RMHP Corneal Collagen Crosslinking

AUTH: RMHP-AC-5089 (AC)

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Description

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The main objective of corneal collagen crosslinking (CXL) is to achieve strengthening of corneal tissue as a means to stop further progression of keratoconus or corneal ectasia. In order to induce cross-links within and between collagen fibers of corneal stroma, long-wave ultraviolet A (UVA) radiation (370 nm) is used combined with a chromophore (riboflavin, vitamin B2). Riboflavin acts as photosensitizer that when exposed to UVA is activated, producing oxygen free radicals that initiate the creation of those new covalent bonds bridging the amino groups of collagen fibrils and possibly other corneal macromolecules such as proteoglycans and nucleic acids. This photopolymerization process results in the increased rigidity of corneal tissue (Galvis et al., 2017). This procedure aims to decrease progressive visual loss due to the evolution of the pathology and delay or avoid invasive surgical procedures such as corneal transplantation (Mastropasqua, 2015).

Clinical Indications for Procedure

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For **PRIME (Medicaid)** and **CHP+** Members, Corneal Collagen Crosslinking is **not a benefit** per Colorado Department of Health Care Policy and Financing (HCPF) guidance.

RMHP considers photochemical collagen cross-linkage experimental and investigational for all other indications because its effectiveness for other indications has not been established.

RMHP considers epithelium-on (transepithelial) collagen cross-linkage experimental and investigational for keratoconus, keratectasia, and all other indications.

RMHP considers performance of photochemical collagen cross-linking in combination with other procedures (CXL-plus) (e.g., intrastromal corneal ring segments, PRK or phakic intra-ocular lens implantation) experimental and investigational.

- The Member has **RMHP Individual and Family Plan (IFP) Commercial** or **Medicare (CareAdvantage or Dual Special Needs Plan (DSNP)** health plan coverage and both progressive keratoconus and progressive corneal ectasia and **ALL** of the following
    - The request is for epithelium-off corneal collagen crosslinking using riboflavin and ultraviolet A light. NOTE: All other indications are considered experimental and investigational. See Reviewer Guidance.
    - The Member has tried and failed conservative treatments (either corrective spectacles or rigid contact lenses).

Evidence Summary

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Keratoconus and post-refractive corneal ectasia are diseases of the cornea for which there limited therapeutic options; the condition is associated with changes in visual function including visual acuity. Initially these ectatic conditions may be managed with glasses and contacts, in some patients corneal transplantation is used as a last measure. The current application includes 3 controlled clinical studies demonstrating that the corneal collagen crosslinking procedure (CCXL) using riboflavin and UVA light over the course of an approximately 60 minute procedure is effective in reducing the corneal curvature, as measured by Kmax. In the corneal ectasia studies, the primary endpoint of reducing the Kmax by 1 diopter was achieved at Month 3 and maintained at Month 6 and Month 12, compared to sham controls. In the keratoconus studies, the same primary endpoint was achieved at Month 6 and Month 12. The adverse events associated with this procedure include corneal opacity (haze), corneal epithelial defects, and other ocular findings related to the procedure which consists of corneal epithelial removal, riboflavin instillation followed by UV light illumination. Most of the adverse events resolve in the first month, however, some continue for 6 to 12 months, and 1-6% of patients continue to report corneal haze and other symptoms at Month 12. This process results in CCXL in the corneal stroma, thereby stabilizing the cornea. Efficacy - If ophthalmologists are trained in performing the procedure and manage patients accordingly, including pre- and post-CCXL care, the benefits of the procedure outweigh the risks of the procedure in this population in whom this treatment addresses an unmet medical need.

See U.S. Food and Drug Administration - https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/203324orig2s000sumr.pdf

Reviewer Guidance

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PRIME Medicaid and CHP+ plans: 0402T is categorized as **not a benefit** on the current Health First Colorado Fee Schedule, July 2023, reviewed 10/12/2023.

Medicare (CareAdvantage and Dual Special Needs Plan (DSNP) plans: apply this medical necessity guideline terms, limitations, and exclusions. 0402T is status C, "Carriers price the code. Carriers will establish RVUs and payment amounts for these services, generally on an individual case basis following review of documentation such as an operative report" per the Medicare Physician Fee Schedule for Colorado entire state, reviewed 10/12/2023.

Individual and Family Plan (IFP) Commercial plans: apply this medical necessity guideline terms, limitations, and exclusions for 0402T.

Note: Progressive keratoconus or corneal ectasia is defined as one or more of the following: • An increase of 1 diopter (D) in the steepest keratometry value; • An increase of 1 D in regular astigmatism evaluated by subjective manifest refraction; • A myopic shift (decrease in the spherical equivalent) of 0.50 D on subjective manifest refraction; • A decrease =0.1 mm in the back optical zone radius in rigid contact lens wearers where other information was not available.

Relevant related HCPCS codes are J2186 and J2787

For all RMHP plans, use this guideline, which overrides similar MCG 27th edition Corneal Cross-Linking ACG: A-1040 (AC).

References

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U.S. Food and Drug Administration https://www.fda.gov/ https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/203324orig2s000sumr.pdf, reviewed 10/12/2023.

Colorado Department of Healthcare Policy and Financing (HCPF), Provider Rates and Fee Schedules, the current Health First Colorado Fee Schedule, July 2023, reviewed 10/13/2023.

Novitas Solutions Medicare Jurisdiction H (Providers in AR, CO, LA, MS, NM, OK, TX, Indian Health & Veteran Affairs) Part B Fee Physician's Fee Schedule, reviewed 10/13/2023.

National Institute for Health and Care Excellence (NICE). Photochemical corneal collagen cross-linkage using riboflavin and ultraviolet A for keratoconus and keratectasia [IPG466]. 2013; https://www.nice.org.uk/guidance/ipg466. Accessed 10/13/2023.

MCG 27th edition Corneal Cross-Linking ACG: A-1040 (AC).

Policy History

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History Summary: Policy created 1/26/2021 with annual review and approval by committee hierarchy thereafter. See archived versions for details. Annual review 10/13/2023.

Codes

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