

Questions to Ask Your Eye Doctor About Keratoconus and Its Treatments



Keratoconus

- What does progressive keratoconus mean?
 - How will keratoconus affect my vision?
 - Will my keratoconus get worse?
 - Has my keratoconus progressed since my last visit?
 - Is keratoconus genetic? Should I make sure my family members get tested?
 - Is there anything that makes keratoconus worse?
 - If I have it in one eye, does that mean I might develop it in the other eye?
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Treatments

- What are my treatment options, and which do you recommend?
 - What treatment options are FDA-approved?
 - What treatment options are covered by insurance?
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Corneal Cross-Linking

- Is the way you perform the procedure FDA-approved?
- If it is not FDA-approved, am I being enrolled in a clinical study?
- Will the procedure you perform be covered by my insurance?
- What is the recovery typically like?
- Will I need contacts or eyeglasses after the procedure?
- What changes in my vision can I expect?

Key Differences

Between iLink and Non-FDA Approved Procedures

Using Photrexa® Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution), Photrexa® (riboflavin 5'-phosphate ophthalmic solution), and the KXL® system, the iLink™ corneal cross-linking procedure is the only FDA-approved therapeutic treatment for patients with progressive keratoconus and corneal ectasia following refractive surgery.*

We encourage you to review the below chart and to ask your doctor if they perform iLink, the only cross-linking procedure that is **FDA-approved** and **covered by insurance**.

Category	iLink: the ONLY cross-linking procedure approved by the FDA	Non-FDA Approved or unregulated procedures
Drugs Used	Rigorously tested and controlled FDA-approved Photrexa®, Photrexa® Viscous	Riboflavin that has not been FDA-approved
Device Used	KXL® system, the only FDA-approved cross-linking device	Unapproved device used may have been modified or illegally imported, no post-market surveillance
Procedure	Epi-off procedure, validated in controlled clinical trials ^{2,3}	Not FDA-approved: No standardized treatment approach
FDA Approved	Yes, for both Photrexa drug formulations and device used	No
Pivotal Clinical Trials	Yes, robustly studied procedure	No
# of US Procedures Performed Annually	More than 60K	Unknown
# of US physician performing procedure	Approximately 600	Unknown
Adverse event reporting	FDA-mandated reporting & approved labeling with known risks/side effects (see prescribing information)	Side effects not tracked or monitored
Insurance Coverage	>95% commercial coverage; All 50 states have >6 plans covering iLink	No; fully out of pocket cash procedure
Typical patient out of pocket cost	Can vary based on your plan; \$0-\$200 (iLink also has a copay assistance plan)	Varies. In some cases, patients have been charged as much as \$4,000/eye

APPROVED USES

Photrexa® Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution) and Photrexa® (riboflavin 5'-phosphate ophthalmic solution) are used with the KXL® System in corneal cross-linking to treat eyes in which the cornea, the clear dome shaped surface that covers the front of the eye, has been weakened from the progression of the disease keratoconus or following refractive surgery, a method for correcting or improving your vision.

Tell your healthcare provider if you are pregnant or plan to become pregnant.

IMPORTANT SAFETY INFORMATION

Ulcerative keratitis, a potentially serious eye infection, can occur. Your doctor should monitor defects in the outermost corneal layer of the eye for resolution.

The most common ocular side effect is haze. Other ocular side effects include inflammation, fine white lines, dry eye, disruption of surface cells, eye pain, light sensitivity, reduced sharpness of vision, and blurred vision. The risk information provided here is not comprehensive. To learn more, talk to your healthcare provider.

Go to [Prescribing Info](#) to obtain the FDA-approved product labeling.

You are encouraged to report all side effects to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.



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¹Photrexa [package insert]. Waltham, MA: Glaukos, Inc. 2016

²Hersh PS, Stulting RD, Muller D, et al; U.S. Crosslinking Study Group. S. Multicenter Clinical Trial of Corneal Collagen Crosslinking for Treatment of Corneal Ectasia after Refractive Surgery. *Ophthalmology* 2017;124(9):1475-84.

³Hersh PS, Stulting RD, Muller D, et al; U.S. Crosslinking Study Group. United States Multicenter Clinical Trial of Corneal Collagen Crosslinking for Keratoconus Treatment. *Ophthalmology* 2017; 124(9):1259-70.