



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Amniotic Membrane Transplant
for the Treatment of Ocular
Conditions**

**Effective Date 5/15/2009
Next Review Date 5/15/2010
Coverage Policy Number 0017**

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INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2009 CIGNA

Coverage Policy

CIGNA covers amniotic membrane transplantation as medically necessary for the treatment of ocular conditions when there is failure, contraindication, or intolerance to medical management (e.g., lubricants/artificial tears, topical and systemic steroids and antibiotics, eyelid taping, patches).

General Background

Disease or severe ocular injuries can compromise ocular surfaces and deplete the stem-cell population that repairs the damaged corneal epithelium, leading to pain, scarring, vascularization, and loss of sight. Treatment of ocular injuries includes: elimination of underlying problems, control of inflammation, prevention of additional loss of tissue, protection of ocular surfaces with a bandage contact lens and possible surgery or corneal transplant. When medical therapies fail, the type of surgery (e.g., ocular surface reconstruction) indicated is dependent upon the "extent of involvement of the cornea (e.g., epithelium, basement membrane or stroma), extent of limbal ischemia, conjunctival necrosis and intact tear supply" (Chandra, et al., 2005; Lemp, 2002).

Amniotic membrane (AM), the innermost layer of the fetal membrane, exhibits properties that are helpful in wound healing, particularly of ocular injuries and has been proposed for various clinical indications for ocular reconstruction. AM may be applied by inlay, overlay or filling, and may act as a graft or as a biological contact lens. The most common complications seen after surgical placement of AM are dehiscence, irritation and pain. Infection, dislodged or loose AM, hemorrhage and early disintegration have also been reported (Lemp, 2002;

John, 2003; Gomes, et al., 2005; Dogru and Tsubota, 2005; Fernandes, et al., Aug 2005; Wang, et al., 2004; Royal College of Ophthalmologists [RCO]).

Amniotic membrane transplantation (AMT) has been proposed as a treatment option for numerous ocular conditions, including: (Anderson, et al., 2003; Gomes, et al., 2005):

- acute inflammatory conditions
- bullous keratopathy
- chemical and thermal injury
- conjunctival cicatrization or scar
- conjunctival surface reconstruction
- conjunctivochalasis
- corneal ulceration
- corneal perforations
- contracted socket
- entropion surgery
- glaucoma surgery/complications
- limbal stem cell deficiency (partial or total, combined with stem cell graft)
- persistent epithelial defects
- pterygium
- Stevens-Johnson Syndrome
- symblepharon lysis
- trabeculectomy bleb leakage or revision
- tumors

U.S. Food and Drug Administration (FDA)

In 2001, the FDA established a registry and implemented regulations to ensure safety for the public in the use of human cells, tissues, and cellular- and tissue-based products. This regulation includes the use of AM in the eye. The tissue must be obtained, processed, maintained and distributed in accordance with these regulatory guidelines (FDA, 2001). AMNIOGRAFT[®] (Bio-Tissue, Inc. Miami, FL) and AmbioDry2[™] (OKTO Ophtho, Costa Mesa, CA) are examples of AM products which are governed under the FDA human cell and tissue regulatory guidelines.

ProKera[™] (Bio-Tissue, Inc., Miami, FL) is an example of a 510(k) approved ophthalmic conformer with amniotic membrane. It is a device with AMNIOGRAFT clipped into it. The device is “intended for use in eyes in which the ocular surface cells are damaged, or underlying stroma is inflamed and scarred” (FDA, 2003).

Bullous Keratopathy

Characterized by corneal stromal edema, bullous keratopathy is a condition caused by corneal endothelial decompensation. With poor visual potential, treatment modalities may include bandage contact lenses, stromal puncture, keratotomy, or conjunctival flap.

While evidence in the peer-reviewed literature supporting AMT for bullous keratopathy is limited and includes retrospective reviews with small patient populations (Chansanti and Horatanaruang, 2005), AMT is an established treatment options for patients with painful recurrent epithelial defects with poor visual potential who do not respond to standard treatment.

Chemical and Thermal Burns

Ocular burns are classified as chemical or thermal. Chemical burns may result from exposure to alkaline or acidic agents and can result in extensive and permanent damage to the eye. Thermal burns result from hot liquids, gases or molten metals. Medical treatment may include the use of topical and systemic ascorbate, citrate, tetracycline and steroids. Surgical options include glued-on hard contact lens, tenoplasty, tissue adhesives and keratoplasty. AMT has been proposed as a treatment option for chemical burns (Prabhasawat, et al., 2007; Arora, et al., 2005; Ivekovic, et al., 2005).

The utility of AMT as an adjunct to medical therapy in treating acute ocular burns has been evaluated in randomized controlled clinical trials, case series and retrospective reviews (n=15–44) (Prabhasawat, et al.,

2007; Tejwani, et al., 2007; Tamhane, et al., 2005; Arora, et al., 2004) . Follow-ups ranged from one week to 18 months. Outcomes included epithelialization, ocular surface reconstruction and improvements in ocular discomfort scores. Improvement in visual acuity was reported in all studies. Complications included symblepharon, limbal stem cell deficiency and superficial corneal vascularization.

Contracted Socket

Contracted socket involves shrinkage or loss of conjunctiva resulting in shrinkage and fibrosis of the socket. Typically, additional tissue is needed, usually through grafting, to prepare the socket for prosthesis. Mucous membrane grafting is the preferred surgical intervention for this condition. However, other grafts (e.g., skin, dermis fat, and forearm) have been attempted. Disadvantages of these methods include the lack of availability from the donor site and foul smelling discharge with conjunctival and mucous grafts. It has been proposed that AMT may be an alternative graft procedure for this condition (Kumar, et al., 2006; Poonyathalange, et al., 2005).

