BlueCross BlueShield of Alabama

Name of Policy:
Corneal Collagen Cross-Linking

Policy #:639
Category: Medical

Latest Review Date: April 2017
Policy Grade: A

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
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 that patient's illness, injury or disease.*

Description of Procedure or Service:

Corneal collagen cross-linking (CXL) is a photochemical procedure approved by the Food and Drug Administration for the treatment of progressive keratoconus and corneal ectasia. Keratoconus is a dystrophy of the cornea characterized by progressive deformation (steepening) of the cornea while corneal ectasia is keratoconus that occurs after refractive surgery. Both lead to functional loss of vision and need for corneal transplantation.

Keratoconus and Ectasia

Keratoconus is 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. Results from a longitudinal study with 7 years of follow-up showed that, over the study period, there was a decrease of 2 high- and 4 low-contrast letters in best-corrected visual acuity (BCVA). About 1 in 5 patients showed a decrease of 10 or more letters in high-contrast visual acuity and one-third of patients showed a decrease of 10 or more letters in low-contrast visual acuity. Over 8 years of follow-up, there was a mean increase of 1.44 diopters (D) in First Definite Apical Clearance Lens (a rigid contact lens to measure corneal curvature) and 1.6 D in flatter keratometric reading.

Ectasia (also known as keratectasia, iatrogenic keratoconus, or secondary keratoconus) is 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. It may result from unrecognized preoperative keratoconus or, less frequently, from the surgery itself. Similar to keratoconus, it is characterized by progressive thinning and steepening of the cornea, resulting in corneal optical irregularities and loss of visual acuity.

Treatment

The initial treatment for keratoconus often consists of hard contact lenses. A variety of keratorefractive procedures have also been attempted, broadly divided into subtractive and additive techniques. Subtractive techniques include photorefractive keratectomy or laser in situ keratomileusis (LASIK), although generally, results of these techniques have been poor. Implantation of intrastromal corneal ring segments is an additive technique in which the implants are intended to reinforce the cornea, prevent further deterioration, and potentially obviate the need for penetrating keratoplasty. Penetrating keratoplasty (i.e., corneal grafting) is the last line of treatment. About 20% of patients with keratoconus will require corneal transplantation. All of these treatments attempt to improve the refractive errors, but are not disease-modifying.

Treatment options for ectasia include intraocular pressure-lowering drugs, and intracorneal ring segments. Frequently, a penetrating keratoplasty is required. None of the currently available treatment options for keratoconus and corneal ectasia halt the progression of disease and corneal transplantation is the only option available when functional vision can no longer be achieved.

Corneal collagen cross-linking (CXL) has the potential to slow the progression of disease. It is performed with the photosensitizer riboflavin (vitamin B2) and ultraviolet A (UVA) irradiation. There are 2 protocols for CXL.

1. Epithelium-off CXL (also known as "epi-off"): In this method, about 8 mm of the central corneal epithelium is removed under topical anesthesia to allow better diffusion of the photosensitizer riboflavin into the stroma. Following de-epithelialization, a solution with riboflavin is applied to the cornea (every 1-3 minutes for 30 minutes) until the stroma is completely penetrated. The cornea is then irradiated for 30 minutes with ultraviolet A 370 nm, a maximal wavelength for absorption by riboflavin, while the riboflavin continues to be applied. The interaction of riboflavin and UVA causes the formation of reactive oxygen species, leading to additional covalent bonds (cross-linking) between collagen molecules, resulting in stiffening of the cornea. Theoretically, by using a homogeneous light source and absorption by riboflavin, the structures beyond a 400-micron thick stroma (endothelium, anterior chamber, iris, lens, retina) are not exposed to an ultraviolet dose that is above the cytotoxic threshold.
2. Epithelium-on CXL (also known as "epi-on" or transepithelial): In this method, the corneal epithelial surface is left intact (or may be partially disrupted) and a longer riboflavin loading time is needed.

Currently, the only CXL treatment approved by the Food and Drug Administration (FDA) is the epithelium-off method. There are no FDA-approved CXL treatments using the epithelium-on method. CXL is being evaluated primarily for corneal stabilization in patients with progressive corneal thinning, such as keratoconus and corneal ectasia following refractive surgery. CXL may also have anti-edematous and antimicrobial properties.

