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THERAPEUTIC OPTOMETRY AND THE USE OF AMNIOTIC MEMBRANE

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INTRODUCTION

- What is AMT?
- When can I use AMT?
- How is AMT applied?
- Case Examples



History of Amnion

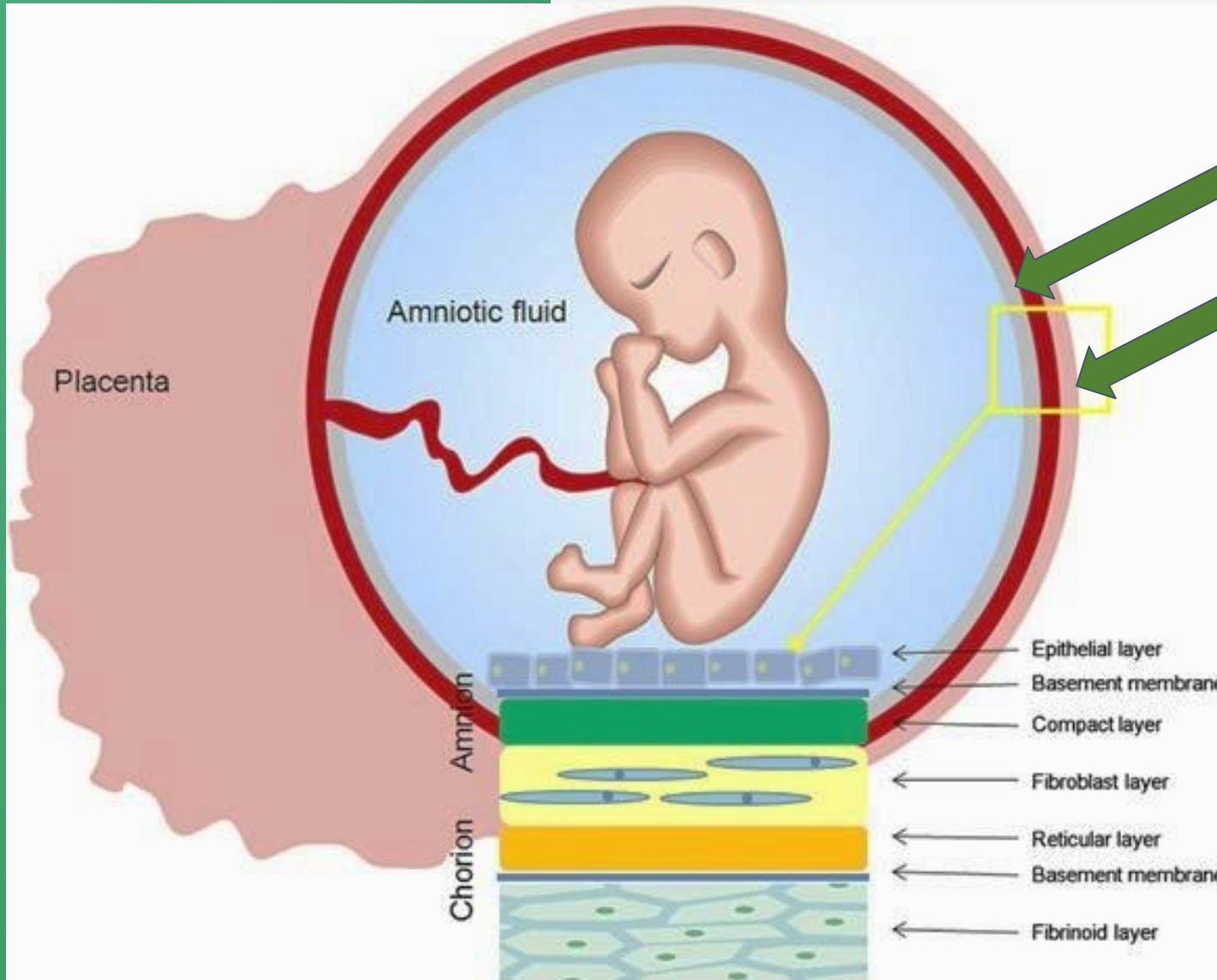
The use of amniotic membrane in medicine is expanding in many specialty areas of medicine. Although used in surgery since the early 1900s, newer methods of processing and storage of amniotic membrane have made the membrane more available, and its use in ophthalmology and optometry has grown exponentially in recent years.

Human amniotic membrane (hAM) is the innermost layer of fetal membranes and is an integral part of the amniotic sac that surrounds the developing fetus throughout gestation. hAM possess many unique properties that contribute to its widespread acceptance for use in regenerative medicine.

Human amniotic membrane (hAM) has been employed as scaffolding material in a wide range of tissue engineering applications, especially due to the structure of the extracellular matrix and excellent biological properties that enhance both wound healing and tissue regeneration. In addition to being the strongest basement membrane in the body and forming an effective barrier, studies have shown that hAM is hypoimmunogenic, promotes epithelization and has anti-inflammatory, angiogenic, antifibrotic and antimicrobial properties.



What is Amnion?



