



# CIGNA MEDICAL COVERAGE POLICY

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

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

**Effective Date .....5/15/2011**  
**Next Review Date .....5/15/2012**  
**Coverage Policy Number .....0017**

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## Hyperlink to Related Coverage Policies

Benign Skin Lesion Removal  
Corneal Transplant

### INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer'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 customer'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 customer'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 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 ©2011 CIGNA

## Coverage Policy

**CIGNA covers amniotic membrane transplantation as medically necessary for the treatment of an ocular disease (e.g., bullous keratopathy, pterygium, Stevens-Johnson syndrome) and/or injury (e.g., corneal ulcerations, chemical and thermal burns) 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 ocular injuries can compromise corneal and conjunctival epithelium, leading to pain, scarring, vascularization, and loss of sight. Depending on the condition and its severity, the stem-cells that aid in the renewal of the damaged epithelium may be depleted. Treatment of ocular injuries includes: elimination of the underlying problem, control of inflammation and prevention of additional loss of tissue by the use of eye drops, antibiotic ointment, pressure patches, bandage contact lens, and/or possible surgery or corneal transplantation. Surgical intervention may involve ocular surface reconstruction with amniotic membrane transplantation (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. Amniotic membrane transplantation (AMT) is an established treatment option for various ocular conditions when standard medical management fails, is not tolerated, or is contraindicated. Application of AM may be by inlay, overlay, or filling, and may act as a graft or as a biological

contact lens. AM may be indicated for the treatment of various ocular diseases such as bullous keratopathy, pterygium, and Stevens-Johnson Syndrome, as well as ocular trauma (e.g., chemical and thermal burns) and corneal ulcerations (Gomes, et al., 2005; Dogru and Tsubota, 2005; Fernandes, et al., Aug 2005; Wang, et al., 2004; John, 2003; Lemp, 2002).

### **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 to the regulatory guidelines. 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 that includes AMNIOGRAFT. 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: eye drops or ointment, bandage contact lenses, stromal puncture, keratotomy, or conjunctival flap.

Randomized controlled trials and retrospective reviews with small patient populations support amniotic membrane transplantation for the treatment of bullous keratopathy. Statistically significant decreases in symptom scores and complete epithelialization were reported (Chawla, et al., 2010; Chansanti and Horatanaruang, 2005). AMT is an established treatment option for patients with painful recurrent epithelial defects with poor visual potential who do not respond to standard therapy.

### **Chemical and Thermal Burns**

Ocular burns are classified by etiologic agent as chemical (e.g., acid, alkali) or radiant energy (e.g., thermal, ultraviolet). Medical treatment may include the use of topical and systemic ascorbate, citrate, tetracycline, or steroids. Surgical options include glued-on hard contact lens, tenoplasty, tissue adhesives and keratoplasty. AMT is a treatment option for chemical burns when the patient fails or cannot tolerate medical management or when medical treatment is contraindicated (Prabhasawat, et al., 2007; Arora, et al., 2005; Ivekovic, et al., 2005).

The utility of AMT as an adjunct to medical therapy in the treatment of acute ocular burns is supported by the evidence in randomized controlled trials, case series and retrospective reviews (Tandon, et al., 2011; Prabhasawat, et al., 2007; Tejwani, et al., 2007; Tamhane, et al., 2005; Arora, et al., 2005). Outcomes included epithelialization, ocular surface reconstruction, and improvement in ocular discomfort scores and visual acuity.

### **Contracted Socket**

Contracted socket involves shrinkage or loss of conjunctiva resulting in shrinkage and fibrosis of the ocular 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, comparative studies, and retrospective reviews (Kumar, et al., 2006; Bajai, et al., 2006; Poonyathalange, et al., 2005) support the efficacy of AMT for the treatment of contracted socket. The studies reported less contractures, less morbidity, better patient comfort, and up to 80% successful prosthetic fitting following AMT.

### **Corneal Ulceration**

Trauma, foreign body, severe dry eye, or a local infection may result in corneal ulcer, a nonpenetrating erosion on the outer layer of the cornea. Treatment, based on the underlying cause and presenting symptoms, may include: antibiotic, antiviral, antifungal and/or corticosteroids eye drops or ointments; 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).

AMT is an established treatment option for corneal ulceration. Randomized controlled trials (Khokhar, et al., 2005) and retrospective reviews (Fuchsluger, et al., 2007; Chen, et al., 2006; Hick, et al., 2005) reported favorable outcomes (e.g., complete epithelialization and healing of corneal ulcerations, and a 23.1%–30.4% decreased rate of reoperation) following AMT.

### **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. Treatment typically includes eye drops or ointments, but surgical removal may be indicated for visual disturbances or persistent discomfort. Surgical interventions 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 (Nakamura, et al., 2006; Ma, et al., 2005).

Randomized controlled trials, case series, and retrospective reviews support the safety and efficacy of AMT in the treatment of primary and recurrent pterygium (Küçükerdönmez, et al., 2007; Keklikci, et al., 2007; Ma, et al., 2005; Nakamura, et al., 2006; Fernandes, et al., 2005; Solomon, et al., 2001; Ma, et al., 2000).

