HOT TOPICS

Hot Reimbursement Topics

Corcoran Consulting Group

Office Visit & Minor Procedure

"CPT Modifier 25 – Significant Evaluation and Management Service By Same Physician On Date of Global Procedure

Pay for an evaluation and management service provided on the day of a procedure with a global fee period if the physician indicates that the service is for a significant, separately identifiable evaluation and management service that is above and beyond the pre- and post-operative work of the procedure."

Source: MCPM, Chapter 12, § 40.2.A8

Outline

1. Modifier 25
2. Blepharoplasty/ptosis surgery
3. Single use drugs and JW modifier
4. Diagnostic test interpretations
5. 2nd eye cataract medical necessity
6. FS laser-assisted cataract surgery
7. New Technology

Office Visit & Minor Procedure

"Evaluation and Management Service Resulting in the Initial Decision to Perform Surgery

...where the decision to perform the minor procedure is typically done immediately before the service, it is considered a routine preoperative service and a visit or consultation is not billed in addition to the procedure."

Source: MCPM, Chapter 12, §40.2A4

Modifier -25 and the OIG

- 35% of claims in 2002 with modifier 25 did not meet requirements
- No substantive improvement on later reviews
- Excessive use of modifier -25 garners (unwanted) attention
- OIG's 2014 Work Plan has kept it
  - Drug compounding was an added oversight in 2014
  - Modifier 25 was on Work Plans in 2012 and 2013
  - Particular attention for intravitreal injections

Source: OIG Report, Nov. 2005, OEI-07-03-00470

Modifier -25

- Use modifier -25

Est. patient with ≥2 problems
- OD vs. OS
- Anterior vs. posterior seg
- Eye vs. systemic dx
- Multiple eye conditions

- Don't use modifier -25

Decision for surgery
Only one reason for exam

Modifier -25 Yes or No?

Your patient is scheduled for intravitreal injection today in OD. There was a recent exam of both eyes, at which the decision was made for this injection. You look at both eyes but proceed with the injection, OD. There are no complaints or findings for the other eye. Does modifier -25 apply?

a) Yes
b) No

CMS Policy Changes to Blepharoplasty With Covered Ptosis Surgery - 10/01/17

- Effective October 1, 2017
- Cosmetic Bleph (CPT 15823) allowed with functional blepharoptosis (67901-67908)

Source: MM 10236. Oct 2017 Update of the Hospital Outpatient Prospective Payment System. Effective 10/01/2017

Modifier -25 Yes or No?

Your patient uses an Amsler grid to monitor her AMD. Today, while here for an AMD exam, she complains of irritation OS. You find a few errant eyelashes and epilate them with forceps. The rest of the DFE finds no change in her AMD.

Does modifier -25 apply?

a) Yes
b) No

CMS Policy Changes on 10/01/17

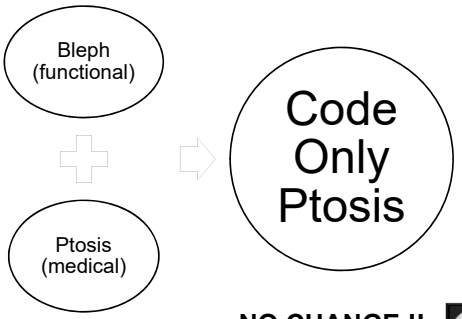
- MM 10236 notes:
- *" … effective October 1, 2017, CMS is revising this policy to allow either cosmetic or medically necessary blepharoplasty to be performed in conjunction with a medically necessary upper eyelid blepharoptosis surgery. Specifically, physicians may receive payment for a medically necessary upper eyelid blepharoptosis from Medicare even when performed with (non-covered) cosmetic blepharoplasty on the same eye during the same visit …"*

Source: MM 10236. Oct 2017 Update of the Hospital Outpatient Prospective Payment System. Effective 10/01/2017

Outline

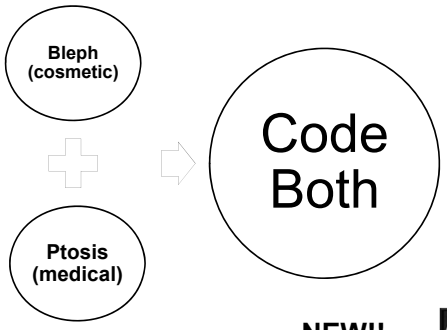
1. Modifier 25
2. Blepharoplasty/ptosis surgery

Cosmetic vs Incidental – on 10/01/17



NO CHANGE !!

