

## **Corneal Collagen Cross-linking for Treatment of Keratoconus**

Dates Reviewed: 06/2018, 06/2019, 06/2020, 06/2021, 05/2022, 06/2023

**Developed By:** Medical Necessity Criteria Committee

## I. Description

Keratoconus is a noninflammatory disorder of the cornea of unknown etiology. It is characterized by progressive thinning and cone-shaped protrusion of the cornea leading to visual impairment. Patients present with blurry vision or a sudden decrease in visual acuity.

Treatment options include spectacle correction if visual acuity is functional. Rigid gas-permeable contact lenses can be used for extended periods of time that smooth out the irregularity of the cornea. These become intolerable to wear for the patient. Surgical interventions include the placement of intrastromal corneal ring segments or keratectomy. Keratoplasty is the most common surgical procedure with a success rate of greater than ninety percent.

Corneal collagen cross-linking is recommended for the management of keratoconus or ectasia after refractive surgery. It has been shown to slow the progression by strengthening collagen fibers. It is a procedure that uses riboflavin drops, ultraviolet light, and a photosensitizer to strengthen bonds in the cornea. In a prospective randomized controlled study of over 200 patients comparing collagen cross-linking to riboflavin drops alone, improvements in maximum keratometry value and directed and uncorrected distance visual acuity were improved in the treatment group at one year. Earlier trials and cohort studies of collagen cross-linking demonstrated flattening of the cornea and improvement in visual, topographic, and wavefront parameters that were maintained up to seven years.

#### II. Criteria: CWQI HCS-0231

- A. Moda Health considers corneal collagen cross-linking (CXL) medically necessary with ALL of the following:
  - a. The patient has a diagnosis of progressive keratoconus or corneal keratectasia following refractive surgery.
  - b. The requested procedure is for epithelium-off photochemical collagen cross-linkage using riboflavin (HCPC: J2787- Avedro's Photrexa) and ultraviolet A.
  - c. The requested procedure is **NOT** for epithelium-on collagen cross-linkage. This is considered experimental and investigational for all indications.
  - d. The requested procedure is **ONLY** indicated for the above diagnoses. All other indications are considered experimental and investigational.

## III. Information Submitted with the Prior Authorization Request:

- 1. Chart notes with documentation of diagnosis
- 2. Description of procedure and type of collagen cross-link to be used.

#### IV. CPT or HCPC codes covered:

| Codes | Description   |  |
|-------|---|--|
| 0402T | Collagen cross-linking of cornea (including removal of the corneal epithelium and |  |
|       | intraoperative pachymetry when performed)   |  |
| J2787 | Avedro's Photrexa   |  |

### V. Annual Review History

| Review Date | Revisions  | Effective Date |
|-------------|--|----------------|
| 06/2018     | New criteria   | 07/01/2018     |
| 06/2019     | Annual Review: Updated permanent code J2787                | 07/01/2019     |
| 06/2020     | Annual Review: No content change                           | 07/01/2020     |
| 06/2021     | Annual Review: No content change                           | 07/01/2021     |
| 05/2022     | Annual Review: No content change                           | 06/01/2022     |
| 06/2023     | Annual Review: Grammar updates, update wording             | 07/01/2023     |
|             | 'progressive' keratoconus, 'corneal keratectasia following |                |
|             | refractive surgery'.                                       |                |

#### VI. References

- 1. WebMD: Corneal Cross-Linking (CXL) Treatment for Keratoconus Explained; https://www.webmd.com/eye-health/corneal-cross-linking-for-keratoconus
- 2. Celia Vimont, Devin A Harrison MD; Corneal Collagen Cross-linking Approved to Treat Keratoconus in U.S.; © American Academy of Ophthalmology 2018; Aug.01, 2016; <a href="https://www.aao.org/eye-health/news/cross-linking-approved-keratoconus-united-states">https://www.aao.org/eye-health/news/cross-linking-approved-keratoconus-united-states</a>
- 3. American Optometric Association, 243 N. Lindbergh Blvd., St. Louis, MO 63141
- Sykakis E , Karim R, Evans JR, Bunce C, Amissah-Arthur KN, Patwary S, McDonnell PJ, Hamada S.; Corneal collagen cross-linking for treating keratoconus. Cochrane Database Syst Rev. 2015 Mar 24;(3):CD010621. doi: 10.1002/14651858.CD010621.pub2; https://www.ncbi.nlm.nih.gov/pubmed/25803325
- 5. Centers for Medicare & Medicaid Services (CMS), Healthcare Common Procedure Coding System, (HCPCS), Public Meeting Agenda, Drugs, Biologicals and Radiopharmaceuticals, Wednesday, May 17, 2017 9:00 am 5:00 pm, CMS Auditorium, 7500 Security Boulevard, Baltimore (Woodlawn), Maryland 21244-1850
- 6. American Academy of Ophthalmology, Practice Management/Coding/Aske the Coding Experts/News; How to Bill for Corneal Cross-Linking, February 23, 2018; https://www.aao.org/practice-management/news-detail/how-to-bill-corneal-cross-linking

- Liz Hillman EyeWorld, Current Issue Educational Events Ophthalmology news -OPHTHALMOLOGY BUSINESS - Crosslinking paperwork: Clearing up confusion August 2017; Source: https://www.eyeworld.org/
- 8. Keratoconus. Retrieved 2023 from https://www.uptodate.com/contents/keratoconus?search=corneal%20collagen%20cross%20lin king&source=search result&selectedTitle=1~150&usage type=default&display rank=1

## Appendix 1 – Applicable Diagnosis Codes:

| Codes   | Description                               |
|---------|---|
|         | ·   |
| H18.60  | Keratoconus, unspecified                  |
| H18.601 | Keratoconus, unspecified, right eye       |
| H18.602 | Keratoconus, unspecified, left eye        |
| H18.603 | Keratoconus, unspecified, bilateral       |
| H18.609 | Keratoconus, unspecified, unspecified eye |
| H18.611 | Keratoconus, stable, right eye            |
| H18.612 | Keratoconus, stable, left eye             |
| H18.613 | Keratoconus, stable, bilateral            |
| H18.619 | Keratoconus, stable, unspecified eye      |
| H18.62  | Keratoconus, unstable                     |
| H18.621 | Keratoconus, unstable, right eye          |
| H18.622 | Keratoconus, unstable, left eye           |
| H18.623 | Keratoconus, unstable, bilateral          |
| H18.629 | Keratoconus, unstable, unspecified eye    |
| H18.7   | Other and unspecified corneal deformities |
| H18.70  | Unspecified corneal deformity             |
| H18.71  | Corneal ectasia                           |
| H18.711 | Corneal ectasia, right eye                |
| H18.712 | Corneal ectasia, left eye                 |
| H18.713 | Corneal ectasia, bilateral                |
| H18.719 | Corneal ectasia, unspecified eye          |
| H18.79  | Other corneal deformities                 |
| H18.791 | Other corneal deformities, right eye      |
| H18.792 | Other corneal deformities, left eye       |
| H18.793 | Other corneal deformities, bilateral      |
| H18.719 | Corneal ectasia, unspecified eye          |

# Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <a href="http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx">http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx</a>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

| Jurisdiction(s): 5, 8 | NCD/LCD Document (s): |
|-----------------------|-----------------------|
| NA                    |                       |
|                       |                       |

# NCD/LCD Document (s):

NA

| Medicare Part B Administrative Contractor (MAC) Jurisdictions |  |                                    |  |  |
|---|--|------------------------------------|--|--|
| Jurisdiction  | Applicable State/US Territory          | Contractor                         |  |  |
| F (2 & 3)   | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC |  |  |