Policy:

Effective for dates of service on or after April 26, 2017:

Corneal collagen cross-linking using riboflavin and ultraviolet A, **meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage for treatment of progressive keratoconus in patients who have failed conservative treatment (e.g. spectacle correction, rigid contact lens).

Progressive keratoconus is defined as **1 or more** of the following:

- An increase of 1 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.

Corneal collagen cross-linking using riboflavin and ultraviolet A **does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational** for all other indications.

Blue Cross and Blue Shield of Alabama **will not cover** complications or later procedures/surgery, even if medically necessary, related to the treatment of corneal ectasia following refractive surgery **(LASIK)** which is a **benefit exclusion**.

Effective for dates of service prior to April 26, 2017:
Corneal collagen cross-linking does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational** for all indications.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

This evidence review was originally created in March 2012 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through January 25, 2017.

Corneal Collagen Cross-Linking for Keratoconus

Randomized Controlled Trials

Wittig-Silva et al reported the first RCT of corneal CXL in 2008. Three-year results were published in 2014. Recruitment for the trial was completed in 2009 with 50 eyes were randomized to CXL treatment and 50 eyes to untreated control. To be eligible for enrollment, clear evidence of progression of ectasia over the preceding 6 to 12 months was required. Progression was confirmed if at least 1 of the following criteria was met: an increase of at least 1 D in the steepest simulated keratometry reading (Kmax); an increase in astigmatism determined by manifest subjective refraction of at least 1 D; an increase of 0.50 D in manifest refraction spherical equivalent; or a 0.1-mm or more decrease in back optic zone radius of the best-fitting contact lens. At the time of analysis for the 2008 report, 20 eyes had reached 1-year follow-up. The 3-year results included 46 CXL-treated and 48 control eyes. LOCF was used for 26 eyes, including 17 eyes from the control group with progressive disease that underwent compassionate-use CXL or corneal transplantation. In the CXL group, there was a flattening of Kmax by -1.03 D, compared with an increase in Kmax of 1.75 in the control group. One eye in the CXL group progressed by more than 2 D, compared with 19 eyes in the control group. Uncorrected visual acuity (UCVA) and best-corrected visual acuity (BCVA) improved in the CXL-treated eyes at 1, 2, and 3 years. In control eyes, UCVA was significantly reduced at 36 months ($p=0.034$) and there was a trend of a decrease in BCVA ($p=0.10$). The difference between groups in UCVA was significant ($p<0.001$). Follow-up is continuing through 5 years.

In 2010, Renesto et al reported 2-year results of a randomized trial that compared CXL to 1 month of riboflavin eye drops in 39 eyes of 31 patients with keratoconus. After 3 months, all patients received intrastromal corneal ring segments. Patients were evaluated at 1 and 3 months after treatment with CXL or riboflavin, and then at 1, 3, 6, 12, and 24 months after ICRS insertion. There were no significant differences between the 2 groups for UCVA, BCVA, or in 3 topographic parameters (flattest K, steepest K, and average keratometry) throughout the 24-month follow-up.

Systematic Reviews

A Cochrane review on the use of corneal CXL for the treatment of keratoconus was published in 2015. The literature search was conducted in August 2014 and did not include all of the phase 3 trials that were submitted to FDA (described previously). Reviewers included 3 small RCTs conducted in Australia, the United Kingdom, and the United States, which enrolled a total of 225 eyes and analyzed 219 eyes. All 3 trials were at high risk for performance bias (lack of masking), detection bias (only 1 trial attempted to mask outcome assessment), and attrition bias (incomplete follow-up). Reviewers did not conduct a meta-analysis due to differences in measuring and reporting outcomes. The overall quality of the evidence was judged to be very low, primarily due to downgrading the evidence due to risk of bias in the included studies, imprecision, indirectness, and publication bias.

In 2016, Meri et al reported results of a systematic review and meta-analysis of ocular functional and structural outcomes in patients with keratoconus who underwent CXL treatment. Reviewers reported a modest but statistically nonsignificant improvement in visual acuity of 1 to 2 Snellen lines at 3 months or more after undergoing CXL. Reviewers concluded that, although CXL appeared to be effective at halting the deterioration of keratoconus, it was only slightly effective at improving visual acuity.