Cosmetic vs Incidental – on 10/01/17



NEW!!

Modifier JW

- "The JW modifier must not be used to report overfill wastage."
- "CMS expects that providers and suppliers will maintain accurate (medical and/or dispensing) records for all beneficiaries as well as accurate purchasing and inventory records for all drugs that were purchased and billed to Medicare."

Source: www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf.

Outline

1. Modifier 25
2. Blepharoplasty criteria
3. Single use drugs and JW modifier

Modifier JW

- JW – used only for billable drug up to the amount on the package label (i.e. botox)
- Do not use JW for manufacture overfill of single dose vials like Lucentis and Eylea
- Add statement to operative notes regarding "zero units wasted" and/or "only manufacture overfill discarded"

Modifier JW

- *Drug Amount Discarded / Not Administered to any Patient*
- Effective 1/1/17
- Use the JW modifier for claims with unused drugs or biologicals from single use vials or single use packages that are appropriately discarded . . .
- Document the discarded drug or biological in the patient's medical record when submitting claims . . .

Source: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9603.pdf

Outline

1. Modifier 25
2. Blepharoplasty criteria
3. Single use drugs and JW modifier
4. Diagnostic test interpretations

Chart Documentation

- ….with interpretation and report

Test Interpretation

- What does it show?
  - *Increased blind spot*
- What does it mean?
  - *Progression of glaucoma*
- What are you going to do about it?
  - *Add a medication*

Interpretation & Report

"Carriers generally distinguish between an 'interpretation and report' of an x-ray or an EKG procedure and a 'review' of the procedure. A professional component billing based on a review of the findings of these procedures, without a complete written report similar to that which would be prepared by a specialist in the field does not meet the conditions for separate payment of the service. This is because the review is already included in the … E/M payment."

Source: CMS MCPM Chapter 13, §100

Visual Field Interpretation

- Plan: Threshold perimetry to re-evaluate POAG
- June 3, 2019
- Mary Smith, COA
- 1 false positive
- Good patient cooperation
- Arcuate scotoma, OU
- POAG, shows progression since last visit
- Add another anti-glaucoma medication

I. C. Better, M.D.

Interpretation & Report

"For example, a notation in the medical records saying 'fx tibia' or 'EKG-normal' would not suffice as a separately payable interpretation and report of the procedure and should be considered a review of the findings payable through the E/M code. An 'interpretation and report' should address the findings, relevant clinical issues, and comparative data (when available)."

Source: CMS MCPM Chapter 13, §100

Illustrative Test Interpretation

TEST: Optic nerve OCT

Interpretation: Normal

What's wrong?

Dx: POAG

Illustrative Test Interpretation

TEST: Optic nerve OCT

Interpretation: Normal

Dx: POAG

Why was test done?
Observations?
Data?

True or False

Documentation of medical necessity for the second eye surgery should be noted when the first eye is stable.

Illustrative Test Interpretation

TEST: Optic nerve OCT

Interpretation: OCT for POAG. No retinal nerve fiber layer loss or changes at this time. No treatment indicated.

Dx: POAG

Improved Interpretation

Second Eye

The indications for the second-eye surgery are the same as for the first eye. The outcome of surgery on the first eye may affect the timing of the second eye surgery.

Prior to performing second-eye surgery, the refractive error of the first eye should be determined in order to select the appropriate IOL power for the second eye.

Source: AAO Preferred Practice Pattern, Adult Cataract (2016)

Outline

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2. Blepharoplasty criteria
3. Single use drugs and JW modifier
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5. 2nd eye cataract medical necessity

Second Eye

- Is patient stable?
- New complaint? (e.g., diplopia, imbalance)
- Repeat
  - Documentation of disability
  - Exam that determines need for surgery
  - Informed consent
- Inside postop period?
  - Use –24 and/or –57 modifier

Illustrative Chart Note
What's wrong?