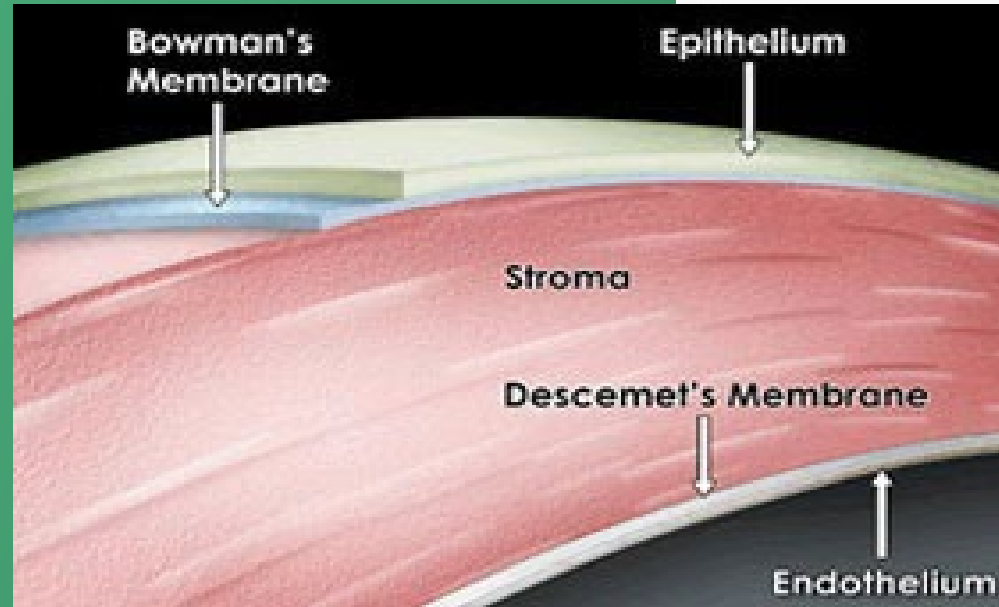
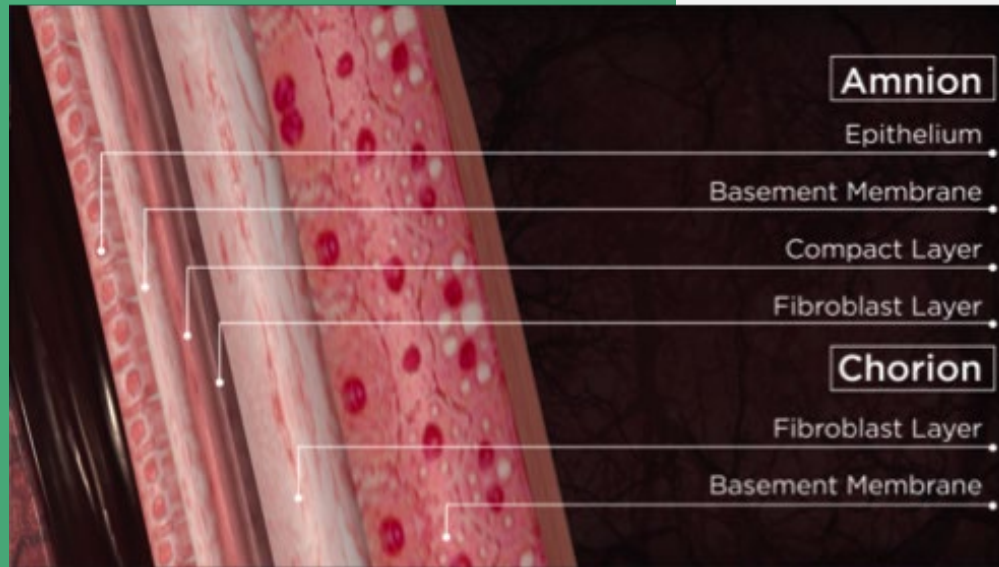
Amnion faces the fetus

Chorion faces the uterus

AMNION & CHORION

- ✓ Avascular
- ✓ Metabolically active
- ✓ Constantly restructure to accommodate fetal growth
- ✓ Can be used to heal the ocular surface

Human Amniotic Membrane



- ✓ Five-layer avascular membrane (~ 0.25mm thick)
- ✓ Rests on a basement membrane → serves as a biological scaffold, regulates morphogenesis, proliferation and differentiation of epithelial cells while preventing apoptosis
- ✓ Sits on a substantia → contains a compact collagenous layer, providing tensile strength
- ✓ Contains a thick fibroblastic layer → consisting of fibroblast embedded in a loose network of reticulum

Amnion Sources

Where We Source Amnion

Ophthalmogix sources its amnion for EvoPatch **only from full-term, healthy, consenting donors who choose to donate.**



Our donors are full-term and healthy, must give written consent and is required to answer a robust health, sexual history and travel questionnaire.



Blood is drawn from the donor and sent for rigorous testing to ensure the donor does not have any communicable or life-threatening diseases. This is done PRIOR to processing birth tissue. Tests are repeated six months after delivery.



Donor medical records are reviewed, and any discrepancy found that contradicts the health, sexual history and travel questionnaire is followed-up, confirmed and validated. If any discrepancies are identified and validated, the tissue is discarded.



Safe & Sterile

Processing

- ✓ Validated to a Sterility Assurance Level (SAL) of 10^{-6} in accordance with ISO 11137-2 Method 1
- ✓ Collection of the donor tissue is performed in an aseptic manner by appropriately licensed tissue establishments
- ✓ Placentas are recovered from planned C-sections which helps to minimize the potential for contamination during recovery
- ✓ Placental donors go through a rigorous pre-screening qualification
- ✓ Placental donors are tested to confirm they are free from disease
- ✓ No chemical cross-linking added during processing
- ✓ Processed in accordance with the safety guidelines provided by the U.S. Food and Drug Administration (FDA) – Human Cellular and Tissue-based Products (HCT/P) (21 CFR Part 1271)
- ✓ Processed in accordance with the standards from the American Association of Tissue Banks (AATB)



Clinical Indications



“The most important thing to remember is that coding needs to be driven by medical necessity. If you can prove medical necessity, you can bill for the testing or procedure. And this can be accomplished with thorough documentation of the signs and symptoms that prompted the testing or procedure, along with interpretation of the testing.”