Randomized controlled trials and retrospective reviews (Kumar, et al., Poonyathalange, et al., 2005) (n=20) reported that the use of AMT resulted in less contractures, less morbidity, better patient comfort and up to 80% successful prosthetic fitting.

Corneal Ulceration

A corneal ulcer is a nonpenetrating erosion on the outer layer of the cornea which develops as a result of trauma, foreign body, severe dry eye or a local infection. Treatment is based on the underlying cause and presenting symptoms and may include: antibiotic, antiviral, antifungal or corticosteroids eye drops; artificial tears; lubricants, patching, and/or therapeutic lenses. In severe cases, corneal transplantation, conjunctival flap or tarsorrhaphy may be indicated (Hick, et al., 2005; Khokhar, et al., 2005).

Randomized controlled trials (Khokhar, et al., 2005) and retrospective reviews (n=23–92) (Fuchsluger, et al., 2007; Chen, et al., 2006; Hick, et al., 2005) reported favorable outcomes for the use of AMT including complete epithelialization and healing of corneal ulcerations and 23.1%–30.4% decreased rate of reoperation.

Pterygium

Pterygium is an ocular disease characterized by fibrovascular overgrowth of degenerative conjunctiva on the cornea caused by dry eye or irritation from wind, dust and/or ultraviolet light. Pterygium is typically treated with eye drops or ointment and may be surgically removed for visual disturbance or persistent discomfort. Surgical intervention may involve a conjunctival transplant or the application of an antimetabolite solution (e.g., mitomycin C). AMT alone, or as an adjunct, has been proposed as a treatment alternative for pterygium. Recurrence is the most common complication following excision of primary pterygia (Nakamura, et al., 2006; Ma, et al., 2005).

Randomized controlled trials, case series and retrospective reviews (n=13-105) have reported favorable outcomes for the use of AMT in the treatment of primary and recurrent pterygium (Küçükerdönmez, et al., 2007; Ma, et al., 2005; Nakamura, et al., 2006; Fernandes, et al., 2005; Solomon, et al., 2001; Ma, et al., 2000). Follow-ups ranged from 6–87 months. Overall recurrence rates ranged from 3.0%–37.5%, but the differences were not significant when compared to other treatment methods such as conjunctival autografting and use of intraoperative mitomycin. Complete epithelialization, early resolution of ocular inflammation, and no recurrence of pterygium were reported outcomes. Complications included symblepharon, recurrence of pterygium; conjunctival cyst, massive subconjunctival hematoma, diplopia secondary to symblepharon, and pyogenic granuloma.

Stevens-Johnson Syndrome (SJS)

SJS, also known as Lyell syndrome or toxic epidermal necrolysis, is an erythema skin disorder that is generally self-limited and nonprogressive. Treatment depends upon the severity of the condition and may include lubricants, artificial tears, ointments, corticosteroids, antibiotics, buccal mucous membrane grafts, stem cell transplantation and AMT are established methods of therapy for SJS (Gomes, et al., 2003; Sugar, 2004; Kunimoto, et al., 2004b).

Although there are a limited number of studies including case series (Gomes, et al., 2003) with small patient populations, AMT is an established treatment option for patients who do not respond to standard medical and other surgical interventions.

Other Indications

AMT has been proposed as a treatment option for various other ocular conditions. These conditions include: use of AMT with superficial keratectomy for corneal degeneration (Rao, et al., 2008); porous stem orbital implant exposure (Chen and Cui, 2007); severe bacterial keratitis (Gicquel, 2007); conjunctival scarring and adhesions due to symblepharon, exposed Ahmed valve, tumor and pterygium (Maharajan, et al., 2007); persistent epithelial defects (Saw, et al., 2007); herpes necrotizing stromal keratitis (Shi, et al., 2007); for treatment of complex herpes ophthalmicus (Dworkin, et al., 2007); extensive ocular surface neoplasia (Gunduz, et al., 2006); dystrophic epidermolysis bullosa (EB), laryngo-onychocutaneous syndrome and measles-related keratitis in children (Goyal, et al., 2006); persistent hydrops related to keratoconus (Wylegala, et al., 2006); repair of severe conjunctival dehiscence (Mocan and Azar, 2005); and defects created after excision for conjunctival intraepithelial neoplasia and tumors (Wang, et al., 2004).

Evidence from randomized controlled trials, a number of uncontrolled studies and case series also suggested that AMT can be effective in the reconstruction and healing of ocular conditions in patients with refractory glaucoma, late-onset glaucoma with filtering bleb leakage, and corneal, conjunctival, or lid defects that have not responded to medical treatment (Sheha, et al., 2008; Rauscher, et al., 2007; Miyai, et al., 2005; Jain and Rastogi, 2004; Prabhasawat, et al., 2000).

Professional Societies/Organizations

The American Academy of Ophthalmologists does not have a published guideline or formal position paper on the use of amniotic membrane transplantation for ocular conditions.

Summary

Professional societies, medical textbook sources and the evidence in the published peer-reviewed literature indicated that amniotic membrane transplantation is a safe and effective treatment option for a carefully selected subset of individuals with certain ocular conditions that are unresponsive to medical therapy and other surgical interventions.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT* Codes	Description
65780	Ocular surface reconstruction; amniotic membrane transplantation

HCPCS Codes	Description
V2790	Amniotic membrane for surgical reconstruction, per procedure

ICD-9-CM Diagnosis Codes	Description
	Multiple/varied

*Current Procedural Terminology (CPT®) © 2008 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	05/15/2008	0017	Amniotic Membrane Transplant for the Treatment of Ocular Conditions

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