

Clinical Policy: Amniotic Membrane Placement on the Ocular Surface

Reference Number: OC.UM.CP.0004
Last Review Date: 11/2022

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Description

The usefulness of amniotic membrane has been attributed to its anti-inflammatory, anti-fibrotic, anti-vascularization, and anti-scarring effects and its ability to enhance epithelial healing. This policy describes the medical necessity requirements for amniotic membrane placement on the ocular surface.

See clinical policy CP.MP.185 Skin Substitutes for Chronic Wounds.

Policy/Criteria

- I. It is the policy of health plans affiliated with Envolve Vision, Inc.[®] (Envolve) that amniotic membrane placement on the ocular surface is **medically necessary** for the following indications:
 - A. Failure of standard therapy for severe ophthalmological conditions demonstrated by ocular surface cell damage and/or underlying inflammation, scarring, or ulceration of the underlying stroma;
 - B. Band keratopathy after treatment with other therapies such as surgery, topical medications, bandage contact lens or patching have failed;
 - C. Bullous keratopathy, associated with an epithelial defect;
 - D. Scleral melting;
 - E. Neurotrophic keratitis;
 - F. Corneal melting;
 - G. Chemical, thermal or radiation burns of the ocular surface;
 - H. Conjunctival defects after treatment with other therapy such as surgery or topical medications have failed;
 - I. Limbal stem cell deficiency;
 - J. Recurrent corneal erosions after treatment failure with other therapy such as bandage contact lens, patching and topical medications;
 - K. Stevens Johnson syndrome.

- II. It is the policy of health plans affiliated with Envolve that the following conditions are considered **not medically necessary** for amniotic membrane placement on the ocular surface:
 - A. Dry eye syndrome;
 - B. Cogan's Dystrophy, unless associated with corneal epithelial removal.

- III. It is the policy of health plans affiliated with Envolve that amniotic membrane placement on the ocular surface is **contraindicated** in the following situations:
 - A. Patients with glaucoma drainage devices or filtering blebs;
 - B. Treatment of a persistent epithelial defect overlying active infectious keratitis or scleritis;

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- C. Pterygium removal, as amniotic membrane graft is associated with a higher incidence of pterygium regrowth than conjunctival autograft.

Background

The normal ocular surface is covered by corneal and conjunctival epithelium. The corneal epithelium is well-known for its rapid self-renewal process, with ultimate tissue regeneration relying on the existence of stem cells located in the limbal epithelium (the junction zone between the corneal and conjunctival epithelia). Total loss or hypofunction of the stem cells can occur as a result of certain conditions that cause damage or alteration of the corneal surface (termed limbal deficiency). Normal healing of corneal epithelial defects is prevented and a unique pathological state ensues manifested by poor epithelialization (persistent defects or recurrent erosions), chronic stromal inflammation (keratitis mixed with scarring), corneal vascularization, and conjunctival epithelial ingrowth. Since some of these features can be found in other corneal diseases, the sine qua non for making the diagnosis of limbal deficiency is the existence of conjunctival epithelial ingrowth onto the corneal surface. Clinically, this pathologic state can be confirmed by detecting conjunctival goblet cells on the corneal surface through the use of impression cytology.

Persistent corneal epithelial defects refractory to conventional treatment remain a therapeutic challenge that often requires surgical intervention. For those with hypofunction of limbal stem cells, treatment is directed at altering the microenvironment to maintain and activate the remaining stem cell population. For those conditions leading to a total loss of stem cells in 1 eye, limbal autograft transplantation is performed by taking a graft from the healthy fellow eye to replace the lost stem cell population. This procedure is not applicable with patients having bilateral diffuse limbal involvement.

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 transplantation of human amniotic membrane has been added to the therapeutic armamentarium. Amniotic membrane obtained from cesarean deliveries is prepared and cryo-preserved under sterile conditions and can be sutured onto the ocular surface. Amniotic membrane-covered surfaces have been shown to induce rapid re-epithelialization (in 2 to 4 weeks) to a smooth and wettable surface and reduce inflammation, vascularization, and scarring, thus allowing successful surface reconstruction. As amniotic membrane transplants typically melt over a period of 1-2 weeks, repeated applications are sometimes necessary for an indicated condition. However, indiscriminate use of human amniotic membrane needs to be discouraged as complications though infrequent can occur. These include risk of transmission of bacterial, viral or fungal infections to the recipient if the donors are not adequately screened for communicable diseases, if the membrane is not processed under sterile conditions or if storage is improper.