Cecelia Koetting, OD, FAAO

LCD: Local Coverage Determination

Dry Eye Reimbursement Codes

| ICD-10 | Indication | ICD-10 | Indication |
|--------|-----------------------------------|--------|---------------------------------|
| H16.23 | Neurotrophic Keratoconjunctivitis | H18.52 | Epithelial Corneal Dystrophy |
| H16.21 | Exposure Keratoconjunctivitis | H18.83 | Recurrent Erosion of the Cornea |
| H16.12 | Filamentary Keratitis | H16.0 | Corneal Ulcer |
| H16.14 | Punctate Keratitis | B00.52 | Dendritic Corneal ulcer |



LCD: Alabama Blue Advantage

Policy

Effective for dates of service on or after June 26, 2019:

- Absence of iris;
- Bullous keratopathy;
- Conjunctivochalasis;
- Corneal degeneration;
- Corneal ectasia, corneal staphyloma, descemetocoele or other corneal deformity;
- Corneal ulceration or defect;
- Corneal disorder due to contact lens or recurrent erosion of cornea;
- Corneal perforation when there is active inflammation after corneal transplant requiring adjunctive treatment;
- Following removal of conjunctival lesion(s);
- Hereditary corneal dystrophies;
- Neurotrophic keratoconjunctivitis;
- Ocular burns;
- Stevens-Johnsons Syndrome;
- Partial limbal stem cell deficiency with extensive diseased tissue where selective removal alone is not sufficient;
- Persistent Epithelial defects that do not respond to conservative therapy;
- Pterygium;
- Pseudopterygiu



Average Reimbursement Rate

Reimbursement

\$1,400/EYE

AMNIOTIC MEMBRANE NATIONAL AVERAGE

CPT CODE: 65778

Placement of amniotic membrane on the eye;
without sutures

Important Information

- ✓ Zero-day net global
- ✓ Includes supplies, thus can not be bundled with 92070- bandage contact lens
- ✓ Considered a surgical code*
- ✓ Subject to in-office/ in-network benefits
- ✓ Can be billed during post-op global*
- ✓ Can NOT be billed with office visit code*

Modifying Indications

-25

To bill an exam the same day as the insertion of the membrane, the exam must meet the definition of modifier -25 in that the exam must be significantly and separately identifiable from the insertion. While medically necessary, if the exam is performed solely to confirm the need for the minor surgery, then the exam is not separately billable.

-50

When performed bilaterally, Medicare requires 65778 -50 and a "1" in the unit field. Other payers may require modifier -50 and a "2" in the unit field while others may require two lines with modifiers -RT and -LT.

-24

Membrane applied to an unanticipated complication during surgery or its global postoperative period.

BCBS In-Office Benefits

Other Facility

In-Network: (Other Medical/Surgical Facility (Non-Psychiatric) or Outpatient) - 80% of the allowed amount (coinsurance applies to OOP) **subject to the benefit period deductible (applies to OOP)**

Out-of-Network: (In-State and Other Medical/Surgical Facility (Non-Psychiatric) or Outpatient) - Non-Covered

Out-of-Network: (All Else) - 50% of the allowed amount (coinsurance does not apply to OOP) subject to the benefit period deductible (does not apply to OOP)

BCBS Example #2

In-Network: (Other Medical/Surgical Facility (Non-Psychiatric) or Outpatient) - 100% of the allowed amount subject to a \$150.00 copay (applies to OOP)

Out-of-Network: (In-State and Other Medical/Surgical Facility (Non-Psychiatric) or Outpatient) - Non-Covered

Out-of-Network: (All Else) - 80% of the allowed amount (coinsurance does not apply to OP) subject to the benefit period deductible (does not apply to OOP)

Bariatric Surgery

BDSC: 100% of the allowed amount subject to a \$150.00 copay (applies to In-Network OOP)

In-Network: Non-Covered Out-of-Network: Non-Covered

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Medicare Plan Coverage

- ✓ Medicare: Subject to Yearly Deductible AND Co-Insurance Patient Responsibility
- ✓ Cigna-HealthSpring: Special Plan without deductible or Copay
- ✓ Viva HealthSpring: Special Plan without deductible or Copay
- ✓ Humana Medicare: Special Plan without deductible or Copay

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VSP

Patients with diabetes (without diabetic eye disease) receive covered-in-full retinal screening. Patients with diabetes, glaucoma, or AMD may be eligible for additional exams and services.

All patients may be eligible for medical eyecare services for non-chronic conditions. This coverage is supplemental to a patient's medical plan.

Patients may be eligible for coordination of benefits with their medical plan. Criteria applies, see VSP Manual.

-Network VSP

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CMS Guidelines

Application for dry eye syndrome is noncovered, given no demonstrated impact on long term outcome.

08/13/2017

Chief Complaint Matches Diagnoses AND Treatment

Chief complaint should indicate Medical Necessity of tests ordered and treatment plan.

