Medical Policy
Corneal Collagen Cross-linking

Policy Number: 015

<table>
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<tr>
<th>Authorization required</th>
<th>Commercial and Qualified Health Plans</th>
<th>MassHealth</th>
<th>Medicare Advantage</th>
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Overview
The purpose of this document is to describe the guidelines Mass General Brigham Health Plan utilizes to determine medical appropriateness for corneal collagen cross-linking. The treating specialist must request prior authorization for the procedure.

Coverage Guidelines
Mass General Brigham Health Plan covers corneal collagen cross-linking for the treatment of progressive corneal thinning caused by progressive keratoconus or corneal ectasia following refractive surgery. Mass General Brigham Health Plan will only authorize the epithelium-off corneal collagen cross-linking protocol, as it is currently the only corneal collagen cross-linking approved by the Food and Drug Administration (FDA).

Mass General Brigham Health Plan covers medically necessary corneal collagen cross-linking treatment in the following instances:

1. For members with progressive keratoconus corneal collagen cross-linking is considered medically necessary when all of the following conditions are met:
   a. Diagnosis of keratoconus based on keratometry and corneal mapping; and
   b. Any of the following changes have occurred within 24 months:
      i. increase of 1.00 diopters (D) or more in the steepest keratometry measurement; or
      ii. increase of 1.00 D or more in manifest cylinder; or
      iii. increase of 0.50 D or more in manifest refraction spherical equivalent (MRSE); and
   c. Member is age 14 years or older; and
   d. Corrected distance visual acuity (CDVA) worse than 20/20 with properly fitted spectacles or contact lenses; and
   e. Corneal thickness 300 microns or more; and
   f. No history of corneal or systemic disease that would interfere with healing post-procedure.

2. For members with a diagnosis of corneal ectasia following refractive surgery, corneal collagen cross-linking is considered medically necessary when all of the following conditions are met:
   a. Member is age 14 years or older; and
   b. Consistent axial topography pattern, including relative inferior steepening with inferior-superior difference of at least 1.5 diopters; and
   c. Corrected distance visual acuity worse than 20/20; and
   d. Corneal thickness of at least 300 micrometers at the thinnest area; and
   e. No history of corneal or systemic disease that would interfere with healing post-procedure.

Exclusions
Mass General Brigham Health Plan does not provide coverage for corneal collagen cross-linking for conditions that do not meet the criteria noted above.

Medicare Variation
Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan’s medical policies are used for coverage determinations.

Definitions
**Corneal Collagen Cross-linking:** A procedure used that uses riboflavin drops, ultraviolet light, and a photosensitizer to strengthen bonds in the cornea. Ultraviolet (UV) light is combined with riboflavin eye drops to create new collagen crosslinks in the cornea, strengthening and stabilizing the cornea. The viscous riboflavin solution is applied to the eye topically before and during UV irradiation using the KXL System.

**Ectasia:** A serious long-term complication of laser in situ keratomileusis (LASIK) surgery and photorefractive keratectomy. It is similar to keratoconus but occurs postoperatively and primarily affects older populations.

**Keratoconus:** A bilateral dystrophy characterized by progressive ectasia (paracentral steepening and stromal thinning) that impairs visual acuity. While frequently diagnosed at a young age, the progression of keratoconus is variable.

**Codes**
The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

This list of codes applies to commercial and MassHealth plans only.

<table>
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<tr>
<th>Authorized CPT/HCPCS Codes</th>
<th>Code Description</th>
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<tr>
<td>0402T</td>
<td>Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)</td>
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<td>J2787</td>
<td>Riboflavin 5'-phosphate, ophthalmic solution, up to 3 mL</td>
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**Effective**
November 2023: Annual update. Medicare Advantage added to table.
December 2022: Annual update. Criteria changed under both #1 and #2 to include list of conditions.
October 2018: Effective date.

**References**

Craig JA, Mahon J, Yellowlees A, Barata T, Glanville J, Arber M, Mandava L, Powell J, Figueiredo F. Epithelium-off photochemical corneal collagen cross-linkage using riboflavin and ultraviolet a for keratoconus and keratectasia:


Tian, Mingxia MS a; Ma, Ping MD b; Zhou, Weiyan MD b; Feng, Jie MS a; Mu, Guoying MD. Outcomes of corneal crosslinking for central and paracentral keratoconus. Medicine. March 2017 96:10(e6247)