CC: Postop check OD, "Doing Great!"
HPI: Phaco/IOL OD 6 days ago, no problems
VA cc: 20/30 OD
Dx: Pseudophake OD, Cataract OS
Plan: Phaco/IOL OS

Outline

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6. Femtosecond laser-assisted cataract surgery

Illustrative Chart Note
What's wrong?

CC: Postop check OD, "Doing Great!" ⇦
HPI: Phaco/IOL OD 6 days ago, no problems — *Asymptomatic*
VA cc: 20/30 OD
Dx: Pseudophake OD, Cataract OS
Plan: Phaco/IOL OS ⇦ *Unsupported by CC*

Covered versus Non-covered

Covered	Non-covered
• Statute or law (SSA) • Regulation (CMS)	• Excluded by statute • Limitations by regulation
• Follow insurance rules	• Patient pay

Better Chart Note

CC: Re-evaluation cataract OS, postop check OD, patient notices annoying imbalance between eyes

HPI: Cataract OS[1] x 3 yrs[2], VA poor[3] for last 9 mos., with annoying imbalance[4] and some diplopia since first surgery, current glasses no help, glare @ night[5], difficulty with driving[6]

Dx: Pseudophake OD, Cataract OS

Plan: Phaco/IOL OS

Foundation

- Cataract surgery (66984, 66982) includes:
  - Corneal incision to permit entry of phaco
  - Capsulorrhexis
  - Lens fragmentation
  - Insertion of an IOL
- Since coverage and payment exists for cataract surgery and included services, a separate charge to use the FS laser for these purposes is precluded

Foundation

- Cataract surgery does NOT include:
  - Toric IOL, presbyopia-correcting IOL
  - Refractive surgery
    - LRI, CRI, AK, LASIK, PRK
- Use of the FS laser for refractive surgery is not part of cataract surgery; a separate charge to the patient is justified and is not covered

Temporary Amniotic Membrane

- Indication
- FDA 510(k) clearance: *"The device is intended for use in eyes in which the ocular surface cells have been damaged, or underlying stroma is inflamed and scarred."*

▲ The original Prokera device has a 100-µm thickness and is recommended for patients with neurotrophic ulcers, severe microbial keratitis, bullous keratopathy, and high-risk corneal transplantations. (Source: Bio-Tissue)

Laser-Assisted Cataract Surgery

- CMS guidance published November 16, 2012

"Medicare coverage and payment for cataract surgery is the same irrespective of whether the surgery is performed using conventional surgical techniques or a bladeless, computer controlled laser.

" If the bladeless, computer controlled laser cataract surgery includes implantation of a PC-IOL or AC-IOL, only charges for those non-covered services specified above may be charged to the beneficiary. These charges could possibly include charges for additional services, such as imaging, necessary to implant a PC-IOL or an AC-IOL but that are not performed when a conventional IOL is implanted."

Temporary Amniotic Membrane

- Chemical burns of the ocular surface
- Corneal epithelial defects, such as may be occur with:
  - Bullous or band keratopathy
  - Epithelial basement membrane dystrophy
  - Recurrent corneal erosions
  - Keratitis (exposure, neurotrophic, filamentary, bacterial or viral)
  - Post-op care after corneal procedures
  - Post-op care after pterygium surgery
- Corneal ulcer
- Partial limbal stem-cell deficiency
- Persistent epithelial defects (delayed healing)
- Stevens-Johnson Syndrome

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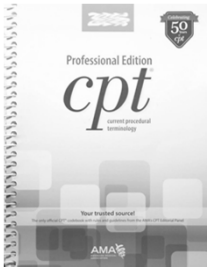
AM in Severe DED

- TFOS DEWS II
- *"Severe DED can lead to persistent epithelial defects, corneal ulceration and corneal scarring. Amniotic membrane grafts could be considered for persistent epithelial defects in cases of ocular cicatricial pemphigoid, Stevens-Johnson syndrome and other severe OSD"*
- *"A particular form of amniotic membrane transplant is the PROKERA® …To date, only a few case studies have been published on its use"*

Temporary Amniotic Membrane

- CPT code
- 65778
- *Placement of amniotic membrane on the ocular surface; without sutures*
- *(For placement of amniotic membrane using tissue glue, use 66999)*



