MEDICAL COVERAGE GUIDELINES
SECTION: VISION

ORIGINAL EFFECTIVE DATE: 04/03/12
LAST REVIEW DATE: 04/15/14
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

CORNEAL COLLAGEN CROSS-LINKING

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Corneal collagen cross-linking (CXL) is a procedure in which about 8mm of the central corneal epithelium is removed under topical anesthesia, followed by an application of a solution with riboflavin (vitamin B_2) to the cornea until the stroma is completely penetrated. The cornea is then irradiated with ultraviolet-A (UVA) along with the continued application of riboflavin. The interaction of riboflavin and UVA causes the formation of reactive oxygen species, leading to additional covalent bonds (cross-linking) between collagen molecules that results in stiffening of the cornea.

CXL has been investigated as a method to stabilize the cornea in patients with progressive keratectasia such as keratoconus and pellucid marginal degeneration. CXL may also have anti-edematous and antimicrobial properties and has been investigated for the treatment of bullous keratopathy and infectious keratitis. No UVA devices have received FDA approval for the treatment of keratoconus.

CORNEAL COLLAGEN CROSS-LINKING (cont.)

Criteria:

- Corneal collagen cross-linking for all indications is considered ***experimental or investigational*** based upon:

  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

Resources:

1. 9.03.28 BCBS Association Medical Policy Reference Manual. Corneal Collagen Cross-linking. Re-issue date 03/14/2013, Issue date 03/08/2012.