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Subject: Amniotic Membrane and Limbal Stem Cell Transplantation for the Treatment of Ocular Conditions

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

The cornea is the clear front of the eye and its surface is composed of an epithelium, a thin layer of stratified squamous cells that form the outermost layer of the cornea. The corneal epithelium can rapidly regenerate. This regeneration relies on the existence of stem cells located in the limbal epithelium (the junction zone between the corneal and conjunctival epithelia).

Amniotic membrane is the innermost layer of the placenta consisting of a thick basement membrane and an avascular stromal matrix. It can be obtained from cesarean deliveries and is prepared and cryo-preserved under sterile conditions. It may be sutured into place, or placed without sutures onto the ocular surface and used as a graft and/or a dressing to facilitate ocular surface reconstruction and promote healing. Amniotic membrane contains an avascular matrix, which inhibits angiogenesis in adjacent tissues, thus minimizing vascularization during ocular healing. It exhibits anti-inflammatory properties and suppresses expression of transforming growth factor-beta (TGF-β) isoforms, minimizing scar tissue.

Limbal stem cells act as a “barrier” to conjunctival epithelial cells and normally prevent them from migrating on to the corneal surface. Limbal stem cell deficiency (LSCD) can develop in traumatic, immunologic, or genetic diseases that affect the ocular surface. LSCD leads to conjunctivalization, with corneal vascularization and opacification and subsequent loss of vision. Limbal stem cell transplantation is a surgical treatment to address LSCD and restore a corneal epithelial phenotype. Based on the source of cells, limbal transplant can be autologous or allogenic. An autograft from the individual’s undamaged eye may be used, or an allograft from a donor’s eye may be used.

The goal of amniotic membrane transplantation and limbal stem cell transplantation is to reconstruct damaged ocular surfaces and promote healing, decrease scarring, reduce inflammation and restore function and appearance of corneal, conjunctival and eyelid tissues after injury due to trauma, disease, or surgery.

POSITION STATEMENT:

Human amniotic membrane grafts with or without suture **OR** limbal stem cell transplantation **meets the definition of medical necessity** for the treatment of any of the following ophthalmic conditions:

- Neurotrophic keratitis with ocular surface damage and inflammation that does not respond to conservative therapy
- Corneal ulcers and melts that do not respond to initial conservative therapy
- Corneal perforation when there is active inflammation after corneal transplant requiring adjunctive treatment
- Bullous keratopathy as a palliative measure in individuals who are not candidates for curative treatment (eg, endothelial or penetrating keratoplasty)
- Partial limbal stem cell deficiency with extensive diseased tissue where selective removal alone is not sufficient
- Moderate or severe Stevens-Johnson syndrome
- Persistent epithelial defects that do not respond within 2 days to conservative therapy
- Moderate or severe acute ocular chemical burn
- Severe dry eye (DEWS 3 or 4)** with ocular surface damage and inflammation that remains symptomatic after Steps 1, 2, and 3 of the dry eye disease management algorithm:

Step 1:

- Education regarding the condition, its management, treatment and prognosis
- Modification of local environment
- Education regarding potential dietary modifications (including oral essential fatty acid supplementation)
- Identification and potential modification/elimination of offending systemic and topical medications
- Ocular lubricants of various types (if meibomian gland dysfunction is present, then consider lipid containing supplements)
- Lid hygiene and warm compresses of various types

Step 2:

- Non-preserved ocular lubricants to minimize preservative-induced toxicity
- Tea tree oil treatment for Demodex (if present)
- Tear conservation
- Punctal occlusion
- Moisture chamber spectacles/goggles

- Overnight treatments (such as ointment or moisture chamber devices)
- In-office, physical heating and expression of the meibomian glands
- In-office intense pulsed light therapy for meibomian gland dysfunction
- Prescription drugs to manage dry eye disease
- Topical antibiotic or antibiotic/steroid combination applied to the lid margins for anterior blepharitis (if present)
- Topical corticosteroid (limited-duration)
- Topical secretagogues
- Topical non-glucocorticoid immunomodulatory drugs (such as cyclosporine)
- Topical LFA-1 antagonist drugs (such as lifitegrast)
- Oral macrolide or tetracycline antibiotics