Temporary Amniotic Membrane

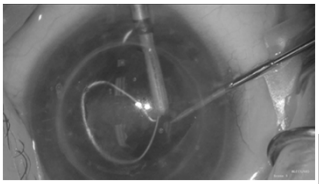
- Chart documentation:
- Medicare expects that a surgical procedure will not be performed as an initial treatment for dry eyes. The chart should include documentation that other, less invasive, therapies were unsuccessful or contraindicated.
- As with any surgical procedure, the patient's informed consent is obtained. An appropriate operative report should be in the medical record; this includes any preparatory drops, which eye was treated, and a description of the brand, size and lot number of the AM. Postoperative instructions should also be noted.

Temporary Amniotic Membrane

- Coverage and payment
- Coverage: **GOOD**
- Payment: 2019 MPFS Nat. Par. $1,444 SOS $57
- Global period: 0 days

IanTech miLOOP

- Indication
- FDA registered Class 1 device: hook, ophthalmic



Temporary Amniotic Membrane

- Related services:
- Functional questionnaire (OSDI, SPEED)
- Tear breakup time (TBUT)
- Corneal staining
- Tear osmolarity
- MMP-9 immunoassay
- Tear film imaging
- Meibomian gland imaging
- Autologous serum eye drops (SEDs)

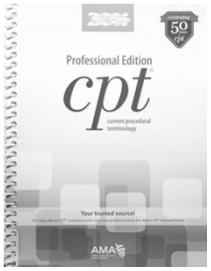
IanTech miLOOP

- The micro interventional loop device, miLOOP, is inserted through a small incision, unfolded in the hydrodissection plane, looped around the lens, and upon retraction, full-thickness lens fragmentation is achieved, cutting it in half. This process could be repeated several times, fragmenting the cataract into multiple pieces that could be aspirated out or even removed manually.

Source: EyeWorld October 2017

IanTech miLOOP

- CPT code
- 66984
- *Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique, e.g., I&A or phaco*



IanTech miLoop

- miLOOP does not, by itself, qualify as complex cataract surgery
  - The instrument is not *required*
  - The choice of surgical instrument belongs to the surgeon – it's elective
  - Not for iris expansion
  - Not to suture an IOL
  - Not for primary posterior capsulorrhexis
  - Not an additional implant (*e.g.,* CTR)

IanTech miLOOP

- Coverage and payment
- Coverage: **EXCELLENT BUT BUNDLED**
- Payment: 2019 MPFS Nat. Par. $654. ASC $977
- Global period: 90 days
- No financial waiver for miLOOP

IanTech miLOOP

- Chart documentation:
- Incorporate a description of the use of the miLOOP within the operative report for cataract surgery
- No special informed consent required
- A financial waiver may not be used to collect money from the beneficiary … the ASC/HOPD bears the financial responsibility … facility cannot charge the surgeon for the instrument

IanTech miLoop

- Related service:
- 66982 is described as *"Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage."*

New Category III Add-on Code

- *+0514T* Intraoperative visual axis identification using patient fixation (List separately in addition to code for primary procedure)

►(Use +0514T in conjunction with 66982, 66984)◄

- Effective: January 1, 2019
- Sunset: January 2024
- For the ASC +0514 has payment indicator "N1"
  - N1 - Packaged service/item; no separate payment made.

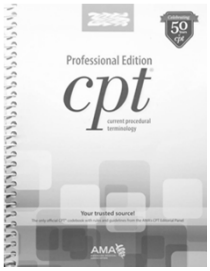
Sources: AMA Website. CPT Category III Codes, CMS 2019 ASC Addenda AA

Intraoperative Visual Axis Identification

- Coverage and payment
- Coverage: **Physicians' claims uncertain**
  ASC Charge, bundled
- Payment: 2019 MPFS Nat. Par. undetermined ASC $0
- Global period: 90 days associated with concurrent cataract procedure

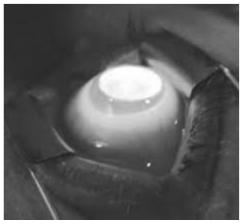
Corneal Collagen Cross-linking

- CPT code
- 0402T
- *Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)*
- *(Do not report 0402T in conjunction with 65435, 69990, 76514)*