For partial limbal deficiency with superficial involvement, amniotic membrane transplantation alone has been shown to be sufficient and superior to autograft limbal transplantation because

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there is no need to administer cyclosporine. For total limbal deficiency, additional autograft limbal transplantation is needed, and amniotic membrane transplantation has been shown to enhance successful engraftment of autograft limbal transplantation by preparing the perilimbal stroma and reducing inflammation and vascularization.

Coding Implications

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CPT® Codes	Description
65778	Placement of amniotic membrane on the ocular surface; without sutures
65779	Placement of amniotic membrane on the ocular surface; single layer, sutured

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

+ Indicates a code requiring an additional character

ICD-10-CM Code	Description
H16.011	Central corneal ulcer, right eye
H16.012	Central corneal ulcer, left eye
H16.013	Central corneal ulcer, bilateral
H16.021	Ring corneal ulcer, right eye
H16.022	Ring corneal ulcer, left eye
H16.023	Ring corneal ulcer, bilateral
H16.031	Corneal ulcer with hypopyon, right eye
H16.032	Corneal ulcer with hypopyon, left eye
H16.033	Corneal ulcer with hypopyon, bilateral
H16.041	Marginal corneal ulcer, right eye
H16.042	Marginal corneal ulcer, left eye
H16.043	Marginal corneal ulcer, bilateral
H16.051	Mooren’s corneal ulcer, right eye
H16.052	Mooren’s corneal ulcer, left eye
H16.053	Mooren’s corneal ulcer, bilateral
H16.061	Mycotic corneal ulcer, right eye
H16.062	Mycotic corneal ulcer, left eye
H16.063	Mycotic corneal ulcer, bilateral
H16.071	Perforated corneal ulcer, right eye
H16.072	Perforated corneal ulcer, left eye
H16.073	Perforated corneal ulcer, bilateral

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ICD-10-CM Code	Description
H16.121	Filamentary keratitis, right eye
H16.122	Filamentary keratitis, left eye
H16.123	Filamentary keratitis, bilateral
H16.231	Neurotrophic keratoconjunctivitis, right eye
H16.232	Neurotrophic keratoconjunctivitis, left eye
H16.233	Neurotrophic keratoconjunctivitis, bilateral
H18.11	Bullous keratopathy, right eye
H18.12	Bullous keratopathy, left eye
H18.13	Bullous keratopathy, bilateral
H18.421	Band keratopathy, right eye
H18.422	Band keratopathy, left eye
H18.423	Band keratopathy, bilateral
H18.831	Recurrent erosion of cornea, right eye
H18.832	Recurrent erosion of cornea, left eye
H18.833	Recurrent erosion of cornea, bilateral
L51.0	Nonbullous erythema multiforme
L51.1	Stevens-Johnson syndrome
L51.3	Stevens-Johnson syndrome-toxic epidermal necrolysis overlap syndrome
L51.9	Erythema multiforme, unspecified
T26.01XA	Burn of right eyelid and periocular area, initial encounter
T26.01XD	Burn of right eyelid and periocular area, subsequent encounter
T26.01XS	Burn of right eyelid and periocular area, sequela
T26.02XA	Burn of left eyelid and periocular area, initial encounter
T26.02XD	Burn of left eyelid and periocular area, subsequent encounter
T26.02XS	Burn of left eyelid and periocular area, sequela
T26.11XA	Burn of cornea and conjunctival sac, right eye, initial encounter
T26.11XD	Burn of cornea and conjunctival sac, right eye, subsequent encounter
T26.11XS	Burn of cornea and conjunctival sac, right eye, sequela
T26.12XA	Burn of cornea and conjunctival sac, left eye, initial encounter
T26.12XD	Burn of cornea and conjunctival sac, left eye, subsequent encounter
T26.12XS	Burn of cornea and conjunctival sac, left eye, sequela
T26.21XA	Burn with resulting rupture and destruction of right eyeball, initial encounter
T26.21XD	Burn with resulting rupture and destruction of right eyeball, subsequent encounter
T26.21XS	Burn with resulting rupture and destruction of right eyeball, sequela
T26.22XA	Burn with resulting rupture and destruction of left eyeball, initial encounter
T26.22XD	Burn with resulting rupture and destruction of left eyeball, subsequent encounter
T26.22XS	Burn with resulting rupture and destruction of left eyeball, sequela
T26.31XA	Burns of other specified part of right eye and adnexa, initial encounter

