The World Leader in Corneal Remodeling™

Photrexa® Viscous (riboflavin 5’-phosphate in 20% dextran ophthalmic solution), Photrexa® (riboflavin 5’-phosphate ophthalmic solution) with the KXL® System

Comprehensive Coding and Billing Guide

Table of Contents

Coverage 3

Coverage Landscape 3

Predeterminations and Prior Authorizations 3

Coding Guidelines 4

Relevant Code Summary 4

Applicable Diagnosis Codes (ICD-10-CM) 5

Procedure Codes (CPT) 6

Drug Codes (HCPCS) 7

Billing and Claims Adjudication 8

Billing a Category III CPT or J-Code 8

Claim processing and turnaround times 8

Claim denials 9

NCCI Edits 9

Patient Billing 9

Reimbursement Methodology and Payment 10

Procedure Payment 10

Drug Payment 11

Low-paid Claims 12

Indications 12

Limitations of Use 12

Warnings and Precautions 12

Adverse Reactions 13

For any questions regarding commercial payer coverage, billing or reimbursement for Photrexa® Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution), Photrexa® (riboflavin 5'- phosphate ophthalmic solution) with the KXL® System, contact the Avedro Reimbursement Customer Hub (ARCH) Program. Our case managers can provide hands on assistance with claims appeals, in addition to resources for coding, billing or claims submission questions. Please contact us by phone at 844-528-3311 between 6:00 am to 5:00 pm PST or by email at info@avedroarch.com. *MA-00644C*

Coverage

Coverage Landscape

As of December 2018, sixty-one national and regional commercial plans payers have issued positive coverage policies for Photrexa Viscous and Photrexa with the KXL System. For a complete list, please visit *https://www.livingwithkeratoconus.com* (click on "Insurance Information").
For payers who do not have published coverage policies for corneal collagen cross-linking (CXL) using Photrexa Viscous and Photrexa for progressive keratoconus or corneal ectasia following refractive surgery, coverage decisions may be made on a claim-by-claim basis.

Providers should verify commercial payer requirements regarding prior authorizations, keeping in mind that some payers will not require prior authorization for codes describing Photrexa Viscous and Photrexa and its associated CXL procedure, but may conduct a medical review at the time of claim processing. Providers should be prepared to furnish medical records and other relevant documents that support the medical necessity of the corneal collagen cross-linking procedure for the patient in question, in order for the claim to be processed.

Predeterminations and Prior Authorizations

Prior authorizations are sometimes required by commercial payers in order to determine medical necessity and coverage of a prescribed service for a specific patient. While obtaining an authorization does not guarantee payment of a claim, it can prevent administrative claim denials due to lack of authorization on file when one is required.

Prior authorization requirements can vary by payer, depending on factors such as the plan type (HMO vs PPO), the payer's medical policies, and the specifics of a patient's plan. It is best for providers to check authorization requirements for a patient's plan in advance of the procedure taking place and obtain any required authorizations. Surgical facilities should coordinate with the rendering physician's office to ensure that the place of service is represented correctly on any authorizations that are obtained by the physician's office.

In cases where payers do not require a mandatory prior authorization for Photrexa Viscous or Photrexa and its associated CXL procedure, providers should ask if a voluntary predetermination is possible. Similar to a prior authorization, a predetermination evaluates a prescribed service for a patient, both for medical necessity and allowed coverage for specific procedure codes under the patient's plan. Providers should obtain a predetermination whenever possible for a patient's plan to prevent claim denials for unforeseen reasons such as a terminated policy, or lack of benefits available for the procedure in question. Like prior authorizations, predeterminations are not a guarantee of payment for the claim, but they are helpful in preventing denials.

For any questions regarding commercial payer coverage, billing or reimbursement for Photrexa® Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution), Photrexa® (riboflavin 5'- phosphate ophthalmic solution) with the KXL® System, contact the Avedro Reimbursement Customer Hub (ARCH) Program. Our case managers can provide hands on assistance with claims appeals, in addition to resources for coding, billing or claims submission questions. Please contact us by phone at 844-528-3311 between 6:00 am to 5:00 pm PST or by email at info@avedroarch.com. *MA-00644C*

When speaking with a payer to ask about authorization requirements, you may be told that while a prior authorization is not required, a predetermination is "highly recommended." This is usually the case with payers who may not have a specific medical policy published regarding the treatment in question, or when the criteria for coverage are very specific. Because policies and coverage criteria can vary from payer to payer, providers should take advantage of the predetermination option, if one is available.