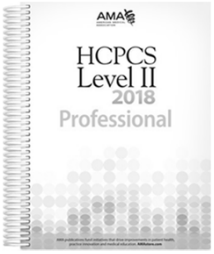
Corneal Collagen Cross-linking

- Indication:
- FDA approved the KXL System and two photoenhancers for CXL treatment of progressive keratoconus and post-LASIK ectasia



Corneal Collagen Cross-linking

- HCPCS J-code
- J2787 - Riboflavin 5'-phosphate, ophthalmic solution, up to 3 mL
- Sept 2018 CPT Panel accepted revision of 0402T (Corneal Collagen Crosslinking) to allow the reporting of medication separately



Source: HCPCS and AMA CPT Panel minutes Sept 2018

Corneal Collagen Cross-linking

- Corneal collagen cross-linking is a technique which uses UV light and a photosensitizer to strengthen chemical bonds in the cornea. The goal of the treatment is to halt progressive and irregular changes in corneal shape known as ectasia. These ectatic changes are typically marked by corneal thinning and an increase in the anterior and/or posterior curvatures of the cornea, and often lead to high levels of myopia and astigmatism. The most common form of ectasia is keratoconus and less often ectasia is seen after laser vision correction such as LASIK.

Corneal Collagen Cross-linking

- Coverage and payment
- Coverage: **BELOW AVERAGE**
- Payment: 2019 MPFS Nat. Par. $1,448. SOS $58
- Global period: 0 days
- Prior authorization recommended
- Financial waiver if not covered
- IRB for experimental use

Corneal Collagen Cross-linking

- Related services:
- Pachymetry
- Corneal topography
- Specular microscopy
- Rigid gas permeable contact lens
- Intraoperative pachymetry
- Intraoperative removal of epithelium (epi-off)
- Application of riboflavin (vitamin B_2)
- Activation of cross-linking with 365 nm UVA light
- Bandage contact lens
- Temporary amniotic membrane (infrequent)

Kahook Dual Blade

- Indications:
- Primary congenital or infantile glaucoma (highest success rates)
- May be performed for secondary glaucomas in children due to Sturge-Weber syndrome, aniridia, neurofibromatosis, and Axenfeld-Rieger syndrome
- Contraindications:
  - Severe filtration angle anomaly
  - Infant with unstable health and increased anesthetic risk
- Advantages of goniotomy
  - No conjunctival incision required
  - Less operating room (OR) time
  - Direct anatomic visualization

Source: AAO

Corneal Collagen Cross-linking

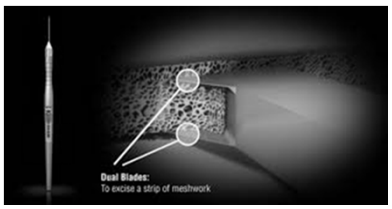
- Chart documentation:
- Operative report with indications, description, and discharge instructions
- IRB approval for experimental and investigational use

Kahook Dual Blade

- Advantages of trabeculotomy
  - Can be performed with opacified cornea
  - Can be converted easily to trabeculectomy if Schlemm canal (SC) is not identified
    - SC may not be identified in about 15% of the cases

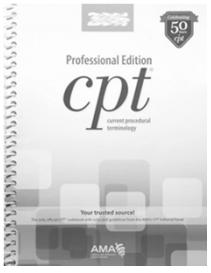
Kahook Dual Blade

- Instrument used to perform:
- *Goniotomy*
- FDA Class 1 device



Kahook Dual Blade

- CPT code
- 65820 Goniotomy
- *(Do not report modifier -63 in conjunction with 65820)*
- *For use of ophthalmic endoscope with 65820, use 66990)*



Kahook Dual Blade

- Coverage and payment
- Coverage: **GOOD**
- Limitations occur for ICD-10 codes
- 2019 Payment:
- MPFS, Par. $776.28
- ASC: $1,771.76
- Global period: 90 days

Summary

- Modifier 25 continues to be scrutinized
- Know coverage guidelines for lid surgery
- Use JW modifier for billable drug waste only
- Monitor medical necessity for DED testing
- Insure medical necessity for 2nd eye cataract
- Monitor confusion surrounding FS laser with cataract extraction

CPT Assistant – December 2018

- Question: Is it appropriate to report CPT code 66174 for therapeutic dilation of Schlemm's Canal and code 65820 for a goniotomy, when these two procedures are performed on the same eye to treat glaucoma?

