AMERICAN ACADEMY
OF OPHTHALMOLOGY®
Protecting Sight. Empowering Lives.

Anticipate the Journey: Advancing Retina Practice Management

MC02 | Nov. 3, 9 a.m. – 12 p.m.

Moscone Center, San Francisco

American Academy of Ophthalmic Executives® (AAOE®)

6934

AMERICAN ACADEMY OF OPHTHALMOLOGY®

AAOE® Program of 2023

November 3-6, 2023 | San Francisco, CA
Moscone Center

Friday Intensive Class (MCO2)

Anticipate the Journey: Advancing Retina Practice Management

Senior Instructor:
Joy Woodke, COE, OCS, OCSR,
Director of Coding & Reimbursement, AAOE

Co-instructors:
Jessica Schroeder, MPH, CPC, OCS
Ankoor R. Shah, MD, Academy Health Policy Committee Member,
RUC Advisor, Medical Director for Coding Product

AAOE 2023 | Friday Intensive Class Presenters

Joy Woodke, COE, OCS, OCSR

Director of Coding & Reimbursement, AAOE

Senior Instructor

Joy Woodke is the Director of Coding & Reimbursement for the AAOE. Her 30+ years of experience in ophthalmology includes all aspects of practice management, accounting, coding and billing. She is the author of *The Profitable Retina Practice* series, the director of the Academy's coding product line, and recipient of the Academy's Secretariat and Achievement Awards.

Jessica Schroeder, MPH, CPC, OCS

Practice Administrator — Cape Fear Retinal Associates, PC

Co-instructor

Jessica Schroeder is the practice administrator at Cape Fear Retinal Associates, PC in Wilmington, NC. She joined the practice in 2018 after working nine years at The Wilmer Eye Institute at Johns Hopkins in all facets of the billing department as well as the Epic trainer for new providers and technicians. She is an AAOE Board Member and has served as an Academy volunteer and assisted in Codequest instruction.

Ankoor R. Shah, MD

Retina Consultants of Texas, Academy Health Policy Committee Member, AAOE Medical Director for Coding Products

Co-instructor

Dr. Ankoor R. Shah is a board-certified medical and surgical retina specialist with Retina Consultants of Texas. Dr. Shah has authored over 100 combined peer-reviewed scientific papers, book chapters, and presentations at national meetings. In addition to his medical and surgical research interests, he has an additional interest in the advocacy and the business of retina. He has been involved nationally as the coding/compliance committee co-chair of Retina Consultants of America, a member of the Health Economics Committee of the ASRS, and an Academy RUC Advisor, Health Policy Committee member and AAOE Board Member and Medical Director for coding products.

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PRESENTATION HANDOUT SLIDES

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Anticipate the Journey: Advancing Retina Practice Management

AAOE Annual Meeting
San Francisco
Friday, November 3, 2023

Speakers Financial Disclosure

- Ankoor R. Shah, MD, FASRS
  - Retina Specialist, Retina Consultants of Texas
  - Academy Health Policy Committee Member and RUC Advisor
  - AAOE Board Member and Medical Director for Coding Products
  - ASRS Practice Management Committee Member
- I have the following financial interests or relationships to disclose:
  - RegenexBio: Consultant/Advisor
  - Notal Vision: Consultant/Advisor
  - Regeneron: Consultant/Advisor
  - Apellis: Shareholder

Financial Disclosure

- Joy Woodke, COE, OCS, OCSR
  - Academy Director of Coding & Reimbursement
- Jessica Schroeder, MPH, CPC, OCS
  - Practice Administrator, Cape Fear Retinal Associates, PC
  - AAOE Board Member

- We have no financial interests or relationships to disclose.