Coding Guidelines

Relevant Code Summary

CPT/HCPCS Codes	Description
Category III CPT **0402T**	Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)
HCPCS **J2787**	Riboflavin 5'-phosphate, ophthalmic solution, up to 3 ML (effective January 1, 2019)

When coding claims for the use of Photrexa Viscous and Photrexa with the KXL System, it is important to use the diagnosis and procedure codes that are the most accurate descriptions of the patient's medical condition, services performed, and medication administered to the patient. The following provides some options for coding that can be used to bill for Photrexa Viscous and Photrexa with the KXL System.

In order for the use of Photrexa Viscous and Photrexa with the KXL System to be considered medically necessary and eligible for coverage by payers, they must be administered in accordance with the FDA's approved indications for on-label use. On April 15, 2016, Avedro obtained FDA approval of Photrexa Viscous and Photrexa. The indications[1] are for use in corneal collagen cross-linking in combination with the KXL System for the treatment of

1.1 Progressive keratoconus

1.2 Corneal ectasia following refractive surgery

The use of Photrexa Viscous and Photrexa under any other circumstances is outside the scope of the CPT code description and may be off-label. Coverage will follow payer guidelines, which typically align with the FDA approved indications for use.

HCPCS Code J2787 is effective January 1, 2019. Providers may begin billing with J2787 for procedures performed on or after January 1, 2019. J3490 should be used for procedures performed with Photrexa Viscous and Photrexa prior to January 1, 2019.

[1] Full Prescribing Information for PHOTREXA VISCOUS, PHOTREXA and the KXL System can be found at http://avedro.com/en-us/.

Applicable Diagnosis Codes (ICD-10-CM)

Health care providers are required to use ICD-10-CM diagnosis codes to describe a patient's medical condition and to justify medical necessity of items and services furnished to patients. Providers should always use ICD-10-CM diagnosis codes that most accurately reflect the patient's condition to the greatest degree of specificity possible.

Diagnosis codes for any particular claim will depend on the individual patient's presentation. Below is the list of potential diagnosis codes in the keratoconus and corneal ectasia series; providers must determine relevant and appropriate diagnosis coding applicable to the specific patient encounter. Not all of these diagnosis codes may be translated to on-label indications for Photrexa Viscous and Photrexa used with the KXL System, which is why it is important for providers to verify valid and billable diagnosis code/CPT code pairs with a patient's specific plan either by calling payers prior to the procedure taking place, or obtaining a voluntary predetermination if no prior authorization is required.

Diagnosis Code	Description
H18.601	Keratoconus, unspecified, right eye
H18.602	Keratoconus, unspecified, left eye
H18.603	Keratoconus, unspecified, bilateral
H18.609	Keratoconus, unspecified, unspecified eye
Diagnosis Code	**Description**
H18.621	Keratoconus, unstable, right eye
H18.622	Keratoconus, unstable, left eye
H18.623	Keratoconus, unstable, bilateral
H18.629	Keratoconus, unstable, unspecified eye
H18.711	Corneal ectasia, right eye
H18.712	Corneal ectasia, left eye
H18.713	Corneal ectasia, bilateral
H18.719	Corneal ectasia, unspecified eye

For any questions regarding commercial payer coverage, billing or reimbursement for Photrexa® Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution), Photrexa® (riboflavin 5'- phosphate ophthalmic solution) with the KXL® System, contact the Avedro Reimbursement Customer Hub (ARCH) Program. Our case managers can provide hands on assistance with claims appeals, in addition to resources for coding, billing or claims submission questions. Please contact us by phone at 844-528-3311 between 6:00 am to 5:00 pm PST or by email at info@avedroarch.com. *MA-00644C*

Procedure Codes (CPT)

Category III CPT Codes

The American Medical Association (AMA) advises that when billing CPT codes, providers should select the procedure or service that *most accurately* identifies the procedure that was performed, and not to select a CPT code that merely approximates the service provided, if a more specific code is available. The Category III CPT code associated with the corneal collagen cross-linking procedure is 0402T - ***Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)***.

Category III CPT codes are temporary codes that represent new and emerging technologies, procedures and services. They typically do not have a national fee schedule payment amount. As such, payers typically will determine payment amounts for Category III CPT 0402T on a claim-by-claim basis, based on the description of the procedure, the provider's billed charges, the provider's contract with the payer, and any additional information associated with the claim that documents the time and complexity of the work associated with the service.