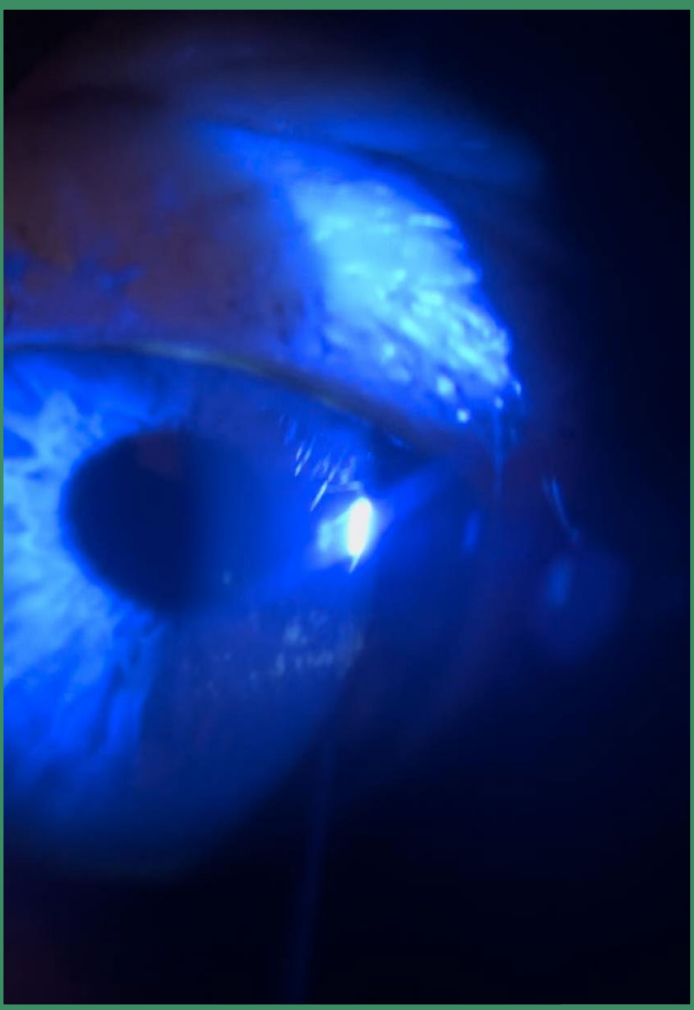
- ✓ Fluctuations in vision/ Reduction in Vision
- ✓ Burning, Foreign Body Sensation, Gritty Sensation
- ✓ Epiphora, Dryness
- ✓ Current or past treatments
- ✓ Justification for treatment, for example, work environment, sports events, (In HPI)

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Documentation

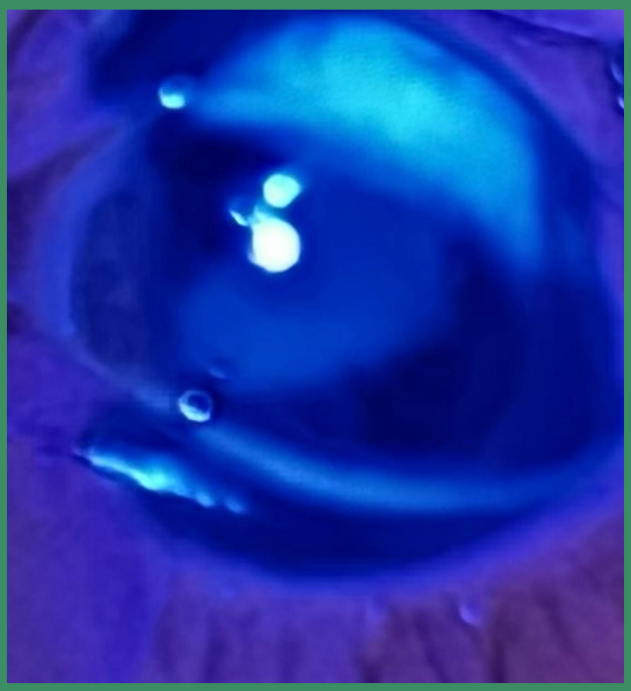
- ✓ Chief Complaint
- ✓ Clinical Findings- VA's, Slit Lamp
- ✓ Conjunctival/ Corneal Documentation
- ✓ Documentation of previous/ Failed Tx
- ✓ Photo-documentation of Findings, Pre and Post Application?
- ✓ Saved, Documented Bar Code
- ✓ Assessment and Plan, Match CC and Justifies Tx

Case One: Chief Complaint Examples



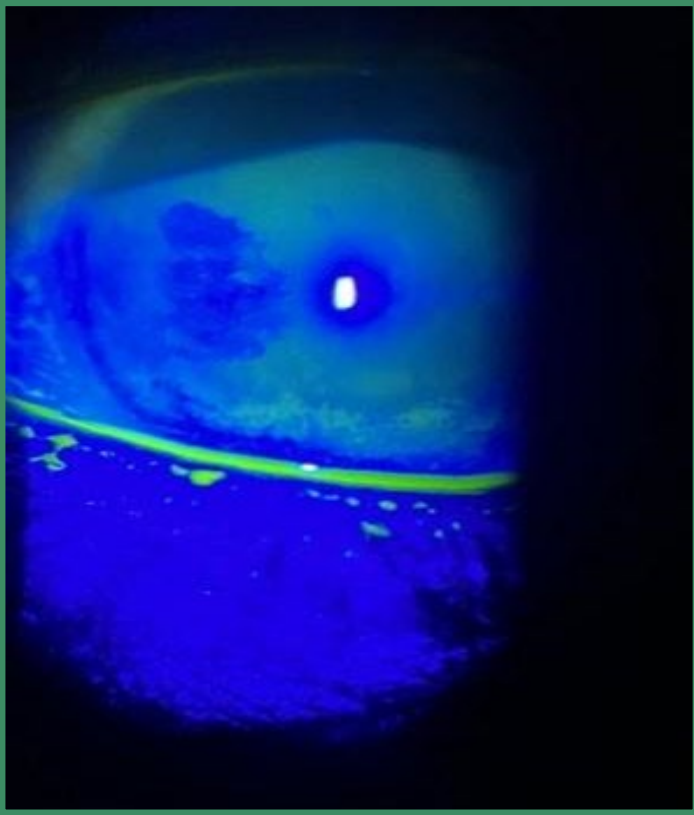
- ✓ Case: Metal in Eye; grinding at work
- ✓ VS:
- ✓ CC: Epithelial defect, OD, FB removal with rust formation
- ✓ HPI: Occurred over weekend, +Pain(7/10), +watering, +Photophobia, Voc: Welder
- ✓ OcHX: Previous FB Scars, Using OTC meds; No Improvement
- ✓ Findings: Peripheral Defect with ulcer formation and surrounding edema
- ✓ Plan: AMT with bandage contact lens AND RX topical antibiotic

