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NUTS AND BOLTS OF IMPLEMENTING CORNEAL CROSS-LINKING IN YOUR PRACTICE

Avedro gathered leading refractive surgeons and eye care professionals for a roundtable discussion during the 2018 annual meeting of the American Society of Cataract and Refractive Surgery in Washington, DC. The discussion centered around current issues experienced by ophthalmologists who perform corneal cross-linking in their practices.

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CXL APPROVAL IN THE US

Richard L. Lindstrom, MD: We now have an FDA-approved product for corneal cross-linking (CXL) in the United States. Dr. Ayres, what was involved in obtaining this approval, and what are the approved indications?

Brandon D. Ayres, MD: It took a long time for CXL to be approved in the US. Reports on the procedure were published as early as 2003, but it was not until 2016 when CXL was FDA approved, proving that CXL was effective for treating progressive keratoconus and corneal ectasia following refractive surgery. The FDA approval encompassed Avedro's Photrexa Viscous, Photrexa, and the KXL system, using an epithelium-off procedure modeled after the Dresden protocol.[1]

INCORPORATING CXL IN YOUR PRACTICE

Dr. Lindstrom: What does it take to incorporate CXL in your practice?

Dr. Ayres: First, you need to let the community know that you treat keratoconus. Incorporating CXL into our practice was a natural transition. We had been treating keratoconus, and we have built great relationships with diagnosing providers, both optometrists and general ophthalmologists.

You also need to determine how you will implement the office-based procedure, particularly when it comes to scheduling and defining staff roles.

Dr. Lindstrom: As Dr. Ayres mentions, CXL is an office-based procedure at Wills Eye Hospital. Dr. Hatch, is that also the case at Massachusetts Eye and Ear?

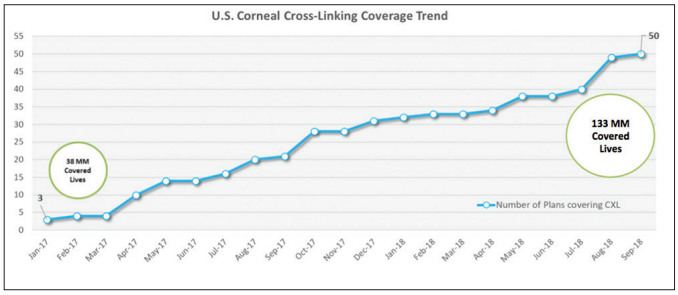
Kathryn M. Hatch, MD: Yes, it is. We are currently performing CXL at the Massachusetts Eye and Ear satellite location in Waltham. I typically perform CXL during clinic, so I can efficiently see patients and perform treatments.

Our process begins with the initial evaluation. We have one person who is our designated "CXL champion." He/she is our go-to administrative expert and is responsible for scheduling the procedures. It is critical to have one staff member who can talk to patients preoperatively and explain what to expect. Additionally, we have two technicians who are quite comfortable with the procedure. They are extremely helpful with reassuring patients and guiding them through the process.

Dr. Lindstrom: As the entire procedure takes about 90 minutes, it can be stressful for patients, so they will need to be counseled.

I also perform CXL during clinic and believe other ophthalmologists choose to perform the procedure on designated days.

Dr. Ayres: Initially, I tried to designate a specific day to treat my CXL patients, but that turned out to be inefficient. Now, with carefully trained staff, I can perform the procedure efficiently during an office day. Like Dr. Hatch, we have two gifted staff members. One staffer is a good scheduler, sympathetic with patients, and is great on the phone with insurance companies making sure we have the necessary approvals. The second person is our bubbliest, friendliest technician who is good at talking to our patients.



An increasing number of commercial payers begin to recognize the medical necessity of CXL. Coverage trend as of 9/21/18. For updated insurance information, visit www.avedro.com.

Dr. Hatch: An outgoing, positive technician can put patients at ease. I also prescribe a small amount of a benzodiazepine, which patients bring to the office with them. We instruct them to take it after they check in, typically about 40 minutes prior to the procedure. Additionally, patients may bring in their iPods or stream internet radio, as music does wonders to create a relaxing atmosphere. I explain to patients that we have a team approach to CXL in our office, and that multiple members of the team will be helping during the treatment.

BENEFITS OF USING AN FDA-APPROVED PROCEDURE

Dr. Lindstrom: Why is it important to use a product manufactured according to FDA guidelines?

Dr. Ayres: For a product to be FDA-approved, the manufacturer must adhere to current Good Manufacturing Practice regulations. This requirement helps alleviate concerns about the quality of a medication and the risk of potential contamination. This is particularly important to minimize the risk of infection when a procedure involves an epithelial defect.

Rajesh K. Rajpal, MD: Ms. Rapuano, as a practice administrator with experience in managing CXL, help us understand the importance of using an FDA-approved product from an insurance perspective.

Sara B. Rapuano, MBA, CPC, COE, OCS: To bill insurance companies, a product needs FDA approval. When we look at the coverage policies, insurers are specifically referencing the FDA-approved version of CXL from Avedro. A patient who seeks CXL from a provider not using FDA-approved products will be self-pay as insurance will not pay for a non-FDA approved procedure.

Dr. Ayres: We also must consider liability. Many of us are performing these procedures, and if you do a lot of anything, in rare instances something unusual happens. We need to ensure we have insurance coverage if there is an issue.

Ms. Rapuano: The Ophthalmic Mutual Insurance Company (OMIC) specifically requires that providers use the FDA-approved version of a product or have authorization to study an investigational drug via an Investigational New Drug (IND) application.

Dr. Rajpal: Physicians, practices, and the community need to understand that an institutional review board (IRB) approval is not enough to protect them from liability. Also, CXL clinical studies need to be performed under an IND.

THE ARCH PROGRAM

Dr. Rajpal: Moving to the Avedro Reimbursement Customer Hub (ARCH) Program. This program has three components: patient assistance, prescription assistance, and a hotline for practices to call for help with the predetermination and appeals process. The aim of the ARCH Program is to support patients through the process, as we see progress in reimbursement from insurance carriers.

Dr. Ayres: The ARCH program has helped streamline the CXL process in our practice. For example, when a patient is ready for the procedure, we send his or her information to ARCH, which works with the insurance company to obtain prior authorization, relieving our staff of this sometimes administratively burdensome task. The program has helped us to treat more patients who are interested in having the procedure covered by their insurance. ■

1. Wollensak G, Spoerl E, Seiler T. Riboflavin/ultraviolet-a-induced collagen crosslinking for the treatment of keratoconus. *Am J Ophthalmol.* 2003;135:620-627.