Clinical Policy: Ophthalmic Riboflavin (Photrexa, Photrexa Viscous)

Reference Number: PA.CP.PHAR.536
Effective Date: 07/2021
Last Review Date: 04/2023

Coding Implications
Revision Log

Description
Photrexa® and Photrexa® Viscous are topical ophthalmic photoenhancers.

FDA Approved Indication(s)
Photrexa and Photrexa Viscous are indicated for use in corneal collagen cross-linking in combination with the KXL™ System for the treatment of:

- Progressive keratoconus
- Corneal ectasia following refractive surgery

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Photrexa and Photrexa Viscous are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria*
Approval of the drug does not translate to an approval of the corneal cross linking procedure

A. Progressive Keratoconus and Corneal Ectasia (must meet all)**:**

1. Diagnosis of one of the following (a or b):
   a. Progressive keratoconus;
   b. Corneal ectasia following refractive surgery;
2. Prescribed by or in consultation with an ophthalmologist;
3. Age ≥ 14 years;
4. Dose does not exceed one kit per eye.

Approval duration: 6 months (up to one kit per eye)

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy*
Approval of the drug does not translate to an approval of the corneal cross linking procedure

A. Progressive Keratoconus and Corneal Ectasia (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. At least 6 months have passed since member's last collagen cross linking procedure;
3. Member is responding positively to therapy as evidenced by a reduction in diopters in the treated eye(s);
4. If request is for a dose increase, new dose does not exceed one kit per eye.

Approval duration: 6 months (up to one kit per eye)

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Riboflavin 5'-phosphate in 20% dextran ophthalmic solution) 0.146% for topical ophthalmic use (Photrexa Viscous) Riboflavin 5'-phosphate ophthalmic solution) 0.146% for topical ophthalmic use (Photrexa)	Dosage and Administration, Section 2: Prescribing Information: • Debride the epithelium using standard aseptic technique using topical anesthesia. • Then instill 1 drop of ***Photrexa Viscous*** topically on the eye every 2 minutes for 30 minutes. • After 30 minutes, examine the eye under slit lamp for presence of a yellow flare in the anterior chamber. If flare is not detected, instill 1 drop of ***Photrexa Viscous*** every 2 minutes for an additional 2 to 3 drops and recheck for yellow flare. Repeat as necessary. • Once flare is observed, perform ultrasound pachymetry. If corneal thickness is less than 400 microns, instill 2 drops of ***Photrexa*** every 5 to 10 seconds until the corneal thickness increases to at least 400 microns.	See dosing regimen

Drug Name	Dosing Regimen	Maximum Dose
	• Irradiation should not be performed unless this 400 micron threshold is met and the yellow flare is seen.	

VI. Product Availability

Cross-linking kit: containing the following components for use with the KXL® System:

- Riboflavin 5'-phosphate ophthalmic solution 0.146% for topical ophthalmic use (Photrexa)
- Riboflavin 5'-phosphate in 20% dextran ophthalmic solution 0.146% for topical ophthalmic use (Photrexa Viscous)

VII. References

1. Photrexa Viscous and Photrexa Prescribing Information. Waltham, MA: Avedro; January 2019. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203324s006lbl.pdf.. Accessed February 2, 2023.
2. Avedro Inc., KXL System: Operator's Manual. Burlington, MA: Avedro, Inc. Copyright 2019. ML-00006 Rev R. Available at https://www.glaukos.com/wp-content/uploads/2021/09/ML-00006-KXL-System-Operators-Manual-US-Rev-R.pdf. Accessed February 2, 2023.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2787	Photrexa Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution) and Photrexa (riboflavin 5'-phosphate ophthalmic solution)

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	07/2021	
2Q 2022 annual review: references reviewed and updated.	04/2022	
2Q 2023 annual review: no significant changes; references reviewed and updated.	04/2023	