- Answer: No, it would not be appropriate to report code 66174, *Transluminal dilation of aqueous outflow canal; without retention of device or stent*, in conjunction with code 65820, *Goniotomy*. Only code 66174 should be reported, as this procedure represents the service performed, and the incision inherent in goniotomy is incidental to code 66174.

Source: AMA

Additional Assistance

(800) 399-6565

Website: www.CorcoranCCG.com

Mobile application: Corcoran 24/7

New Technology: Plus / Minus

+ New innovation?	- Coding uncertainty
+ New testing options?	- Coverage 'iffy'
+ Better outcomes?	- Often patients pay
+ More efficient?	- Requires waivers

ADDENDUM

Corcoran Consulting Group
A Division of Ardare Corporation

REIMBURSEMENT ISSUES RELATED TO MODIFIER 25

1

QUESTION: What does modifier 25 mean?

ANSWER: CPT defines modifier 25 as a *"Significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service."* It indicates that the patient's condition required an additional E/M service beyond the usual pre-operative care provided for the procedure or service. Additional language in CPT emphasizes the importance of chart documentation. It states, *"A significant, separately identifiable E/M service is defined or substantiated by documentation that satisfies the relevant criteria for the respective E/M service to be reported."* CPT adds that *"This modifier is not used to report an E/M service that resulted in a decision to perform surgery."*

2

QUESTION: What types of procedures or services require the use of modifier 25?

ANSWER: Append modifier 25 to an exam (992xx or 920xx) when a *separately identifiable service* has been performed on the same day as a minor procedure. Medicare defines minor procedures as those with zero (0) or ten (10) days of postoperative care. Examples include foreign body removal (65222), laser trabeculoplasty (65855), epilation for correction of trichiasis (67820), and intravitreal injection (67028).

3

QUESTION: Must we have more than one diagnosis on the claim to use modifier 25?

ANSWER: No. The CPT definition of modifier 25 specifically states, *"…different diagnoses are not required for reporting of the E/M services on the same date."* If the patient does have more than one problem being addressed at the visit, it is appropriate to use different diagnoses on the claim. (See Case Study #1)

4

QUESTION: If there is only one diagnosis, how do we determine when to bill the visit as well as the procedure?

ANSWER: The CPT definition says that a separately identifiable service must be provided. Case Study #2 illustrates a separately identifiable exam that is reimbursable in addition to the procedure because the physician had to cope with more than one occurrence of the same problem in different ways. Append modifier 25 to the CPT code for the exam; the minor procedure does not require a modifier, other than RT and LT.

5

QUESTION: When is the use of modifier 25 not appropriate?

ANSWER: If the only purpose of the exam is preoperative care, then a claim for an office visit with modifier 25 would not be appropriate.

Without an unrelated diagnosis, the majority of office visits will not meet the modifier 25 definition. The same day exam is rarely anything but usual preoperative work. In unusual situations like Case Study #2, the same diagnoses may support both an office visit and a minor procedure on the same day.

6

QUESTION: Does use of modifier 25 affect the value ascribed to the exam?

ANSWER: Not for Medicare or most payers. In general, use of modifier 25 makes full reimbursement of both the office visit and the minor procedure possible. Without it, the exam may be considered preoperative and not paid at all. A few payers have recently indicated that use of modifier 25 will reduce the allowance for the exam, although we have not seen it.

April 21, 2019

Corcoran Consulting Group
A Division of Ardare Corporation

REIMBURSEMENT ISSUES RELATED TO MODIFIER 25

7

QUESTION: Will the use of modifier 25 attract attention from Medicare?

ANSWER: Excessive use of this modifier may garner unwanted attention. A November, 2005, report (OEI-07-03-00470) released by the Office of Inspector General (OIG) indicated that 35% of 2002 claims with modifier 25 did not meet program requirements. They recommended that CMS work with Medicare Administrative Contractors (MACs) to reduce inappropriate claim submission with modifier 25. Recovery audit contractors (RACs) are also closely scrutinizing the use of modifier 25.