Case Two: Finger to Eye in Baseball Game



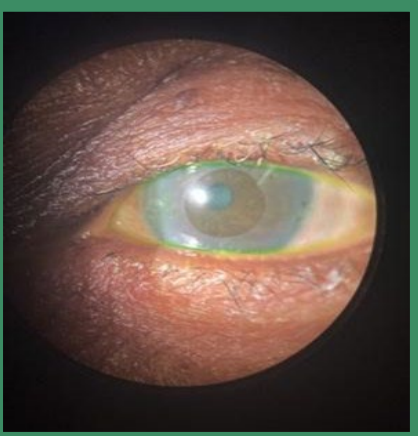
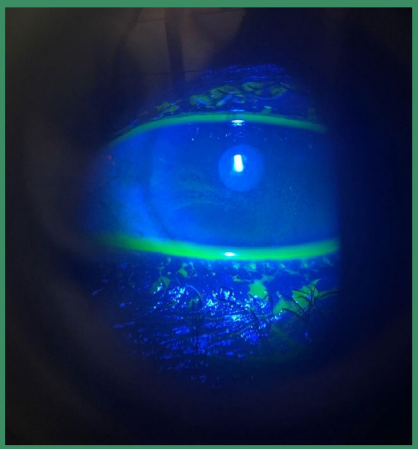
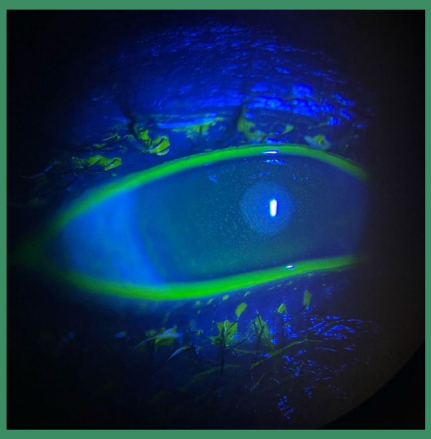
- ✓ CC: Finger to Eye in Baseball Game
- ✓ VS
- ✓ CC: Severe Pain OS
- ✓ HPI: Finger to eye, +Pain, +FBS, +Photophobia, Occurred 2 days ago
- ✓ OcHX: Previous Abrasion and RCE three months ago with topical TX
- ✓ Findings: Central Corneal Defect consistent with RCE defect in previous exams
- ✓ Plan: AMT with Bandage Contact, applied second AMT three days later to ensure epithelial adhesion while patient AND parents opted for child to play in ALL-STARS

Case Three



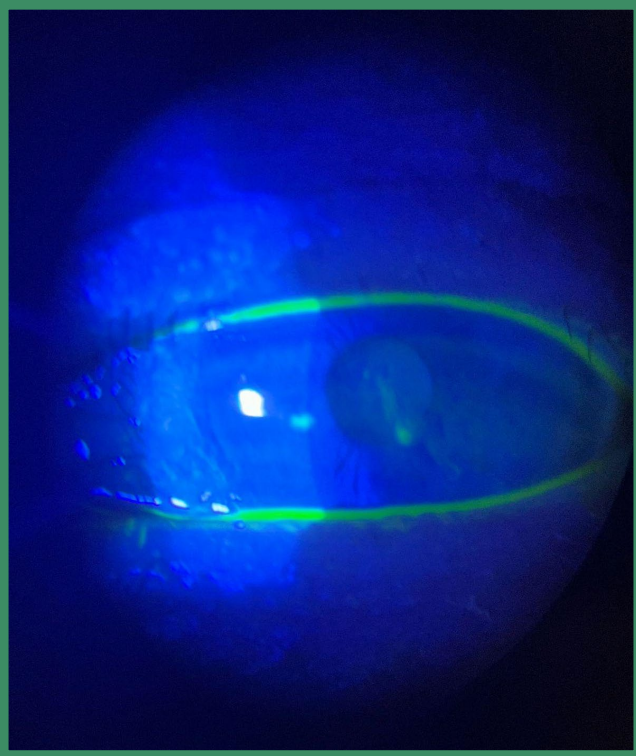
- ✓ CC: 1 Day S/P Phaco OS, Sore/ Sharp Pain
- ✓ HPI: OS, Under Lower Lid, Denies Rubbing, +Compliant on Gtts
- ✓ Notes: Surgical notes show normal, non-complicated procedure
- ✓ Findings: Large Corneal Defect/Abrasion Inferior Cornea
- ✓ Plan: AMT with pressure patch and Bill with Modifier for Unanticipated Finding

