BlueCross BlueShield of Kansas City

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Amniotic Membrane Transplantation

Policy Number: 7.01.507
Origination: 2/2006
Last Review: 2/2014
Next Review: 2/2015

Policy

BCBSKC will provide coverage for amniotic membrane transplantation (AMT) when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

Use of amniotic membrane transplantation for the treatment of ocular conditions may be considered **medically necessary** when there is failure, contraindication, or intolerance to alternative methods of medical management. Alternative methods to AMT include, but may not be limited to:

- Lubricants/artificial tears; or
- Topical and systemic steroids and antibiotics; or
- Bandage soft contact lenses; or
- Eye shields; or
- Pressure patching; or
- Surgery (i.e., corneal transplant).

When Policy Topic is not covered

Use of amniotic membrane transplantation for all other indications is considered **not medically necessary**.

Description of Procedure or Service

The objective of amniotic membrane transplantation is to reconstruct damaged ocular surfaces and promote healing of corneal, conjunctival, and eyelid tissues after injury due to trauma, disease, or surgery.

Severe ocular injuries due to trauma or disease degrade the corneal and limbal epithelium, which are essential to the health of the eye. In many cases, the epithelial damage is so extensive that the corneal surface cannot regenerate. The injury may not heal, or non-corneal epithelium may migrate from the periphery of the wound, sometimes resulting in pain, scarring, vascularization, and loss of sight. In addition, there are a number of conditions affecting the conjunctiva and the eyelid that can cause pain, lead to injury to the cornea, and interfere with the normal appearance and function of the eye. Amniotic membrane (AM) has been used on various types of wounds for many years as a biological bandage. Recently, numerous groups have begun to use amniotic membrane transplantation (AMT) as a method for reconstructing damaged ocular surfaces and to promote healing following surgical repair of a variety of conditions of the cornea, conjunctiva, and eyelid. AM 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 during the healing process. In addition, AM does not express histocompatibility antigens, thereby reducing the risk of an immune mediated reaction to the transplanted tissue and decreasing the need for immunosuppressive drugs. The goals of AMT for treatment of ocular conditions are to decrease scarring, reduce inflammation, and restore function and appearance.

Human amniotic membrane that is obtained from cesarean deliveries is used. The tissue is prepared and cryopreserved under sterile conditions. Use of this tissue induces rapid re-epithelialization of corneal epithelium to a good surface for successful reconstruction. Using an operative microscope, any necrotic corneal epithelium is debrided. The preserved amniotic membrane tissue is trimmed to fit the defect area. The membrane must be placed a certain side up and down. The surface of basement membrane cells faces upward and the stromal cell surface is down. The membrane is then sutured into place and the sutures are trimmed and made flush or even below the surface of the corneal epithelium. This process is repeated until all of the thinning areas or defect areas are repaired in line with the surrounding normal-thickness of corneal tissue. The instruments are removed and a topical antibiotic/steroid treated bandage contact lens is placed.

Rationale

A search of the published literature yielded a number of experimental studies, uncontrolled prospective clinical trials, and case series reports describing the use of amniotic membrane transplantation (AMT) for ocular reconstruction and following surgery in patients with a variety of injuries or disorders involving the cornea, the conjunctiva, and/or the eyelid. Study populations included patients with a variety of different ocular disorders; many had failed previous conventional therapy. Outcome measures generally included some objective and some subjective assessments; very few studies provided detailed, quantitative data. Specific outcome measures for corneal conditions included the assessment of visual acuity, degree of epithelization, measures of pain and inflammation, bulbar and fornix depth, stromal integrity, amount of scarring, and overall appearance of the grafted membrane. For studies that evaluated AMT as an adjunct to surgery for conditions of the eyelid, outcome measures included degree of epithelialization, recurrence of condition, cosmetic appearance, tarsal shrinkage, and complications. Follow-up times were variable, and were not always adequate to assess the durability of repair. Most of the studies were small, and the majority of work reported by researchers in the United States was from the Bascom Palmer Eye Institute. One of the researchers associated with this institution holds the patent for the method of preservation and clinical use of AMT and has a financial interest in Bio-Tissue, Inc. (Miami, FL), which is a tissue bank that procures, processes and distributes preserved amniotic membrane for research and clinical uses.

The evidence from the available studies suggests that AMT used alone or as an adjunct to surgery, may promote healing of a variety of corneal disorders. Healing rates in patients with corneal injury or disease ranged between 45% and 100%, with restoration of the corneal surface, and decreased pain, inflammation, scarring, and vascularization reported. In some cases, vision and ocular appearance also improved. The success rates varied, largely due to the extent of ocular damage. AMT was effective as the primary treatment measure in eyes with partial limbal stem cell deficiency; however, eyes with total limbal cell deficiency generally required limbal stem cell transplantation. Study findings suggest that corneal perforations or central corneal melts require penetrating keratoplasty or other surgical measures, although AMT can be used in conjunction with such techniques to stabilize the ocular surface.

AMT also appears to provide benefits for patients who have undergone surgery for removal of a conjunctival or eyelid mass or to correct entropion, or for patients with scarring due to disease, injury, or prior treatment. Success rates for healing varied, depending on the underlying cause and extent of injury.

AMT is generally considered to be a safe procedure. On rare occasions, AM may dissolve prior to corneal epithelization, leading to graft failure. In addition, preexisting corneal perforations may lead to failure of the graft. One study linked repeated transplantation of AM from the same host to subsequent development of hypopyon iritis. This reaction was thought to have been a localized immunologic response, which responded to corticosteroid treatment. Although transplanted tissue is tested for a number of infectious agents and no studies have shown transplant tissue-related infections, the possibility of transmission of infectious agents from the donor tissue to the recipient remains a safety consideration.

No definitive patient selection criteria for the use of AMT for the treatment of ocular disorders have been established. The available evidence suggests that AMT may provide a viable option for patients with severe corneal injuries who have failed to respond to medical treatment and who are not suitable candidates for corneal transplantation. There is also some evidence of benefit for patients following surgical treatment of certain conditions involving the conjunctiva and/or eyelid. However, the most appropriate clinical role for AMT remains to be defined.

References:

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Billing Coding/Physician Documentation Information

65426	Excision or transposition of pterygium; with graft
65778	Placement of amniotic membrane on the ocular surface for wound healing; self-retaining
65779	Placement of amniotic membrane on the ocular surface for wound healing; single layer, sutured
65780	Ocular surface reconstruction; amniotic membrane transplantation, multiple layers
V2790	Amniotic membrane for surgical reconstruction, per procedure

Additional Policy Key Words

N/A

Policy Implementation/Update Information

2/1/06	New policy; considered investigational.
2/1/07	No policy statement changes.
2/1/08	No policy statement changes.
2/1/09	No policy statement changes.
3/15/10	Policy statement revised to indicate this may be medically necessary. The change is effective 3/15/2010.
1/1/11	Coding updated.
2/1/11	No policy statement changes.
2/1/12	No policy statement changes.
2/1/13	No policy statement changes.
2/1/14	No policy statement changes.

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