Clinical Policy: Ophthalmic Riboflavin (Photrexa, Photrexa Viscous)

Reference Number: LA.PHAR.536
Effective Date:
Last Review Date: 05.01.23
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Please note: This policy is for medical benefit

Description
Photrexa® and Photrexa® Viscous are topical ophthalmic photoenhancers indicated for use with the KXL™ System.

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 Louisiana Healthcare Connections® 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 (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND

criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

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 Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

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 – LA.PMN.53 for Medicaid or evidence of coverage documents.

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%	Dosage and Administration, Section 2: Prescribing Information:	See dosing regimen

Drug Name	Dosing Regimen	Maximum Dose
dextran ophthalmic solution) 0.146% for topical ophthalmic use (Photrexa Viscous) Riboflavin 5'-phosphate ophthalmic solution) 0.146% for topical ophthalmic use (Photrexa)	• 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. • 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/scripts/cder/daf/. Accessed January 27, 2022.
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 January 27, 2022.

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.

CLINICAL POLICY
Ophthalmic Riboflavin

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	LDH Approval Date
Policy created.	05.01.23	

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.