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The Department of Vermont Health Access Clinical Criteria

Subject: Corneal Collagen Cross-linking Last Review: November 8, 2023* Past Revisions: April 5, 2022, August 7, 2020, July 1, 2018

*Please note: Most current content changes will be highlighted in yellow.

Description of Service or Procedure

Corneal collagen cross-linking (CXL) is a minimally invasive procedure to treat progressive keratoconus and corneal ectasia after refractive surgery. CXL can strengthen the cornea to stop keratoconus progression, protecting vision and delaying or eliminating corneal transplant. This procedure involves removing approximately 8 mm of the central corneal epithelium to allow for good diffusion of riboflavin which is a photosensitizer into the stroma. Riboflavin solution is then applied frequently for 30 minutes until the stroma is completely penetrated. The cornea is then exposed to ultraviolet light for 30 minutes while riboflavin continues to be applied. This process induces cross-links within and between collagen fibers of corneal stroma. This photopolymerization process increases the rigidity of the corneal tissue helping the cornea retain its shape.

Disclaimer

Coverage is limited to that outlined in Medicaid Rule or Health Care Administrative Rules that pertains to the member's aid category. Prior Authorization (PA) is only valid if the member is eligible for the applicable item or service on the date of service.

Medicaid Rule

Medicaid and Health Care Administrative Rules can be found at <u>https://humanservices.vermont.gov/rules-policies/health-care-rules/health-care-administrative-rules-hcar/adopted-rules</u>

- 7102.2 Prior Authorization Determination
- 4.101 Medical Necessity for Covered Services
- 4.104 Medicaid Non-Covered Services
- 4.106 Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services



Coverage Position

Corneal collagen cross-linking may be covered for members:

- When the procedure is prescribed by a licensed ophthalmologist enrolled in the Vermont Medicaid program, operating within their scope of practice as described on the Vermont Office of Professional Regulation's website*, Statute, or rule who is knowledgeable regarding corneal collagen-cross linking, and who provides medical care to the member AND
- When the clinical criteria below are met.

* Vermont's Office of Professional Regulation's website: <u>https://sos.vermont.gov/opr/</u>

Coverage Criteria

Corneal collagen cross-linking may be considered medically necessary as a treatment of progressive keratoconus or corneal ectasia after refractive surgery for members when:

- 1. The individual has failed conservative treatment (e.g., spectacle correction, rigid contact lens and/or surgical interventions) **AND**
- 2. The individual does not have active herpes simplex virus (HSV) or history of (HSV) keratitis, thin corneas, or corneal hydrops, concurrent ocular infection, severe corneal scarring or opacification, history of poor epithelial wound healing, an autoimmune disorder or currently pregnant **AND**
- 3. The individual has one or more of the following on exam:
 - a. An increase of at least one diopter in the steepest keratometry value,
 - b. An increase of at least one diopter in regular astigmatism evaluated by subjective manifest refraction,
 - c. A myopic shift (decrease in the spherical equivalent) of 0.50 diopter on subjective manifest refraction, **OR**
 - d. A decrease of ≥ 0.1 mm in the black optical zone radius in rigid contact lens wearers where other information was not available
- 4. The individual has deterioration in vision, such that adequate functional vision on a daily basis with contact lenses or glasses can no longer be achieved
- 5. The individual has a diagnosis of keratoconus or corneal ectasia

Note: Procedure codes 0402T (collagen cross-linking of cornea) and J2787 (Riboflavin) both require prior authorization.

Early and Periodic Screening, Diagnostic and Treatment (EPSDT) exception: Vermont Medicaid will provide comprehensive services and furnish all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions for Medicaid members under age 21.

Please note, Vermont Medicaid Clinical Criteria is reviewed based on available literature, evidence- based guidelines/standards, Medicaid rule and policy, and Medicare coverage determinations that may be appropriate to incorporate when applicable.

Clinical criteria for repeat service or procedure

Repeat corneal collagen cross-linking will be based on <u>Health Care Administrative Rule (HCAR)</u> <u>4.101 - Medical Necessity for Covered Services</u>

Type of service or procedure not covered (this list may not be all inclusive)

Corneal collagen cross-linking is experimental and investigational for all other uses.

Corneal collagen cross-linking for the treatment of other conditions/diseases, including use of the epithelium-on (epi-on or transepithelial) method, is considered investigational.

References

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- Hayes, Inc. Health Technology Assessment. *Comparative Effectiveness of Corneal Cross-Linking for Treatment of Keratoconus*. Landsdale, PA: Hayes, Inc.; January 2022.
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