PROVIDER POLICIES & PROCEDURES

CORNEAL COLLAGEN CROSS-LINKING

The primary purpose of this policy is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for corneal collagen cross-linking. By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

Corneal collagen cross-linking (CXL) is a procedure used to treat progressive keratoconus and corneal ectasia. Ultraviolet (UV) light is combined with riboflavin eye drops to create new collagen crosslinks in the cornea, strengthening and stabilizing the cornea and delaying the progression of deformation associated with keratoconus. The viscous riboflavin solution is applied to the eye topically before and during UV irradiation.

In epithelium-off cross linking, the epithelium is removed. Riboflavin eye drops are applied to the corneal surface before the procedure to enable penetration into the corneal tissue and then every 3-5 minutes during the procedure. The corneal surface is exposed to UVA radiation, usually for up to 30 minutes. Currently, the only CXL treatment approved by the FDA is the epithelium-off method.

In epithelium-on (transepithelial) cross linking, the corneal epithelial surface is left intact, which requires a longer riboflavin loading time. There are currently no FDA-approved CXL treatments using the epithelium-on method.

CLINICAL GUIDELINE

Coverage guidelines for CXL are made in accordance with the CT Department of Social Services (DSS) definition of Medical Necessity. The following criteria are guidelines *only*. Coverage determinations are based on an assessment of the individual and their unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

Epithelium-off photochemical CXL using riboflavin and ultraviolet A may be considered medically necessary for treatment of progressive keratoconus or corneal ectasia following refractive surgery when conservative treatment (e.g., spectacle correction, rigid contact lens) has been tried without success and the individual does not have either of the following contraindications: a corneal thickness of fewer than 400 microns or a prior herpetic ocular infection.

Progressive keratoconus or corneal ectasia is defined as one or more of the following:

1. An increase of 1 diopter (D) in the steepest keratometry value; or
2. An increase of 1 D in regular astigmatism evaluated by subjective manifest refraction; or

3. A myopic shift (decrease in the spherical equivalent) of 0.50 D on subjective manifest refraction; or
4. A decrease ≥ 0.1 mm in the back optical zone radius in rigid contact lens wearers where other information was not available.

Epithelium-on (transepithelial) CXL is considered *experimental and investigational* for keratoconus, keratectasia and all other indications and therefore *not* medically necessary.

CXL is considered *experimental and investigational* in all other situations including, but not limited to treatment of infectious keratitis and in combination with other procedures (e.g., intrastromal corneal ring segments, PRK or phakic intra-ocular lens implantation) and therefore *not* medically necessary.

EPSDT Special Provision
Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

PROCEDURE
Prior authorization of CXL is required. Requests for coverage will be reviewed in accordance with the processes in place for reviewing requests for surgical procedures. Coverage determinations will be based upon a review of requested and/or submitted case-specific information.

The following information is needed to review requests for CXL:
A. Fully completed Corneal Collagen Cross-Linking Prior Authorization Request Form; and
B. Other information as requested by CHNCT.

EFFECTIVE DATE
This Policy is effective for prior authorization requests for CXL for individuals covered under the HUSKY Health Program beginning July 1, 2019.

LIMITATIONS
N/A

CODES:

Code	Definition
66999	Unlisted procedure, anterior segment of eye
J3490	Unclassified drugs

DEFINITIONS

1. **HUSKY A**: Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
2. **HUSKY B**: Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
3. **HUSKY C**: Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
4. **HUSKY D**: Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
5. **HUSKY Health Program**: The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
6. **HUSKY Limited Benefit Program or HUSKY, LBP**: Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
7. **Medically Necessary or Medical Necessity**: (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B)recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.
8. **Prior Authorization**: A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

ADDITIONAL RESOURCES AND REFERENCES:

- Avedro Inc. Photorexa® Viscous and Photorexa® Prescribing Label. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/203324s000lbl.pdf. Accessed on March 11, 2019
- Center for Drug Evaluation and Research: FDA. Summary Review: Application Number 203324Orig2s000. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/203324Orig2s000SumR.pdf. Accessed on March 11, 2019.
- Hersh PS, Stulting RD, Muller D, et al. United States Multicenter Clinical Trial of Corneal Collagen Crosslinking for Keratoconus Treatment. Opthalmology 2017; 124:1259.

- National Institute for Health and Care Excellence (NICE). Photochemical corneal collagen cross-linkage using riboflavin and ultraviolet A for keratoconus: A systematic Review. 2013. Available at: https://www.nice.org.uk/guidance/ipg466/evidence/photochemical-corneal-collagen-crosslinkage-using-riboflavin-and-ultraviolet-a-for-keratoconus-systematic-review-pdf-366211981. Accessed on March 12, 2019
- National Library of Medicine, StatPearls 2023, Collagen Cross Linking for Keratoconus. Vishal Vohra, Sahib Tuteja, Bharat Gurnani, and Harshika Chawla
- O'Brart DP, Patel P, Lascaratos G, et al. Corneal Cross-linking to Halt the Progression of Keratoconus and Corneal Ectasia: Seven-Year Follow-up. Am J Opthalmol 2015; 160:1154.
- Wayman L. (2018). Keratoconus. In J. Trobe (Ed.). UpToDate. Retrieved from https://www.uptodate.com/contents/search

PUBLICATION HISTORY

Status	Date	Action Taken
Original Publication	April 2018	Approved at the April 10, 2019 Medical Reviewer meeting. Approved by the CHNCT Clinical Quality Subcommittee on June 19, 2019. Approved by DSS on June 21, 2019.
Update	August 2019	Removed codes 0402T and J2787 from the *Codes* section. Codes are not payable under the Connecticut HUSKY Health program. Change approved by DSS on August 8, 2019.
Reviewed	August 2020	Reviewed and approved without changes at the August 12, 2020 Medical Reviewer meeting. Reviewed and approved without changes by the CHNCT Clinical Quality Subcommittee on September 21, 2020. Approved by DSS on October 7, 2020.
Reviewed	September 2021	Reviewed and approved without changes at the August 11, 2021 Medical Reviewer meeting. Reviewed and approved without changes by the CHNCT Clinical Quality Subcommittee on September 20, 2021. Approved by DSS on September 30, 2021.
Reviewed	September 2022	Reviewed and approved without changes at the July 13, 2022 CHNCT Medical Reviewer meeting. Reviewed and Approved without changes by the CHNCT Clinical Quality Subcommittee on September 19, 2022. Approved by DSS on September 28, 2022.
Updated	September 2023	Update to Clinical Guideline section: added "the individual does not have either of the following contraindications: a corneal thickness of fewer than 400 microns or a prior herpetic ocular infection" to criteria. Change reviewed and approved at the July 12, 2023, CHNCT Medical Reviewer meeting. Change approved by the CHNCT Clinical Quality Subcommittee on September 18, 2023. Approved by DSS on October 2, 2023.