Anticipate the Journey

- Packing for a journey
- Where are we going?
  - Prepare for uncertainty
  - Foresight
- What do we need?
  - Knowledge
  - Data
  - Resources

Anticipate the Journey

- Key to our success
  - Community
- It takes a team!
- AAOE
  - aao.org/retina
  - AAOE-talk

Course Agenda

Operational and Financial Management

- Jessica Schroeder

Retinal Therapeutics and Considerations

- Ankoor Shah, MD

The Journey to Reimbursement

- Joy Woodke, COE, OCS, OCSR

Panel Discussions

- Audience Polls & Discussions
- Q & A
- Rapid Fire Topics

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Operational and Financial Management

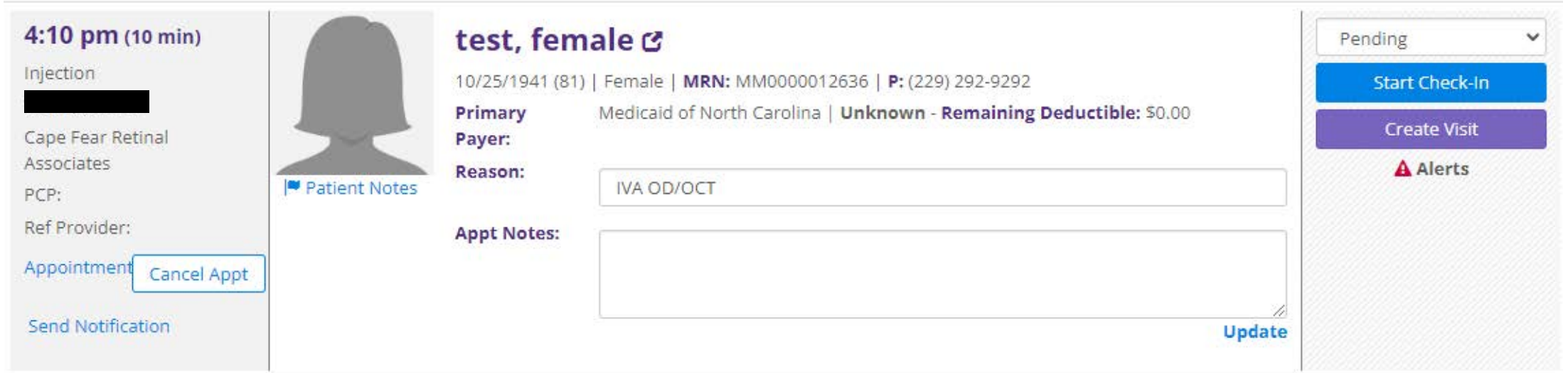
Jessica Schroeder MPH, CPC, OCS-R

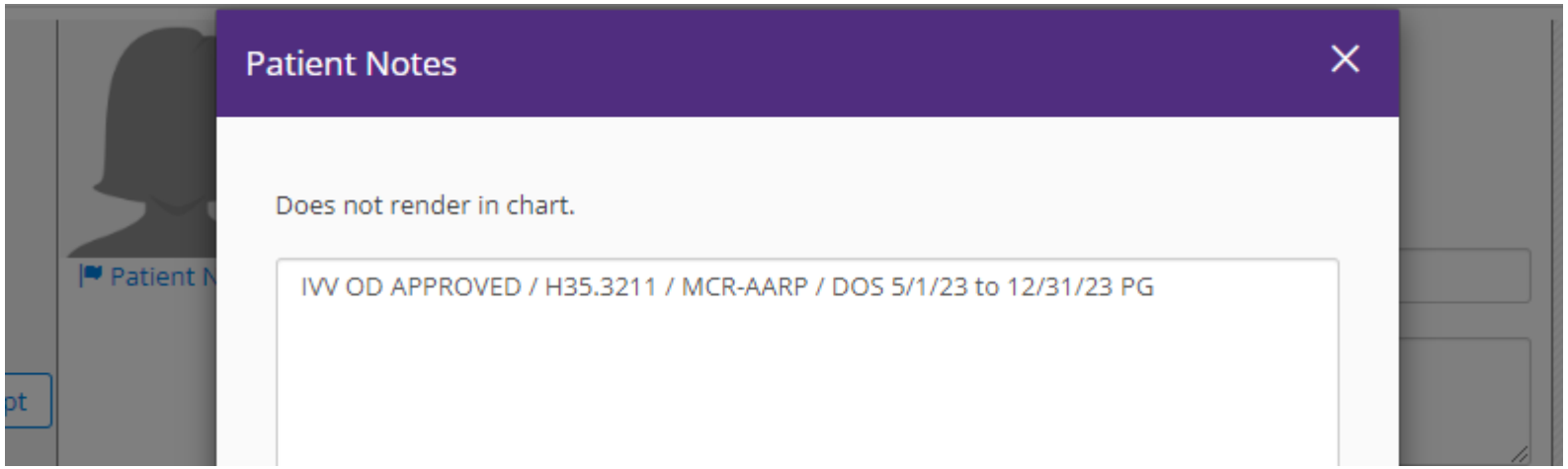
Drug Management-Operational

Billing Team

One Week out

- Check eligibility results
- Check current authorization status
- Is approval documented?
  o Sticky note in patient chart.