Step 3:

- Oral secretagogues
- Autologous/allogeneic serum eye drops
- Therapeutic contact lens options
- Soft bandage lenses
- Rigid scleral lenses

****Dry eye severity level DEWS 3 to 4:**

- Discomfort, severity, and frequency – severe frequent or constant
- Visual symptoms – chronic and/or constant, limiting to disabling
- Conjunctival Injection - +/- or +/+
- Conjunctive Staining – moderate to marked
- Corneal Staining – marked central or severe punctate erosions
- Corneal/tear signs – Filamentary keratitis, mucus clumping, increase in tear debris
- Lid/meibomian glands – Frequent
- Tear film breakup time - < 5
- Schirmer score (mm/5 min) - < 5

Human amniotic membrane grafts with suture or glue also **meet the definition of medical necessity** for the treatment of the following ophthalmic indications:

- Corneal perforation when corneal tissue is not immediately available, **OR**
- Pterygium repair when there is insufficient healthy tissue to create a conjunctival autograft

Human amniotic membrane grafts with or without suture and limbal stem cell transplantation are considered **experimental or investigational** for all other ocular conditions, as there is a lack of clinical scientific evidence published in peer-reviewed literature to permit conclusions on safety and net health outcomes.

Injection of human amniotic fluid for the treatment of ophthalmic conditions is considered **experimental or investigational**. There is insufficient published clinical evidence to support safety and effectiveness.

BILLING/CODING INFORMATION:

CPT Coding:

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
65781	Ocular surface reconstruction; limbal stem cell allograft (eg, cadaveric or living donor)
65782	Ocular surface reconstruction; limbal conjunctival autograft (includes obtaining graft)

HCPCS Coding:

V2790	Amniotic membrane for surgical reconstruction, per procedure

ICD-10 Diagnosis Codes That Support Medical Necessity:

H04.121 – H04.129	Dry eye syndrome
H11.001 – H11.069	Pterygium
H11.151 – H11.153	Pinguecula
H11.21 – H11.213	Conjunctival scars
H11.221 – H11.223	Conjunctival adhesions and strands (localized)
H11.231 – H11.233	Conjunctival granuloma
H11.241 – H11.243	Symblepharon
H11.31 – H11.33	Conjunctival hemorrhage
H11.411 – H11.413	Vascular abnormalities of conjunctiva
H11.441 – H11.443	Conjunctival cysts
H11.811 – H11.819	Pseudopterygium
H16.001 – H16.049	Corneal ulcer
H16.051 – H16.053	Superficial keratitis
H16.061 – H16.079	Mycotic and perforated corneal ulcer
H16.111 – H16.113	Macular keratitis
H16.121 – H16.123	Filamentary keratitis
H16.131 – H16.133	Photokeratitis
H16.141 – H16.143	Punctate keratitis
H16.231 – H16.239	Neurotrophic keratoconjunctivitis
H16.241 – H16.243	Ophthalmia nodosa
H16.251 – H16.253	Phlyctenular keratoconjunctivitis
H16.261 – H16.263	Vernal keratoconjunctivitis, with limbar and corneal involvement
H16.311 – H16.313	Corneal abscess