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ICD-10-CM Code	Description
T26.31XD	Burns of other specified part of right eye and adnexa, subsequent encounter
T26.31XS	Burns of other specified part of right eye and adnexa, sequela
T26.32XA	Burns of other specified part of left eye and adnexa, initial encounter
T26.32XD	Burns of other specified part of left eye and adnexa, subsequent encounter
T26.32XS	Burns of other specified part of left eye and adnexa, sequela
T26.41XA	Burn of right eye and adnexa, part unspecified, initial encounter
T26.41XD	Burn of right eye and adnexa, part unspecified, subsequent encounter
T26.41XS	Burn of right eye and adnexa, part unspecified, sequela
T26.42XA	Burn of left eye and adnexa, part unspecified, initial encounter
T26.42XD	Burn of left eye and adnexa, part unspecified, subsequent encounter
T26.42XS	Burn of left eye and adnexa, part unspecified, sequela
T26.51XA	Corrosion of right eyelid and periocular area, initial encounter
T26.51XD	Corrosion of right eyelid and periocular area, subsequent encounter
T26.51XS	Corrosion of right eyelid and periocular area, sequela
T26.52XA	Corrosion of left eyelid and periocular area, initial encounter
T26.52XD	Corrosion of left eyelid and periocular area, subsequent encounter
T26.52XS	Corrosion of left eyelid and periocular area, sequela
T26.61XA	Corrosion of cornea and conjunctival sac, right eye, initial encounter
T26.61XD	Corrosion of cornea and conjunctival sac, right eye, subsequent encounter
T26.61XS	Corrosion of cornea and conjunctival sac, right eye, sequela
T26.62XA	Corrosion of cornea and conjunctival sac, left eye, initial encounter
T26.62XD	Corrosion of cornea and conjunctival sac, left eye, subsequent encounter
T26.62XS	Corrosion of cornea and conjunctival sac, left eye, sequela
T26.71XA	Corrosion with resulting rupture and destruction of right eyeball, initial encounter
T26.71XD	Corrosion with resulting rupture and destruction of right eyeball, subsequent encounter
T26.71XS	Corrosion with resulting rupture and destruction of right eyeball, sequela
T26.72XA	Corrosion with resulting rupture and destruction of left eyeball, initial encounter
T26.72XD	Corrosion with resulting rupture and destruction of left eyeball, subsequent encounter
T26.72XS	Corrosion with resulting rupture and destruction of left eyeball, sequela
T26.81XA	Corrosions of other specified parts of right eye and adnexa, initial encounter
T26.81XD	Corrosions of other specified parts of right eye and adnexa, subsequent encounter
T26.81XS	Corrosions of other specified parts of right eye and adnexa, sequela
T26.82XA	Corrosions of other specified parts of left eye and adnexa, initial encounter

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ICD-10-CM Code	Description
T26.82XD	Corrosions of other specified parts of left eye and adnexa, subsequent encounter
T26.82XS	Corrosions of other specified parts of left eye and adnexa, sequela
T26.91XA	Corrosion of right eye and adnexa, part unspecified, initial encounter
T26.91XD	Corrosion of right eye and adnexa, part unspecified, subsequent encounter
T26.91XS	Corrosion of right eye and adnexa, part unspecified, sequela
T26.92XA	Corrosion of left eye and adnexa, part unspecified, initial encounter
T26.92XD	Corrosion of left eye and adnexa, part unspecified, subsequent encounter
T26.92XS	Corrosion of left eye and adnexa, part unspecified, sequela

Reviews, Revisions, and Approvals	Date	Approval Date
Annual Review	12/2019	12/2019
Converted to new template	04/2020	06/2020
Updated contraindications	07/2020	10/2020
Annual Review	12/2020	12/2020
Annual Review	12/2021	12/2021
Annual Review	11/2022	11/2022

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and

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accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Envolve Vision, Inc., or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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