McAnena et al (2016) reported results of a systematic review and a meta-analysis assessing the efficacy of CXL treatment for keratoconus in pediatric patients. A total of 13 articles, published between May 2011 and December 2014, examining 490 eyes of 401 patients (mean age, 15.25 years), were included in the meta-analysis. Bias assessment of individual studies was not included. Reviewers reported a significant improvement in BCVA at 6 months (standardized mean difference [SMD], -0.66; 95% confidence interval [CI], -1.22 to -0.11; p=0.02), which was maintained at 1 year (SMD = -0.69; 95% CI, -1.15 to -0.22; p<0.01). Two-year data were available for 3 studies (n=131 eyes) and the improvement in BCVA remained significant (SMD= -1.03; 95% CI, -2 to -0.06; p=0.04).

Uncontrolled Studies

Longer term follow-up is being reported from Europe, where corneal CXL has been performed for a greater number of years. Indications for treatment typically include progression of steepening (increase in Kmax by at least 1 D in 1 year), deteriorating visual acuity, or the need to be fitted for new contact lenses more than once in 2 years. The largest and longest series to date are described next.

In 2008, Raiskup-Wolf et al reported outcomes of 241 eyes (272 patients) treated with CXL, with a minimum of 6 months of follow-up. Follow-up examinations were performed at 1, 6, and

12 months, and then annually. Mean follow-up was 26 months, with a range of 12 months (n=142) to 6 years (n=5). In the first year (n=142), steepening (Kmax) improved or remained stable in 86% of eyes, and BCVA improved by at least 1 line in 53% of the eyes. Three years after treatment (n=33), Kmax improved by a mean of 2.57 D in 67% of eyes while BCVA improved by at least 1 line in 58% of eyes.

A 2010 publication from the Siena Eye Cross Study reported 52-month mean follow-up (range, 48-60 months) for 44 keratoconic eyes treated with CXL. Follow-up evaluations were performed at 1, 2, 3, 6, 12, 24, 36, 48, and 60 months after CXL. Topographic analysis showed the following mean K reading reductions: -1.96 D after 1 year, -2.12 D after 2 years, -2.24 D after 3 years, and -2.26 D after 4 years of follow-up. By comparison, in fellow eyes untreated for the first 24 months, the mean K value increased by 1.2 D at 1 year and 2.2 D at 2 years. In treated eyes, UCVA improved by a mean of 2.41 lines after 12 months, 2.75 lines after 24 months, 2.80 lines after 36 months, and 2.85 lines after 48 months. There was no significant decrease in endothelial cell density, central corneal thickness, or intraocular pressure over follow-up. Temporary adverse effects included stromal edema in the first 30 days (70% of patients) and temporary haze (9.8% of patients). No persistent adverse effects were observed.

The French National Reference Center for Keratoconus published their findings in 2011. Of 142 eyes enrolled in the study, 6-month follow-up was available for 104 (73%) and 12-month follow-up was available for 64 (45%). At 12 months after treatment, the BCVA had stabilized in 48% of eyes, improved in 40%, and decreased in 12%. Keratoconus progression had stopped in 69%, and Kmax had decreased by more than 2 D in 21% of eyes. There was a 7% complication rate in the total sample, with 5 eyes (3.5% of 142 or 7.8% of 64) losing 2 or more Snellen lines of visual acuity. This retrospective study had a low proportion of patients available at the 12-month follow-up.

A 2012 publication from the Siena CXL Pediatrics trial reported 12- to 36-month follow-up after CXL in 152 patients ages 18 years or younger with keratoconus progression. Visual acuity increased by an average of 0.15 Snellen lines, whereas a clinically relevant change is generally considered to be 2 Snellen lines.

In 2015, the same group published 10-year follow-up of CXL treatment in 34 eyes (24 patients) with progressive keratoconus. Mean patient age at the time of treatment was 28 years (range, 14-42 years). Corneal steepening improved slightly between baseline and 10-year follow-up ($p<0.001$), while corrected distance visual acuity improved by 0.14 logMAR ($p=0.002$). Two eyes had repeat CXL, one after 5 years and one after 10 years, without adverse sequelae. One of the 34 eyes treated developed a permanent corneal scar. These studies are limited by their retrospective designs and the small number of cases with extended follow-up.