Global Periods and Post-Operative Follow-up Visits

Category III CPT codes (i.e. 0402T) do not have associated post-procedure global periods, *so any subsequent follow-up visits or services may be billed independently from the initial procedure*.

Examples of CPT codes that may be used to bill for post-operative follow-up visits may include the following:

CPT Code	Description
99212	Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self-limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family
99213	Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent face-to-face with the patient and/or family.

99214	Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 25 minutes are spent face-to-face with the patient and/or family.
99215	Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family.
92012	Ophthalmological services: medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; intermediate, established patient
92014	Ophthalmological services: medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; comprehensive, established patient, 1 or more visits

Modifiers

Modifiers are two-digit codes that are appended to a CPT or HCPCS code on a claim, to provide payers with additional information that may be necessary in order to process the claim. Providers should verify which modifiers are allowed by a payer beforehand, to avoid claim denials for the use of an inappropriate modifier.

Some examples of modifiers that might be applicable:

Modifier	Description
-LT	Left side. Used to identify procedures performed on the left side of the body.
-RT	Right side. Used to identify procedures performed on the right side of the body.

Drug Codes (HCPCS)

Physician-administered drugs such as Photrexa Viscous and Photrexa are typically represented by HCPCS J-codes. These codes represent non-pharmacy medications that are physician-administered to patients in a medical setting. HCPCS Code J2787 is effective January 1, 2019. Providers may begin billing with J2787 for procedures performed on or after January 1, 2019. J3490 should be used for procedures performed with Photrexa Viscous and Photrexa prior to January 1, 2019.

For any questions regarding commercial payer coverage, billing or reimbursement for Photrexa® Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution), Photrexa® (riboflavin 5'- phosphate ophthalmic solution) with the KXL® System, contact the Avedro Reimbursement Customer Hub (ARCH) Program. Our case managers can provide hands on assistance with claims appeals, in addition to resources for coding, billing or claims submission questions. Please contact us by phone at 844-528-3311 between 6:00 am to 5:00 pm PST or by email at info@avedroarch.com. *MA-00644C*

Billing and Claims Adjudication

Billing a Category III CPT or J-Code

When submitting a claim for a Category III CPT code, providers should also submit detailed medical notes which capture both the procedural information that documents the time and complexity of the work associated with the service and the patient's medical condition. Submitting medical documents with claims serves the purpose of informing the payer as to why the treatment was selected for the patient, capturing the level of work and materials necessary to complete the procedure, and supporting the patient's medical necessity for the service.

When submitting a claim for a drug with a J-code, providers may be required to specify additional information on the claim form for each drug administered during the procedure. Check with the payer beforehand, to verify their requirements for billing with J-codes.

Some examples of the information that may be required are:

- The National Drug Code(s) (NDC)
  - Photrexa Viscous and Photrexa Cross-linking Kit: 25357-025-03 (single-use foil pouches of Photrexa Viscous and Photrexa are provided in a single-box kit)
  - Photrexa Viscous: 25357-022-01 (bulk pack of ten, single use foil pouches)
  - Note, most providers are now using the drugs packaged as a kit. Reference the purchase invoice to confirm the correct NDC number to bill.
- The dispensing unit of measure
- The amount administered to the patient
- An invoice for the original purchase of the drug

Note that formatting requirements for reporting the NDC may require that the National Drug Code (NDC) is preceded by the identifier code "N4" immediately followed by an 11-digit NDC. Do not use spaces or punctuation. The NDCs for Photrexa Viscous and Photrexa are only 10 digits each, so it may be required to add an extra "0" to the beginning of the 3-digit portion of the NDC, in order to meet the format requirements. For example, the Photrexa Cross-linking Kit NDC (25357-025-03) would look like this: N425357002503. NDC formatting can vary payer to payer so it is best to check with the payer in question for specific formatting guidelines.

Please refer to the sample claim forms and instructions included in this billing guide for more information regarding coding on claims.

Claim processing and turnaround times

The payer will review the claim and accompanying documents prior to issuing a payment decision. Most payers complete manual review and adjudicate claims within 30-45 business days of receipt.

Claim denials

If your claim for corneal collagen cross-linking using Photrexa Viscous and/or Photrexa is denied, you could pursue an appeal of the decision. For resources related to filing a claim appeal, please contact the Avedro Reimbursement Customer Hub (ARCH) program at 844-528-3311 or info@avedroARCH.com.