Case Four



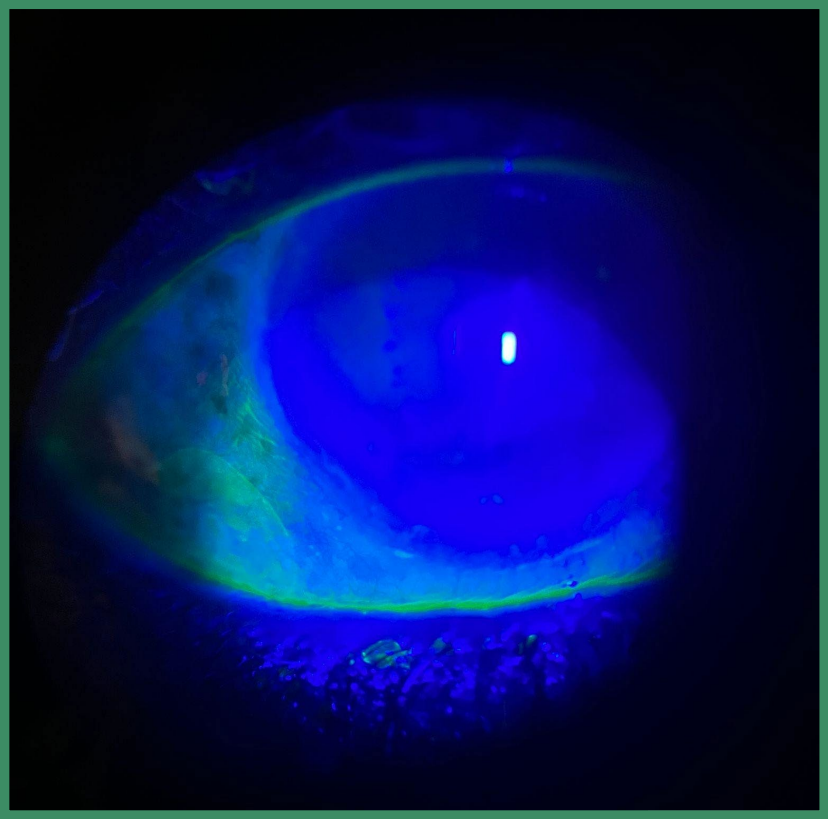
- ✓ CC: Dec VA OU, Severe gritty sensation
- ✓ HPI: OU, PFree AT QID, NI, Previous plugs and Topical Eysuvis TID
- ✓ OcHX: Hx of DES, NK with +Swab, Currently on Chemo meds long term
- ✓ Findings: Bilateral NK, Severe SPK, Stromal haze, reduced VAs
- ✓ Plan: AMT Bilateral with justification of reduced VA, severity of Corneal health, Pre-approval with notes that patient has conflicts with transportation and chemo treatments

Case Five



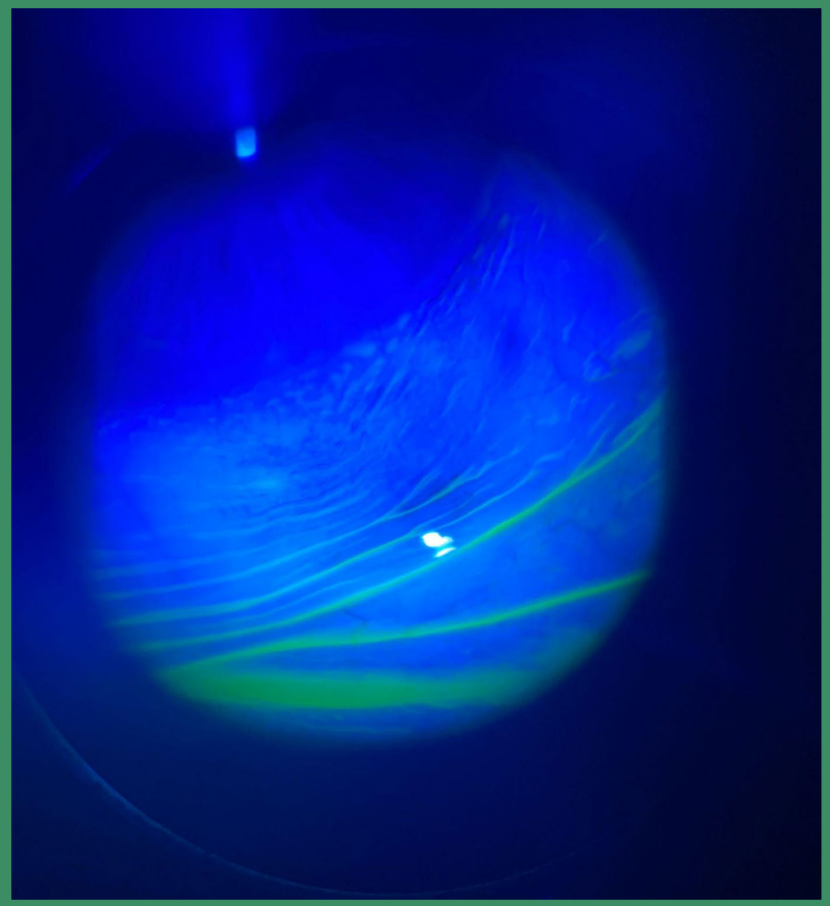
- ✓ CC: Reduced Vision OS, Light Sensitive
- ✓ HPI: HSV Keratitis OS, +Dec VA, +Swab, +Light Sensitive, +FBS
- ✓ OCHx: Hx of recurrent HSV-K, Not On ANY Meds
- ✓ Plan: AMT OS, RX Valtrex, then Add Viroptic q4H in two days

