Medical Policy:

Amniotic Membrane Transplantation for Ocular Reconstruction

POLICY NUMBER	LAST REVIEW
MG.MM.SU.49cC2	April 8, 2022

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. 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. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth 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). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program 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 EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. 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. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Amniotic membrane transplantation (AMT)	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.
Corneal epithelial device (E.g., PROKERA®)	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.
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:
1. Chemical / thermal ocular surface injuries
2. Contact lens-induced keratopathy or toxic effects from lens-cleaning solutions
3. Multiple surgeries or cryotherapies to limbal region
4. Stevens-Johnson syndrome

B. **Stem cell hypofunction** — in one or both eyes secondary to any:
1. Aniridia (hereditary)
2. Bullous keratopathy
3. Chronic limbitis
4. Keratitis associated with multiple endocrine deficiency (hereditary)
5. Neurotrophic keratopathy (neuronal or ischemic)
6. Peripheral corneal ulcerative keratitis
7. Pterygium and pseudopterygium

C. **Conjuctival reconstruction/revision of scars and symblepharon**

D. **Corneal ulcers/thinning perforation/persistent corneal epithelial defect**

Note: EmblemHealth 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.

Limitations and Exclusions

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).

Procedure Codes

65778	Placement of amniotic membrane on the ocular surface; without sutures
65779	Placement of amniotic membrane on the ocular surface; single layer, sutured
65781	Ocular surface reconstruction; limbal stem cell allograft (eg, cadaveric or living donor)
65782	Ocular surface reconstruction; limbal conjunctival autograft (includes obtaining graft)
65780	Ocular surface reconstruction; amniotic membrane transplantation, multiple layers
V2790	Amniotic membrane for surgical reconstruction, per procedure

ICD-10 Diagnoses

H11.001	Unspecified pterygium of right eye
H11.002	Unspecified pterygium of left eye
H11.003	Unspecified pterygium of eye, bilateral
H11.009	Unspecified pterygium of unspecified eye
H11.011	Amyloid pterygium of right eye
H11.012	Amyloid pterygium of left eye
H11.013	Amyloid pterygium of eye, bilateral
H11.019	Amyloid pterygium of unspecified eye
H11.021	Central pterygium of right eye
H11.022	Central pterygium of left eye
H11.023	Central pterygium of eye, bilateral
H11.029	Central pterygium of unspecified eye
H11.031	Double pterygium of right eye
H11.032	Double pterygium of left eye
H11.033	Double pterygium of eye, bilateral
H11.039	Double pterygium of unspecified eye
H11.041	Peripheral pterygium, stationary, right eye
H11.042	Peripheral pterygium, stationary, left eye
H11.043	Peripheral pterygium, stationary, bilateral
H11.049	Peripheral pterygium, stationary, unspecified eye
H11.051	Peripheral pterygium, progressive, right eye
H11.052	Peripheral pterygium, progressive, left eye
H11.053	Peripheral pterygium, progressive, bilateral
H11.059	Peripheral pterygium, progressive, unspecified eye
H11.061	Recurrent pterygium of right eye
H11.062	Recurrent pterygium of left eye
H11.063	Recurrent pterygium of eye, bilateral
H11.069	Recurrent pterygium of unspecified eye
H11.10	Unspecified conjunctival degenerations
H11.231	Symblepharon, right eye
H11.232	Symblepharon, left eye
H11.233	Symblepharon, bilateral
H11.239	Symblepharon, unspecified eye
H11.811	Pseudopterygium of conjunctiva, right eye
H11.812	Pseudopterygium of conjunctiva, left eye
H11.813	Pseudopterygium of conjunctiva, bilateral
H11.819	Pseudopterygium of conjunctiva, unspecified eye
H16.001	Unspecified corneal ulcer, right eye