### **Stevens-Johnson Syndrome (SJS)**

SJS, also known as Lyell syndrome or toxic epidermal necrolysis, is an erythema skin disorder that is generally self-limiting and nonprogressive. Painful blisters and lesions occur on the skin and mucous membranes and can cause severe eye problems. Treatment depends on the severity of the condition and may include: lubricants, artificial tears, ointments, corticosteroids, antibiotics, buccal mucous membrane grafts, stem cell transplantation, and AMT (Gomes, et al., 2003; Sugar, 2004; Kunimoto, et al., 2004).

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 SJS patients when standard medical management fails, is not tolerated, or is contraindicated.

### **Other Indications**

AMT has been proposed as a treatment option for various other ocular conditions. These conditions include: 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, or ocular tumors (Maharajan, et al., 2007); persistent epithelial defects (Saw, et al., 2007); herpes necrotizing stromal keratitis (Shi, et al., 2007); 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); severe conjunctival dehiscence (Mocan and Azar, 2005); defects created after excision for conjunctival intraepithelial neoplasia and tumors (Wang, et al., 2004); conjunctivochalasis, corneal perforation, entropion surgery, limbal stem cell deficiency (partial or total, combined with stem cell graft), and symblepharon lysis (Anderson, et al., 2003; Gomes, et al., 2005).

Evidence from randomized controlled trials, comparison studies, and case series also reported 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 management (Sheha, et al., 2008; Rauscher, et al., 2007; Miyai, et al., 2005; Jain and Rastogi, 2004; Prabhasawat, et al., 2000).

### **Professional Societies/Organizations**

In a preferred practice pattern guideline on the management of conjunctivitis (2008), the American Academy of Ophthalmologists stated that if patients with ocular mucous membrane pemphigoid conjunctivitis are not responding to medical management, AMT for “fornix reconstruction is possible if eyes are not severely dry and inflammation is under control.”

## Summary

Professional societies and evidence in the published peer-reviewed scientific literature support the safety and effectiveness of amniotic membrane transplantation for ocular surface reconstruction. AM may be indicated in the treatment of various ocular diseases (e.g., bullous keratopathy, Stevens-Johnson syndrome, pterygium) and injuries (e.g., corneal ulcerations, chemical and ocular burns) when medical management fails, is not tolerated, or is contraindicated.

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## Coding/Billing Information

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

**Covered when medically necessary:**

<b>CPT<sup>®</sup>* Codes</b>	<b>Description</b>
65778	Placement of amniotic membrane on the ocular surface for wound healing; self-retaining (effective 1/01/2011)
65779	Placement of amniotic membrane on the ocular surface for wound healing; single layer, sutured (effective 1/01/2011)
65780	Ocular surface reconstruction; amniotic membrane transplantation

<b>HCPCS Codes</b>	<b>Description</b>
V2790	Amniotic membrane for surgical reconstruction, per procedure

<b>ICD-9-CM Diagnosis Codes</b>	<b>Description</b>
053.21	Herpes zoster keratoconjunctivitis
053.22	Herpes zoster iridocyclitis
053.29	Herpes zoster with ophthalmic complications, other
054.42	Dendritic keratitis
054.43	Herpes simplex disciform keratitis
054.44	Herpes simplex iridocyclitis
054.49*	Herpes simplex with ophthalmic complications, other
055.71	Measles keratoconjunctivitis
190.0-190.9	Malignant neoplasm of the eye
365.00- 365.83	Glaucoma
370.00- 370.07	Corneal Ulcer
370.50- 370.55	Interstitial and deep keratitis
371.23	Bullous Keratopathy
371.24	Corneal edema due to wearing of contact lenses
371.42	Recurrent erosion of cornea
371.43	Band-shaped keratopathy
371.48	Peripheral degenerations of cornea
371.60- 371.62	Keratoconus
371.82	Corneal disorder due to contact lens
372.10- 372.15	Chronic conjunctivitis

372.40-372.45	Pterygium
372.63	Symblepharon
372.64	Scarring of conjunctiva
372.81	Conjunctivochalasis
373.00-373.02	Blepharitis
374.04	Cicatricial entropion
379.60-379.63	Inflammation (infection) of postprocedural bleb
694.61	Benign mucous membrane pemphigoid, with ocular involvement
695.13	Stevens-Johnson Syndrome (SJS)
695.14	Stevens-Johnson syndrome-toxic epidermal necrolysis overlap syndrome
695.15	Toxic epidermal necrolysis
757.39	Other specified anomalies of the skin, other
940.2	Alkaline chemical burn of cornea and conjunctival sac
940.3	Acid chemical burn of cornea and conjunctival sac
940.4	Other burn of cornea and conjunctival sac
940.5	Burn with resulting rupture and destruction of eyeball
940.9	Unspecified burn of eye and adnexa
941.12	Erythema due to burn (first degree) of eye (with other parts face, head, and neck)
941.22	Blisters, with epidermal loss due to burn (second degree) of eye (with other parts of face, head, and neck)
941.32	Full-thickness skin loss due to burn (third degree NOS) of eye (with other parts of face, head, and neck)
941.42	Deep necrosis of underlying tissues due to burn (deep third degree) of eye (with other parts of face, head, and neck), without mention of loss of a body part
941.52	Deep necrosis of underlying tissues due to burn (deep third degree) of eye (with other parts of face, head, and neck), with loss of a body part
998.32	Disruption of external operation (surgical) wound
998.33	Disruption of traumatic injury wound repair

**\*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.**

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## Policy History

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

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