In 2016, Padmanabhan et al retrospectively analyzed 377 eyes of 336 patients (mean age, 15 years) who underwent CXL for progressive keratoconus. There was significant improvement in mean BSCVA from 0.33 to 0.27 logMAR ($p<0.05$). The authors found that the benefits of CXL in stabilizing keratoconus were maintained for more than 2 years in most pediatric eyes.

Adverse Events

The safety analysis conducted by FDA included 512 eyes (293 keratoconus, 219 corneal ectasia) in 364 patients who received CXL treatment. As described earlier, the procedure involves removing the corneal epithelium to enhance the riboflavin solution's penetration. As a result, patients may develop a range of ocular adverse reactions, including corneal opacity (haze), corneal epithelial defects, punctate keratitis, corneal striae, eye pain, reduced visual acuity, blurred vision, dry eye, and photophobia among others. Most adverse reactions resolved in the first month, while others took up to 12 months to resolve. However, in 1% to 6% of patients, these adverse reactions could continue beyond 12 months.

Summary of Evidence

For individuals who have progressive keratoconus who receive collagen cross-linking (CXL) using riboflavin and ultraviolet A, the evidence includes multiple randomized controlled trials (RCTs), systematic reviews, and nonrandomized studies. Relevant outcomes are change in disease status, functional outcomes, and treatment-related morbidity. In both pivotal RCTs, the primary end point (an intermediate outcome) of reducing maximum corneal curvature (Kmax) by 1 diopter (D) was achieved at month 3 and maintained at months 6 and 12 in CXL-treated patients, compared to sham controls. In the 2 RCTs, the difference in mean change in Kmax from baseline to 12 months was 1.9 and 2.3 D, respectively, favoring the CXL-treated patients. Long-term follow-up for visual acuity outcomes are needed. The adverse events associated with CXL include corneal opacity (haze), corneal epithelial defects, and other ocular findings. Most adverse events resolved in the first month but, in a few (1%-6%) patients, continued for 6 to 12 months. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence

In 2013 the National Institute for Health and Care Excellence (NICE) issued guidance on corneal collagen cross-linking (CXL) using riboflavin and ultraviolet A updated and replaced its 2009 guidance. The 2013 guidance stratified NICE recommendations for corneal CXL as follows:

"Most of the published evidence on photochemical corneal collagen cross linkage (CXL) using riboflavin and ultraviolet A (UVA) for keratoconus and keratectasia relates to the technique known as 'epithelium-off' CXL'. 'Epithelium on (transepithelial) CXL' is a more recent technique and less evidence is available on its safety and efficacy. Either procedure (epithelium off or epithelium on CXL) can be combined with other interventions, and the evidence base for these combination procedures (known as 'CXL-plus') is also limited. Therefore, different recommendations apply to the variants of this procedure, as follows.

> 1.1 Current evidence on the safety and efficacy of epithelium off CXL for keratoconus and keratectasia is adequate in quality and quantity. Therefore, this procedure can be used provided that normal arrangements are in place for clinical governance, consent and audit.
>
> 1.2 Current evidence on the safety and efficacy of epithelium on (transepithelial) CXL, and the combination (CXL-plus) procedures for keratoconus and keratectasia is

inadequate in quantity and quality. Therefore, these procedures should only be used with special arrangements for clinical governance, consent and audit or research."

U.S. Preventative Services Task Force Recommendations
Not applicable.

Key Words:
Corneal Collagen Cross-linking, refractory surgery, LASIK, Keratoconus, Photrexa Viscous®; Avedro, Photrexa®; Avedro, corneal ectasia, CXL, KXL

Approved by Governing Bodies:
In 2016, riboflavin 5'-phosphate in 20% dextran ophthalmic solution (Photrexa Viscous®; Avedro) and riboflavin 5'-phosphate ophthalmic solution (Photrexa®; Avedro) were approved by the U.S. Food and Drug Administration for use with KXL System in corneal collagen cross-linking for the treatment of progressive keratoconus and corneal ectasia after refractive surgery.

Benefit Application:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply.
FEP: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:
CPT Codes:

0402T	Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)

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Policy History:

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Medical Policy Administration Committee, May 2017
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