H16.002	Unspecified corneal ulcer, left eye
H16.003	Unspecified corneal ulcer, bilateral
H16.009	Unspecified corneal ulcer, unspecified eye
H16.011	Central corneal ulcer, right eye
H16.012	Central corneal ulcer, left eye
H16.013	Central corneal ulcer, bilateral
H16.019	Central corneal ulcer, unspecified eye
H16.021	Ring corneal ulcer, right eye
H16.022	Ring corneal ulcer, left eye
H16.023	Ring corneal ulcer, bilateral
H16.029	Ring corneal ulcer, unspecified eye
H16.031	Corneal ulcer with hypopyon, right eye
H16.032	Corneal ulcer with hypopyon, left eye
H16.033	Corneal ulcer with hypopyon, bilateral
H16.039	Corneal ulcer with hypopyon, unspecified eye
H16.041	Marginal corneal ulcer, right eye
H16.042	Marginal corneal ulcer, left eye
H16.043	Marginal corneal ulcer, bilateral
H16.049	Marginal corneal ulcer, unspecified eye
H16.051	Mooren's corneal ulcer, right eye
H16.052	Mooren's corneal ulcer, left eye
H16.053	Mooren's corneal ulcer, bilateral
H16.059	Mooren's corneal ulcer, unspecified eye
H16.061	Mycotic corneal ulcer, right eye
H16.062	Mycotic corneal ulcer, left eye
H16.063	Mycotic corneal ulcer, bilateral
H16.069	Mycotic corneal ulcer, unspecified eye
H16.071	Perforated corneal ulcer, right eye
H16.072	Perforated corneal ulcer, left eye
H16.073	Perforated corneal ulcer, bilateral
H16.079	Perforated corneal ulcer, unspecified eye
H16.231	Neurotrophic keratoconjunctivitis, right eye
H16.232	Neurotrophic keratoconjunctivitis, left eye
H16.233	Neurotrophic keratoconjunctivitis, bilateral
H16.239	Neurotrophic keratoconjunctivitis, unspecified eye
H18.10	Bullous keratopathy, unspecified eye
H18.11	Bullous keratopathy, right eye
H18.12	Bullous keratopathy, left eye
H18.13	Bullous keratopathy, bilateral
H18.40	Unspecified corneal degeneration

H18.421	Band keratopathy, right eye
H18.422	Band keratopathy, left eye
H18.423	Band keratopathy, bilateral
H18.429	Band keratopathy, unspecified eye
H18.461	Peripheral corneal degeneration, right eye
H18.462	Peripheral corneal degeneration, left eye
H18.463	Peripheral corneal degeneration, bilateral
H18.469	Peripheral corneal degeneration, unspecified eye
H18.49	Other corneal degeneration
H18.501	Unspecified hereditary corneal dystrophies, right eye
H18.502	Unspecified hereditary corneal dystrophies, left eye
H18.503	Unspecified hereditary corneal dystrophies, bilateral
H18.509	Unspecified hereditary corneal dystrophies, unspecified eye
H18.511	Endothelial corneal dystrophy, right eye
H18.512	Endothelial corneal dystrophy, left eye
H18.513	Endothelial corneal dystrophy, bilateral
H18.519	Endothelial corneal dystrophy, unspecified eye
H18.521	Epithelial (juvenile) corneal dystrophy, right eye
H18.522	Epithelial (juvenile) corneal dystrophy, left eye
H18.523	Epithelial (juvenile) corneal dystrophy, bilateral
H18.529	Epithelial (juvenile) corneal dystrophy, unspecified eye
H18.531	Granular corneal dystrophy, right eye
H18.532	Granular corneal dystrophy, left eye
H18.533	Granular corneal dystrophy, bilateral
H18.539	Granular corneal dystrophy, unspecified eye
H18.541	Lattice corneal dystrophy, right eye
H18.542	Lattice corneal dystrophy, left eye
H18.543	Lattice corneal dystrophy, bilateral
H18.549	Lattice corneal dystrophy, unspecified eye
H18.551	Macular corneal dystrophy, right eye
H18.552	Macular corneal dystrophy, left eye
H18.553	Macular corneal dystrophy, bilateral
H18.559	Macular corneal dystrophy, unspecified eye
H18.591	Other hereditary corneal dystrophies, right eye
H18.592	Other hereditary corneal dystrophies, left eye
H18.593	Other hereditary corneal dystrophies, bilateral
H18.599	Other hereditary corneal dystrophies, unspecified eye
H18.821	Corneal disorder due to contact lens, right eye
H18.822	Corneal disorder due to contact lens, left eye
H18.823	Corneal disorder due to contact lens, bilateral

H18.829	Corneal disorder due to contact lens, unspecified eye
H18.831	Recurrent erosion of cornea, right eye
H18.832	Recurrent erosion of cornea, left eye
H18.833	Recurrent erosion of cornea, bilateral
H18.839	Recurrent erosion of cornea, unspecified eye
L51.1	Stevens-Johnson syndrome
T26.10xA	Burn of cornea and conjunctival sac, unspecified eye, initial encounter
T26.11xA	Burn of cornea and conjunctival sac, right eye, initial encounter
T26.12xA	Burn of cornea and conjunctival sac, left eye, initial encounter
T26.60xA	Corrosion of cornea and conjunctival sac, unspecified eye, initial encounter
T26.61xA	Corrosion of cornea and conjunctival sac, right eye, initial encounter
T26.62xA	Corrosion of cornea and conjunctival sac, left eye, initial encounter

References

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Revision History

Apr. 10, 2020	Added persistent corneal epithelial defect as a covered indication
Mar. 9, 2018	Added that the Prokera corneal bandage is covered