, Inc. Local Coverage Determination (LCD): Amniotic Membrane – Sutureless Placement on the Ocular Surface (L36237). Jacksonville, FL: First Coast; effective October 13, 2016.

REVIEW AND REVISION HISTORY		
Date	**Description**	**Approver & Title**
January 15, 2024	Approval by PAC Committee	Approved by PAC Committee
November 2023	Administrative revisions (non-clinical)	Dr. Smith Blanc, Director of UM
July 17, 2023	Approval by PAC Committee (clinical documentation changes made)	Approved by PAC Committee
January 23, 2023	Approval by PAC Committee	Approved by PAC Committee
January 17, 2022	Approval by PAC Committee	Approved by PAC Committee
January 18, 2021	Approval by PAC Committee	Approved by PAC Committee
January 27, 2020	Approval by PAC Committee	Approved by PAC Committee
October 12, 2020	Approval by PAC Committee	Approved by PAC Committee
April 13, 2020	Approval by PAC Committee	Approved by PAC Committee
January 28, 2019	Approval by PAC Committee	Approved by PAC Committee
January 29, 2018	Approval by PAC Committee	Approved by PAC Committee
January 9, 2017	Approval by PAC Committee	Approved by PAC Committee