NCCI Edits

National Correct Coding Initiative (NCCI)[2] edits are released by the Centers for Medicare and Medicaid Services (CMS) to prevent improper payment when incorrect combinations of CPT codes are billed by the same provider for the same patient on the same date of service. NCCI policies are based on AMA CPT guidance, coding guidelines developed by specialty societies, and reviews of current coding practices. The purpose of the NCCI edits is to prevent improper payment when incorrect code combinations are reported. Private payers may also implement CMS' NCCI edits, or have edits of their own.

Per published CPT guidance and NCCI edits, do not bill Category III CPT 0402T with the following codes[3], as they are considered inclusive components of Category III CPT 0402T or vice versa:

65435 - Removal of corneal epithelium; with or without chemocauterization (abrasion, curettage)

66990 - Use of ophthalmic endoscope (List separately in addition to code for primary procedure)

76514 - Ophthalmic ultrasound, diagnostic; corneal pachymetry, unilateral or bilateral (determination of corneal thickness)

This is not a comprehensive list of NCCI edits, so providers should check the latest CMS release for any updates prior to billing. Providers may be able to bill separately for other procedures not included in CPT 0402T.

Patient Billing

In some circumstances, providers may be able to bill patients for services that are not covered by insurance. The requirements and restrictions regarding patient billing are often dependent on variables such as the provider's network status, and different payers' administrative policies. It is always a best practice to verify the payer's specific guidelines regarding patient billing prior to rendering the service to the patient, so that you do not inadvertently violate any contractual obligations or restrictions that may be in place.

In-Network Providers

Providers participating in a payer's network will be obligated to follow the payer's guidelines regarding claims submission and patient billing. These guidelines are usually found in the payer's Provider Manual/Handbook that is typically available on the payer's website or provider portal. If it is not clear

[2] Q1 2016 NCCI edits (effective January 1, 2017), published by CMS.

[3] AMA CPT Assistant February 2016, Volume 26 Issue 2

what the payer's guidelines are, a call to provider relations is recommended, prior to rendering any services to the patient.

Out-of-Network Providers
Providers who are not participating in a payer's network do not have the same restrictions as in-network providers, because they are not contracted with the payer. Non-participating providers are not obligated to submit a claim for any services rendered but may opt to do so as a courtesy for their patients who have plans with out-of-network benefits available.

Reimbursement Methodology and Payment

Procedure Payment

Each payer establishes its own reimbursement methods and rates for procedures in physicians' offices and facilities. Private payers often follow Medicare's methodology but final reimbursement may be informed by alternate data or provider contracts.

Physician offices
In addition to facility reimbursement, the physician performing the service may also submit a claim to the payer for his/her professional component of the service. Under Medicare, physicians are paid based on the Medicare Physician Fee Schedule (MPFS). Payments for CPT codes are determined by the review of the Relative Value Update Committee (RUC) and valuation by the Centers for Medicare and Medicaid Services (CMS). Medicare does not establish payment rates for Category III CPT codes such as 0402T on the MPFS. Individual Medicare contractors may establish their own payment rates.

Commercial payers use a variety of reimbursement methodologies and guidelines to reimburse for physician services. Possible methods include payment based on established fee schedules, including the Medicare Physician Fee Schedule (MPFS), or payment based on a charge-related basis (such as a set percentage of the billed charges), in addition to others. Payments for CPT codes under the MPFS are based on the review of the Relative Value Update Committee (RUC) and valuation by the Centers for Medicare and Medicaid Services (CMS). Medicare does not establish payment rates for Category III CPT codes such as 0402T on the MPFS. Individual Medicare contractors may establish their own payment rates.

Payment methodologies vary from payer to payer and the above are only a few examples of how payment is determined for a claim. Providers should contact the specific payer in question with any payment-related inquiries. Payers have fee schedules for established and covered procedures which are usually accessible by calling the payer or through the payer's online provider portal.

Facilities

Private payers may refer to Medicare's payment rates and policies for hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs). Under Medicare, HOPDs are paid based on the Outpatient Prospective Payment System (OPPS). Under OPPS, services are assigned to payment categories called Ambulatory Payment Classifications (APCs). Ambulatory surgical centers (ASCs) are paid based on the Ambulatory Surgical Center (ASC) Payment System. The table below reflects the 2018 national average payment rates for 0402T under the OPPS and ASC Medicare fee schedules. Please note: these payment rates may vary by geographic location, and commercial payers generally have their own mechanisms for calculating payment, which typically reflect higher payment rates than Medicare. See important disclaimer on Page One. In 2018, CMS reassigned CPT code 0402T to APC 5503 (Level 3 Extraocular, Repair, and Plastic Eye Procedures) from APC 5502 (Level 2 Extraocular, Repair, and Plastic Eye Procedures).