In our analysis of CMS data, we find that about 13% of exams were associated with modifier 25 in 2017. That is, for every 100 exams paid to ophthalmologists in 2017, 12 were billed with modifier 25. For optometry, the frequency was about 4%. If your utilization significantly exceeds this amount, scrutiny by Medicare is likely.

CASE STUDY # 1

Your patient with systemic lupus erythematosus is being followed for potential toxicity due to Plaquenil therapy. During today's exam, the patient also complains of a strong foreign body sensation in both eyes that has not responded to artificial tears suggested by a pharmacist. Your examination identifies keratoconjunctivitis sicca and associated dry mouth. You diagnose secondary Sjogren's syndrome.

Due to the severity of the condition, you recommend continuation of the artificial tears as well as punctal occlusion with plugs in the lower puncta. The plugs are inserted today, and another follow-up visit is scheduled in 2 weeks. The primary ICD-10 code assigned to the exam (M32.- *Systemic lupus erythematosus…*) is different from the code for punctal occlusion (M35.01 *Sicca syndrome …*). Subordinate ICD-10 codes for the exam include Z79.899 (*Other long term (current) drug therapy*).

8

QUESTION: What is the best way to document a minor procedure?

ANSWER: The exam and minor surgery may appear on the same page in the medical record, but we don't recommend it. We suggest a separate operative report for the surgery. It should contain the indications for the procedure, a description of the procedure, and discharge instructions. A Minor Procedure Operative Report form is available for download at no charge on our website. A clearly documented consent for the procedure should also be included, either written or verbal.

CASE STUDY # 2

Your Type II diabetic patient presents with macular edema OU and mild NPDR OU, OS>OD. You perform an intravitreal injection of ranibizumab 0.3mg OS and continue NSAID gtts OD.

Your diagnosis code for the exam and the injection are both E11.321- (*Type 2 DM with mild NPDR and macular edema …*) However, the exam will have a 7th character of 3, indicating bilateral disease, and the injection will have a 7th character of 2, indicating left eye.

April 21, 2019

Corcoran Consulting Group
A Division of Ardare Corporation

REIMBURSEMENT FOR CORNEAL COLLAGEN CROSS-LINKING

1 ***QUESTION:*** What is corneal collagen cross-linking?

ANSWER: Corneal collagen cross-linking (CXL) uses a combination of riboflavin (vitamin B2) and ultraviolet (UVA) light to make collagen in the corneal stroma stronger and more flexible. In keratoconus and corneal ectasia, the corneal stroma has weakened, and the cornea thins and bulges out, distorting vision. In most cases, CXL is ideally performed early in the disease process before vision deteriorates to the point where glasses or contact lenses no longer correct vision.

2 ***QUESTION:*** What is involved in the CXL procedure?

ANSWER: The FDA-approved version of CXL involves removing the corneal epithelium (epi-off), placing riboflavin on the corneal stroma for about 30 minutes, measuring corneal thickness (pachymetry) to make sure the cornea is thick enough to proceed, and then shining the UVA light on the cornea for about 30 minutes.

While some surgeons don't remove the epithelium (epi-on), The American Academy of Ophthalmology Preferred Practice Pattern (PPP) notes that it *"may decrease the risk of complications associated with epithelial removal, but it may also decrease its efficacy."*[1]

3 ***QUESTION:*** What conditions are treated with CXL?

ANSWER: CXL is used for the treatment of progressive keratoconus, and ectasia following refractive surgery.[2,3,4] Clinical studies are being performed on the use of CXL for the treatment of corneal infections.[5,6]

4 ***QUESTION:*** Has CXL been approved by the FDA?

ANSWER: In April, 2016, Avedro, Inc. received approval from the U.S. Food and Drug Administration (FDA) for Photrexa® Viscous, Photrexa® and the KXL System. Photrexa® Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution) 0.146% and Photrexa® (riboflavin 5'-phosphate ophthalmic solution) 0.146% are photoenhancers indicated for use with the KXL System in CXL for the treatment of progressive keratoconus or corneal ectasia following refractive surgery. The approved protocol requires epithelium removal (epi-off). The FDA does not currently approve epi-on CXL or CXL to treat corneal infections.

