Corneal Cross Linking (CXL) Reimbursement & Compliance Update

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INTRODUCTION

This review explores standard uses along with some other potential ones that may be performed combining Corneal Cross Linking (CXL) with other covered procedures or even off-label ones—all discussions being within the framework of compliance and legal uses of the product.

More attention recently has been drawn to CXL with the advent of Medicare coverage of the procedure effective January 1, 2019. Detailed coverage information is available on the Avedro, Inc. website (www.Avedro.com)[1] and coding/reimbursement information is found in the CXL Coding & Reimbursement Table at the end.[2, 3]

COMPLIANCE AND LEGAL ISSUES

The FDA approval of CXL or any other product is **not** synonymous with **payment** coverage by any given insurer. Furthermore, many of its uses require an understanding of the legal and compliance guidelines.

Qualifications of the Physician. Any duly licensed ophthalmologist may perform CXL for the indicated and medically necessary conditions of:

- progressive keratoconus
- corneal ectasia following refractive surgery.

Off-Label Use. One of the most familiar – but least understood – concepts in medicine is the word "Off-Label". When a drug or device is used off-label, there are numerous compliance regulations that must be followed, some of which are presented here.

- An **approved** usage occurs when the product (drug or device) is used in accordance with the usages specified on the product label approved by the FDA. These drugs and devices may or may not be a covered benefit for patients with Medicare, Medicaid or commercial payer health insurances.

- An **off-label use** is simply one wherein the product is used for treatment for a condition or usage **not approved by the FDA on the label** although the drug or device is FDA-approved for another indication. An off-label use of a FDA approved drug and/or device may be awarded coverage by Medicare or other insurer; however, *Medicare does not grant pre-approvals*. For Medicaid and commercial payers, coverage is determined on a case-by-case basis. This coverage is normally facilitated by a peer-to-peer discussion between the physician and the insurer's medical director and should include specifics regarding why that individual patient should be covered in terms of clinical management.
- A **non-approved** medical product is one that **does not have approval, clearance or licensure from the FDA to be marketed**. A non-approved medical product(s) will not be paid for by any payer in the USA, and if knowingly submitted for payment, could be considered insurance fraud.

Informed Consent. When a drug or device is used off-label, it is mandatory that a **separate informed consent** be used that specifies it is being used as such. OMIC has a sample form on its website (http://www.omic.com/informed-consent-for-off-label-use-of-a-drug-or-device/). In the event of risk management events, such as malpractice lawsuits, the physician is not protected without it.

Example: The FDA has approved CXL **only** for use with removal of the epithelium (epithelium-off procedure). **An epithelium-on procedure would be considered off-label**, thus requiring **both** an informed consent for off-label use as an off-label procedure and a second informed consent for the CXL procedure itself. If **non FDA-approved drugs and/or devices** are used then the procedure actually becomes an illegal one!

Furthermore, off-label usage of a device or drug is generally non-covered in terms of payment, with occasional notable exceptions, for specific uses specified by the insurer, such as the use of Avastin for treatment of wet macular degeneration…but that also went through a period of noncoverage for some Medicare carriers until it was approved for payment.

FDA Approved CXL Products. Only the FDA-approved Avedro, Inc. products (Photrexa Viscous, Photrexa, and the KXL system) may be used. Any other products, such as compounded drugs or drugs imported from another country, may never be used. In addition, the above-named Avedro, Inc. products have orphan drug status signifying that for seven years from issuance (April 15, 2016 in this case) the company has exclusive rights for marketing the drug and that the FDA may not approve another drug application within that time frame that uses the same drug (riboflavin) for the same indications.

THE FUTURE

As the anterior segment fields are merging, there very well may be a time in the not-so-distant future when combination surgeries such as insertion of Intacs + CXL are performed. Various other anterior segment procedures may also become candidates for combination surgery with CXL. Let's see what the future brings!

References:

1. Avedro, Inc.: https://avedro.com/wp-content/uploads/2019/04/MA-00644C_Comprehensive-Billing-Guide_04.11.2019.pdf (Accessed May 17, 2019)
2. American Society of Cataract and Refractive Surgery: http://ascrs.org/Corneal_Cross_Linking_Billing_Guidelines (Accessed May 17, 2019)
3. FDA (Food and Drug Administration: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/203324Orig2s000SumR.pdf (Accessed May 17, 2019)

[Note: CXL Coding & Reimbursement Table follows on the next page]

CXL Coding & Reimbursement

CPT AND J CODES

CPT CODE: 0402T

- **Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)**
- **This is officially a Category III code as indicated by the T, indicating Emerging Technology codes that are Temporary. These codes are also referred to as "T" codes.**

J CODE: J2787

- **Healthcare Common Procedure Coding System (HCPCS) J2787– Riboflavin 5'-phosphate, ophthalmic solution, up to 3mL, for Photrexa riboflavin drug formulations**
- **CMS established a J-code, used in corneal cross-linking, effective January 1, 2019. This J-code for Photrexa riboflavin drug formulations will streamline the claims process for billing corneal cross-linking. Additionally, it will allow patients and payers to take advantage of any discounts or rebates related to the reimbursement for the drug..**

OBTAINING REIMBURSEMENT[1, 2, 3]

STEP 1
Check with the insurance plan to ascertain that there is any policy regarding coverage or non-coverage.

- **If the plan covers the procedures obtain all necessary information and parameters.**
- **If the plan does not cover the procedure ascertain that you may bill the patient and if there are any restrictions or issues.**
- **For each insurer that covers the procedure, determine whether one or both codes should be used.**

STEP 2
Determine if you are obliged to, or want to, file a Predetermination or Preauthorization with that insurer.

STEP 3
The patient may be billed only if there is no insurance coverage and the Compliance issues addressed in this paper are adhered to.

ADVANCED BENEFICIARY NOTICES FOR MEDICARE (ABN)

MEDICARE: Since 0402T is a Category III code the price is determined by the Medicare Administrative Contractor (MAC) and, if not set by the MAC will not be paid. In order to bill the patient the practice should have an ABN filled out by the patient with the reason listed as not paid by the MAC. Medicare, through its MLN series, will be issuing a new interactive tutorial on how to fill out the ABN form.