Code	2019 HOPD Medicare National Payment Rate	2019 ASC Medicare National Payment Rate
0402T (APC 5503)	$1,812.68	$804.74

Commercial payers can use a variety of reimbursement methodologies and guidelines to reimburse for outpatient department services. Possible methods include setting reimbursement rates which follow the Medicare APC grouping model and assign the service to an established fixed payment group, or payment based on a charge-related basis (such as a set percentage of the billed charges), in addition to others.

Contracts

Commercial payers will have specific contracts negotiated with participating network physicians or surgical facilities. A contract may contain language specific to a type of procedure or a CPT code or possibly language that applies to Category III codes in general. For example, a contract may state that the provider agrees to accept a specific percent of billed charges for a specific code, or that they will accept the payer's rate for reasonable and customary charges for a code. Commercial payers typically have a specific provider relations contact assigned to physician's office or the surgical facility, who can discuss the provider's specific contract in detail if there are any questions about what it does and does not cover, or specific payment terms.

Drug Payment

Commercial payers establish their own reimbursement methodologies for physician-administered drugs, including payment based on a percentage of Wholesale Acquisition Cost (WAC), published by third-party price reporting warehouses, Average Sales Price (ASP), if available, Average Wholesale Price (AWP), or

invoice prices. Payer contract specifics may also impact how drug payment is calculated. Including the purchase invoice for the drug(s) with claim submission will assist payers in determining reimbursement rates for the drug(s).

Low-paid Claims

To minimize the chances of receiving a low-paid claim, set charge amounts which adequately reflect the work, complexity, and resources required to provide the service. Providers should contact their patients' commercial insurers to understand a payer's policy on corneal collagen cross-linking and any special instruction for claims submission. Low-paid claims can also result from specific network contract terms; therefore, it may be helpful to discuss any existing contracts with Provider Relations prior to submitting any claims.

Should you receive payment for which does not adequately compensate the time, complexity of work performed, and materials required for the corneal collagen cross-linking procedure using Photrexa Viscous and Photrexa with the KXL system, please contact the Avedro Reimbursement Support Program at 844-528-3311 Monday through Friday between 6 am to 5 pm PST or email: info@avedroARCH.com for information and resources regarding appeals.

Indications

PHOTREXA® VISCOUS (riboflavin 5'-phosphate in 20% dextran ophthalmic solution) and PHOTREXA® (riboflavin 5'-phosphate ophthalmic solution) are photoenhancers indicated for use with the KXL System in corneal collagen cross-linking (CXL) for the treatment of progressive keratoconus and corneal ectasia following refractive surgery.

Limitations of Use

The safety and effectiveness of CXL has not been established in pregnant women, women who are breastfeeding, patients who are less than 14 years of age and patients 65 years of age or older.

Photrexa Viscous and Photrexa should be used with the KXL System only.

Warnings and Precautions

Ulcerative keratitis can occur. Patients should be monitored for resolution of epithelial defects.

Adverse Reactions

In progressive keratoconus patients, the most common ocular adverse reactions in any CXL treated eye were corneal opacity (haze), punctate keratitis, corneal striae, corneal epithelium defect, eye pain, reduced visual acuity, and blurred vision. In corneal ectasia patients, the most common ocular adverse reactions were corneal opacity (haze), corneal epithelium defect, corneal striae, dry eye, eye pain, punctate keratitis, photophobia, reduced visual acuity, and blurred vision.

These are not all of the side effects of Photrexa® Viscous, Photrexa® and the CXL treatment. For more information, see Prescribing Information.

You may report an adverse event to Avedro by calling 1-844-528-3376, Option 1 or you may contact the U.S. Food and Drug Administration (FDA) directly at 1-800-FDA-1088.

Full Prescribing Information for PHOTREXA VISCOUS, PHOTREXA and the KXL System can be found at http://avedro.com/en-us/.

For any questions regarding commercial payer coverage, billing or reimbursement for Photrexa® Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution), Photrexa® (riboflavin 5'- phosphate ophthalmic solution) with the KXL® System, contact the Avedro Reimbursement Customer Hub (ARCH) Program. Our case managers can provide hands on assistance with claims appeals, in addition to resources for coding, billing or claims submission questions. Please contact us by phone at 844-528-3311 between 6:00 am to 5:00 pm PST or by email at info@avedroarch.com. *MA-00644C*