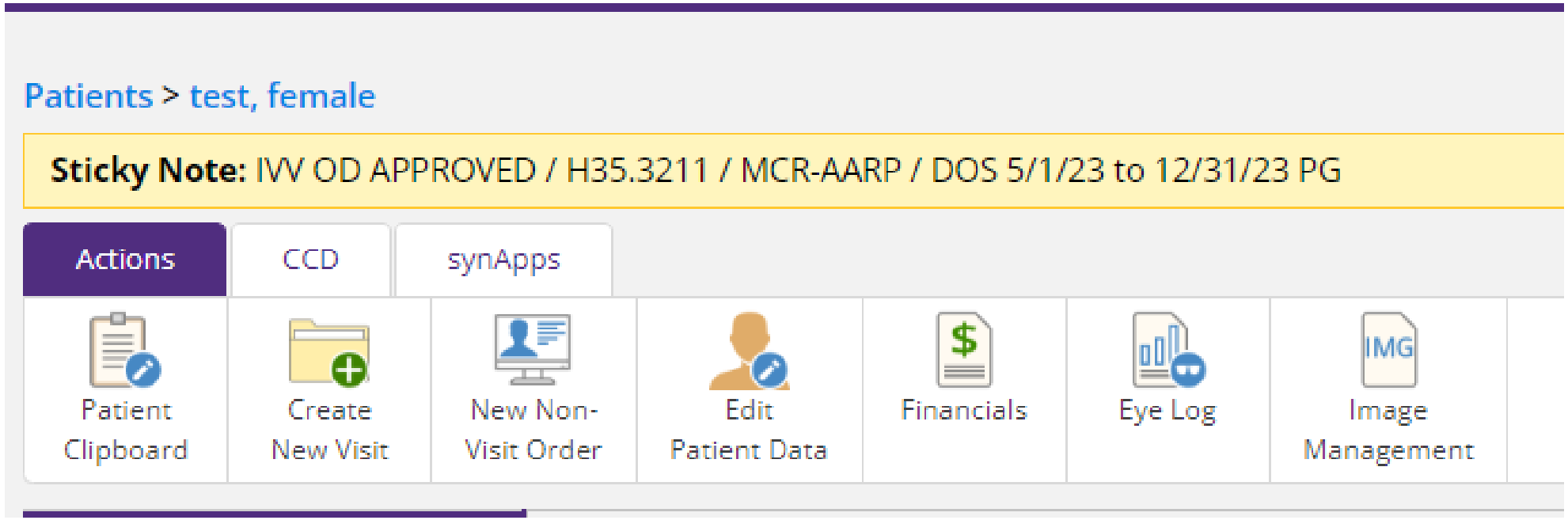

4:10 pm (10 min)
Injection
[redacted]
Cape Fear Retinal Associates
PCP:
Ref Provider:
Appointment
Cancel Appt
Send Notification
Patient Notes
test, female
10/25/1941 (81) | Female | MRN: MM0000012636 | P: (229) 292-9292
Primary Payer:
Medicaid of North Carolina | Unknown - Remaining Deductible: $0.00
Reason:
IVA OD/OCT
Appt Notes:
Update
Pending
Start Check-In
Create Visit
Alerts


Patient Notes
Does not render in chart.
IVV OD APPROVED / H35.3211 / MCR-AARP / DOS 5/1/23 to 12/31/23 PG

Billing Team

Same Day

- Rotate “Teams” Time
- Work drug approvals
- Help with insurance updates


Patients > test, female
Sticky Note: IVV OD APPROVED / H35.3211 / MCR-AARP / DOS 5/1/23 to 12/31/23 PG
Actions
CCD
synApps
Patient Clipboard
Create New Visit
New Non-Visit Order
Edit Patient Data
Financials
Eye Log
Image Management
IMG