Case Six



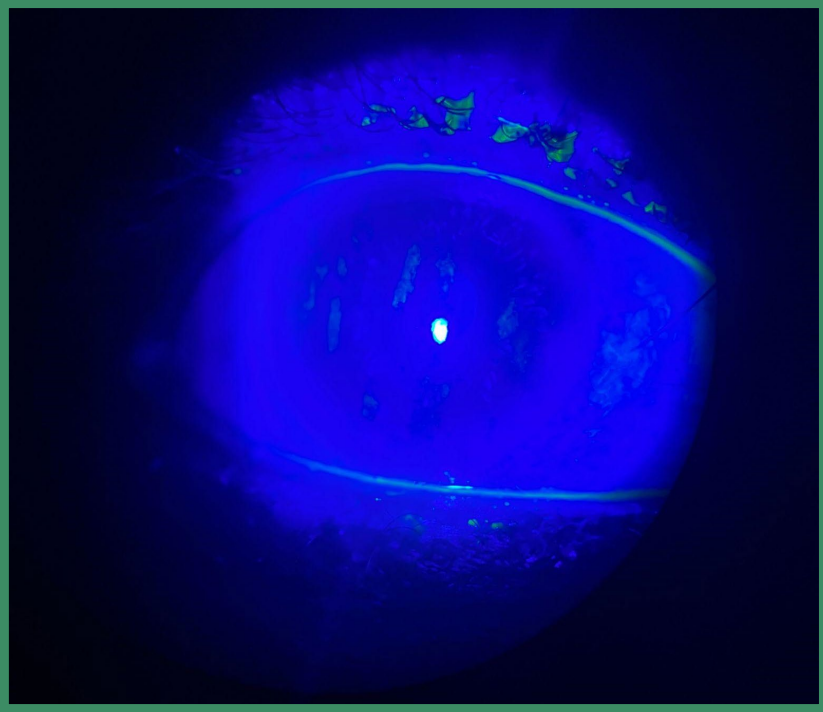
- ✓ CC: Gritty FB sensation
- ✓ HPI: DES, +FBS, OU, +Watering
- ✓ OcHX: Topical Eysuvis for 1 month, Minimal Improvement, Hx of Restasis and Plugs; Minimal Improvement
- ✓ Plan: AMT to CCH area and continue Eysuvis

CCH Continued



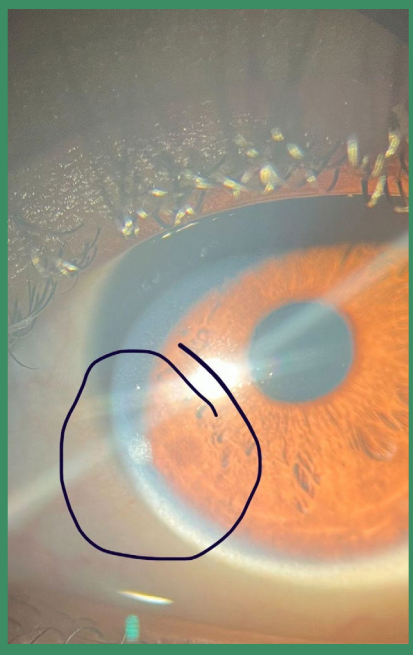
CCH treatment: Document failed treatments, Does not require any surgical repair for AMT application.

Case Seven

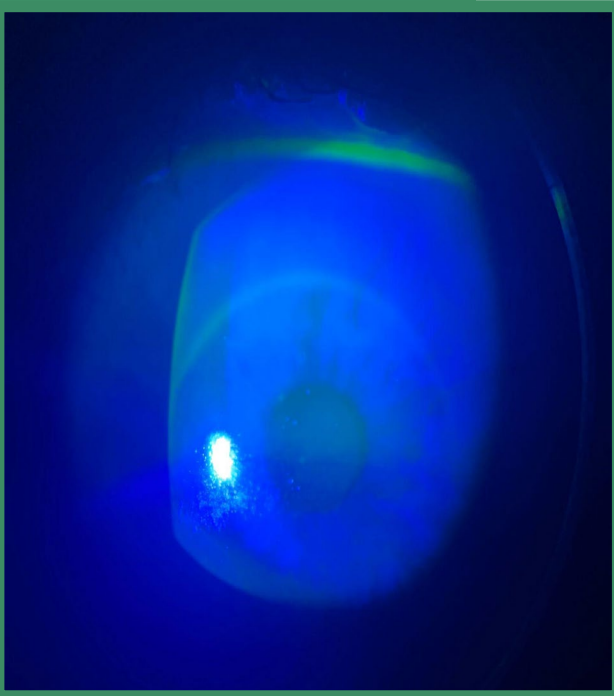


- ✓ CC: FBS, OU
- ✓ HPI: +Gritty Sensation, +Dec VA, +Rubs eyes Constantly
- ✓ Findings: Filamentary Keratitis with mucus plugs central OS, Debride in office and AMT with Bandage Contact Lens

