Keratolimbal Allograft and Amniotic Membrane Transplant

Archived Medical Policy

Archived medical policies are no longer subject to periodic review, are maintained for reference, and may be returned to active status if the need is identified.

Policy # 00079
Original Effective Date: 03/25/2002
Archived Date: 04/19/2006

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services are Considered Investigational:
Note: Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products

Based on review of available data, the Company considers keratolimbal allograft and amniotic membrane transplant for the treatment of ocular conditions to be investigational for all conditions.

Background/Overview
Keratolimbal transplantation involves surgical implantation of viable limbal tissue from either a fellow healthy eye or a donor eye. Resident stem cell population may replenish limbal stem cells and restore corneal surface to normality. Limbal tissue transplantation from multiple sources has been explored including; cadaveric keratolimbal allograft (KLAL), live or living related conjunctival limbal allograft (Ir-CLAL), limbal autograft, and amniotic membrane.

Amniotic membrane transplantation (AMT) is being proposed for the treatment of ocular conditions. AMT is being investigated for use in the restructuring of damaged ocular surfaces and as an aid in the healing of damaged ocular tissues.

Ocular injuries due to trauma or disease degrade the cornea and limbal epithelium, which are needed for healthy eyes. If the damage is extensive, the corneal surface can not regenerate. This can result in non-healing of the eye.

The goal of AMT for the treatment of ocular conditions is to decrease scarring, reduce inflammation, and restore function and appearance.

FDA or other Governmental Regulatory Approval
Food and Drug Administration (FDA):
The FDA has finalized regulations on the manufacture and use of human cells and tissues for clinical use. In this document, it is stated that the use of amniotic tissues for corneal injuries is considered a "nonhomologous use" and therefore it is regulated under the PHS Act (section 361) and the Federal Food, Drug, and Cosmetic Act, which oversees drugs, devices, and biologics. The amniotic membrane tissue must be procured, processed, stored and distributed in accordance with regulatory guidelines.
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Rationale/Source
This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

References

Policy History
Original Effective Date: 3/25/02
Archive Effective Date: 04/19/2006
3/21/02 Medical Policy Committee review
3/25/02 Managed Care Advisory Council approval
6/24/02 Format revision. No substance change to policy
3/09/04 Medical Director review
3/16/04 Medical Policy Committee review. Format revision. No substance change to policy
3/29/04 Managed Care Advisory Council approval
03/01/2006 Medical Director review
03/15/2006 Medical Policy Committee review
04/05/2006 Format revision. FDA information added. No substance change to policy
04/19/2006 Medical Director review
04/19/2006 Medical Policy Committee review. Archived policy
Next Scheduled Review Date: Archived Medical Policy.

*Investigational – A medical treatment, procedure, drug, device, or biological product is investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination We make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other non-affiliated technology evaluation center(s);

2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or

3. reference to federal regulations.

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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.