5 ***QUESTION:*** What CPT code should be used to report CXL?

ANSWER: Use Category III CPT code 0402T (*Collagen cross-linking of cornea including removal of the corneal epithelium and intraoperative pachymetry when performed*) to report this procedure for dates of service on or after January 1, 2016. 0402T may not be reported in combination with CPT codes 65435, 69990, or 76514.

6 ***QUESTION:*** Is riboflavin (B2) separately reported on a claim for reimbursement?

ANSWER: Sometimes. Effective January 1, 2019, HCPCS code J2787 (*Riboflavin 5'-phosphate, ophthalmic solution, up to 3 ml*) describes this product. Since the drug is 6 units, bill 2 "3 ml" units on the claim if the payer accepts the code. There may be a few payers for which the drug is incidental and included in the payment for the 0402T procedure and not billed. Be sure and check.

April 23, 2019

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REIMBURSEMENT FOR CORNEAL COLLAGEN CROSS-LINKING

7 ***QUESTION:*** Is CXL covered by health insurance?

ANSWER: Sometimes. Many third party payers cover CXL.[7] It is no less-common for payers to consider all forms of CXL to be experimental and investigational (and therefore not cover it at all). Some reimburse only for "epi-off CXL" and not "epi-on CXL".[7] Before performing the procedure, check with the payer about the specific details in their coverage policy. If CXL is covered for the method you will use, ensure that the payment rate will be sufficient before proceeding. Your only leverage on pricing is before performance and it is sometimes negotiable.

8 ***QUESTION:*** What is the global period for 0402T?

ANSWER: There is no defined global period for any Category III CPT code for Medicare. Other payers usually agree, although some may assign a global period.

9 ***QUESTION:*** If coverage of CXL is unlikely or uncertain, how should we proceed?

ANSWER: Explain to the patient why CXL is necessary, and that Medicare or other third party payers will likely deny the claim. Ask the patient to assume financial responsibility for the charge. A financial waiver can take several forms, depending on insurance.

- An Advance Beneficiary Notice of Noncoverage (ABN) is required for services where Part B Medicare coverage is ambiguous or doubtful, and may be useful where a service is never covered. You may collect your fee from the patient at the time of service or wait for a Medicare denial. If both the patient and Medicare pay, promptly refund the patient or show why Medicare paid in error.
- For Part C Medicare (Medicare Advantage), determination of benefits is required to identify beneficiary financial responsibility prior to performing noncovered services. MA Plans have their own waiver processes and are not permitted to use the Medicare ABN form.
- For commercial insurance beneficiaries, a Notice of Exclusion from Health Plan Benefits (NEHB) is an alternative to an ABN.

1 American Academy of Ophthalmology. Preferred Practice Pattern. Corneal Ectasia. 2018. Link here. Accessed 04/23/19.

2 Randleman JB, Woodward M, et.al. Risk assessment for ectasia after corneal refractive surgery. *Ophthalmology*. 2008 Jan;115:37–50. Link to PubMed abstract here. Accessed 04/22/19.

3 Binder PS and Trattler WB. Evaluation of a risk factor scoring system for corneal ectasia after LASIK in eyes with normal topography. *J Refract Surg*. 2010 Apr;26(4):241-250. Link to PubMed abstract here. Accessed 04/22/19.

4 Randleman JB, Trattler WB, Stulting RD. Validation of the Ectasia Risk Score System for preoperative laser in situ keratomileusis screening. *Am J Ophthalmol*. 2008 Apr;145(5):813–818. Link to PubMed abstract here. Accessed 04/22/19.

5 Makdoumi K, Mortensen J, and Crafoord S. Infectious keratitis treated with corneal crosslinking. *Cornea*. 2010 Dec;29(12):1353-8. Link to PubMed abstract here. Accessed 04/22/19.

6 Kent C. Sr Ed. Alternate Uses for Corneal Cross-linking. *Review of Ophthalmology*. March 5, 2014. Link here. Accessed 04/22/19.

7 Aetna. Corneal Remodeling. Last Review 01/29/19. Link here. Accessed 04/22/19.

April 23, 2019