H16.321 – H16.323	Diffuse interstitial keratitis
H16.331 – H16.333	Sclerosing keratitis
H16.391 – H16.393	Other interstitial and deep keratitis
H16.421 – H16.423	Pannus (corneal)
H16.431 – H16.433	Localized vascularization of cornea
H16.441 – H16.443	Deep vascularization of cornea
H17.00 – H17.03	Adherent leukoma
H17.10 – H17.12	Central corneal opacity
H17.811 – H17.813	Minor opacity of cornea
H17.821 – H17.823	Peripheral opacity of cornea
H18.021 – H18.023	Argentous corneal deposits
H18.031 – H18.033	Corneal deposits in metabolic disorders
H18.041 – H18.043	Kayser-Fleischer ring
H18.10 – H18.13	Bullous keratopathy
H18.311 – H18.313	Idiopathic corneal edema
H18.321 – H18.323	Folds in Descemet's membrane
H18.331 – H18.333	Rupture in Descemet's membrane
H18.411 – H18.413	Arcus senilis
H18.43	Other calcerous corneal degeneration
H18.441 – H18.443	Keratomalacia
H18.451 – H18.453	Nodular corneal degeneration
H18.461 – H18.463	Peripheral corneal degeneration
H18.50 – H18.59	Corneal dystrophy
H18.711 – H18.713	Corneal ectasia
H18.721 – H18.723	Corneal staphyloma
H18.731 – H18.733	Descemetocele
H18.811 – H18.813	Anesthesia and hypoesthesia of cornea
H18.821 – H18.839	Erosion of cornea
L12.30	Acquired epidermolysis bullosa, unspecified
L12.31	Epidermolysis bullosa due to drug
L12.35	Other acquired epidermolysis bullosa
L51.0 – L51.9	Erythema multiforme [Stevens-Johnson syndrome]
T26.11XD,S – T26.12D,S	Burn of cornea and conjunctival sac
T26.21D,S – T26.22D,S	Burn with resulting rupture and destruction of eyeball
T26.31D,S – T26.32,D,S	Burns of other specified parts of eye and adnexa
T26.41D,S – T2642D,S	Burn of eye and adnexa
T26.61D,S – T26.62D,S	Corrosion of cornea and conjunctival sac
T26.71D,S – T26.72D,S	Corrosion with resulting rupture and destruction of eyeball
T26.81D,S – T26.82D,S	Corrosions of other specified parts of eye and adnexa

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request

DEFINITIONS:

Bullous keratopathy: the presence of corneal epithelial bullae, resulting from corneal endothelial disease (failure of the corneal endothelium to maintain the normally dehydrated state of the cornea).

Hereditary aniridia: a congenital, hereditary, bilateral, extreme form of iris hypoplasia in which the iris appears absent on superficial clinical examination.

Neurotrophic keratopathy: a degenerative disease of the corneal epithelium resulting from impaired corneal innervation. Symptoms include reduction in corneal sensitivity or complete corneal anesthesia. This disease is responsible for producing epithelial keratopathy, ulceration and perforation.

Pseudopterygium: a conjunctival scar joined to the cornea; it looks like a pterygium but is not attached to the tissue.

Pterygium: a fleshy triangular growth of bulbar conjunctiva that may spread across and distort the cornea, induce astigmatism, and change the refractive power of the eye.

Stevens-Johnson syndrome: a severe cutaneous hypersensitivity reaction; drugs, especially sulfa drugs, antiepileptics, and antibiotics, are the most common causes. Macules rapidly spread and coalesce, leading to epidermal blistering, necrosis, and sloughing.

RELATED GUIDELINES:

None applicable.

OTHER:

Other names and terms used to report amniotic membrane and amniotic fluid preparations:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Prokera®

AmbioDisk™

AmnioGraft®

Artacent® Ocular

Vendaje Optic™

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 06/22/23.

GUIDELINE UPDATE INFORMATION:

02/15/15	New Medical Coverage Guideline.
10/01/15	Revision; updated ICD9 and ICD10 coding sections.
02/15/16	Scheduled review. Maintained position statement. Revised program exceptions section and updated references.
03/15/17	Scheduled review. Maintained position statement. Updated references. Reformatted guideline.
03/15/18	Scheduled review. Maintained position statement; updated references.
04/15/19	Scheduled review. Revised position statement and ICD10 coding section. Updated references.
04/15/20	Scheduled review. Revised description, position statement, and index terms. Updated references.
06/15/21	Scheduled review. Maintained position statement and updated references.
07/15/23	Scheduled review. Maintained position statement and updated references.
08/21/23	Update to Program Exceptions section.