Case Eight

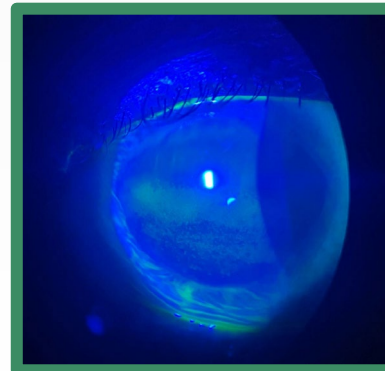
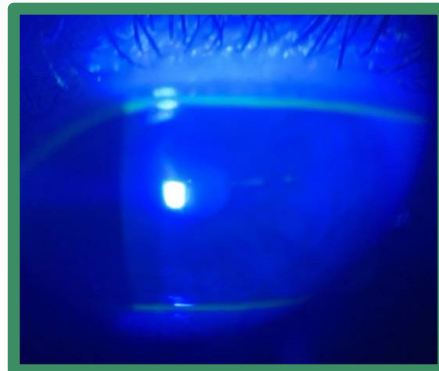
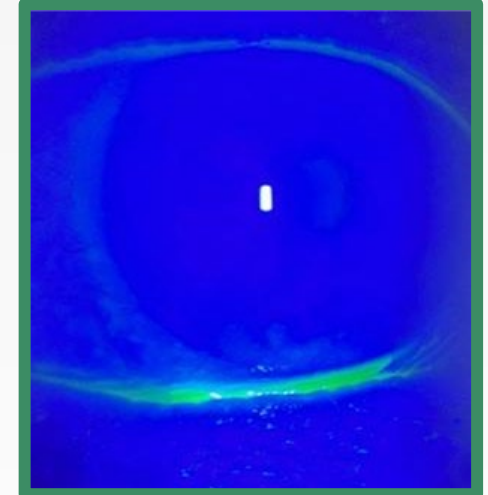
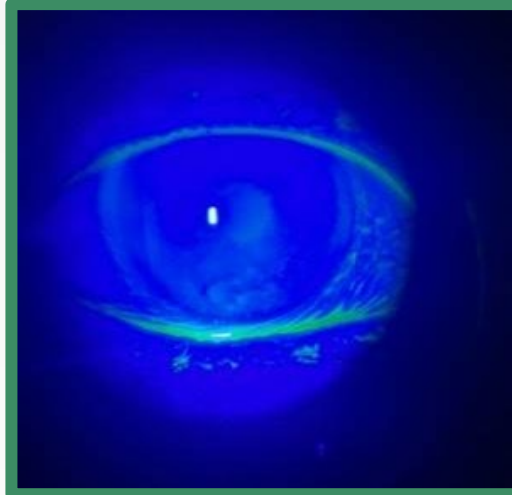
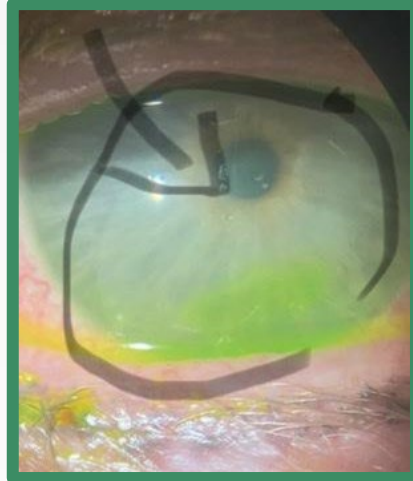
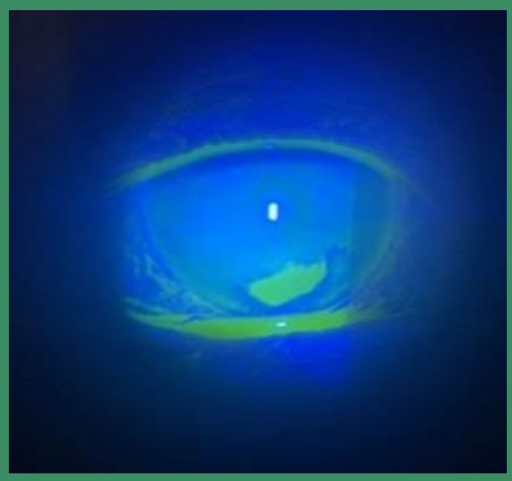


- ✓ CC: Painful OS
- ✓ HPI: OS, CL wearer, +Pain 8/10, +2 days, +Light Sensitive, +Watering
- ✓ Findings: Peripheral Ulcer
- ✓ Plan: AMT with bandage CL, Rx Antibiotics



Additional Cases

- ✓ RCE case
- ✓ Corneal defect from 4 Wheeler in Woods
- ✓ RCE case round two
- ✓ Chemical/ Aerosol Spray to eye



Audits/Denials

- ✓ Documentation is KEY
- ✓ Trust your findings AND plan
- ✓ Submit ALL Supporting Documents, History, Forms, Patient Consents
- ✓ Include Photos - Pre and Post AMT Application
- ✓ Include your justification/ Medical Reasoning in plan

Denials WILL occur *
Re-submit with all documentation.
Hire a bulldog for a billing specialist.

CPT 65778

Reference Links

Billing and Coding in Dry Eye: Showing Medical Necessity Can Ensure Reimbursement

Cecelia Koetting, OD, FAAO, Ophthalmology Management, April 2021

<https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=53441>

<https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=53441>

<https://www.corcoranccg.com/products/faqs/amniotic-tissue/#:~:text=A%3A%20CPT%20code%2065778%20describes,ocular%20surface%3B%20without%20sutures>

<https://www.reviewofoptometry.com/article/the-ins-and-outs-of-corneal-wound-healing/preview/roeditorial>

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How Ophthalmologix Helps You and Your Practice



OPHTHALOGIX KOL ACCESS

Ophthalmologix ensures you and your team will have access to our KOLs Dr. Mike Johnson, OD and Dr. Alex Kabiri, OD.



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Every quarter, Ophthalmologix organizes a live webinar designed to educate you on indications, treatments, trends and more.





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