Clinical Policy: Ophthalmic Riboflavin (Photrexa, Photrexa Viscous)

Reference Number: CP.PHAR.536
Effective Date: 06.01.21
Last Review Date: 05.22
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

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

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 health plans affiliated with Centene Corporation® 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 for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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 Centene 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. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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% dextran ophthalmic solution) 0.146% for topical ophthalmic use (Photrexa Viscous) Riboflavin 5'-phosphate ophthalmic	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	See dosing regimen

Drug Name	Dosing Regimen	Maximum Dose
solution) 0.146% for topical ophthalmic use (Photrexa)	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.

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.	02.11.21	05.21
2Q 2022 annual review: no significant changes; references reviewed and updated.	01.27.22	05.22

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. The Health Plan 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. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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 the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.