Check In

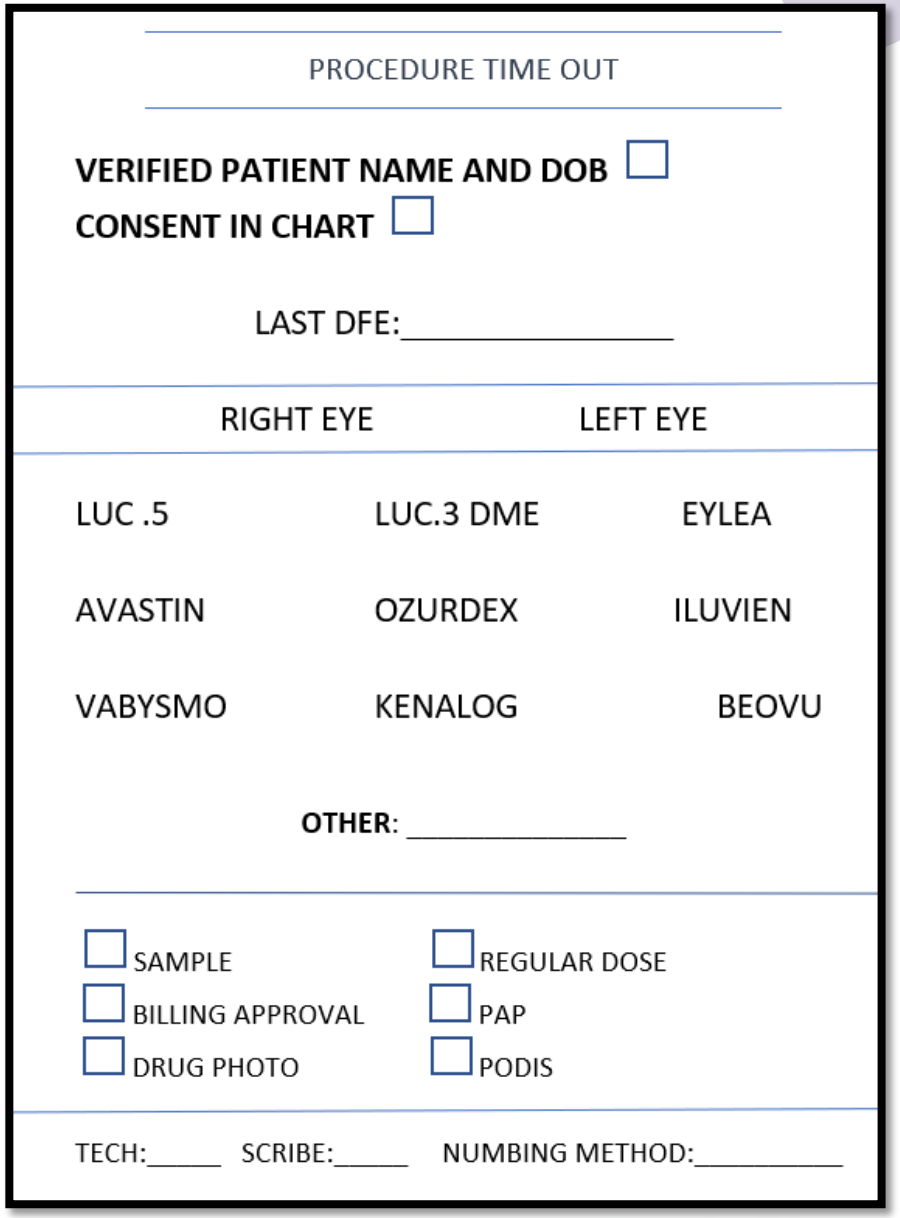
- Review eligibility report
  - Contact billing team with errors
- Collect new insurance information
  - Contact billing team with changes

Clinical Staff

Screener will complete “Time Out” Sheet while screening patient.

Screener will message billing team if approval is missing from “sticky note”

Sheet is reviewed and medication is logged out of inventory system.



PROCEDURE TIME OUT

VERIFIED PATIENT NAME AND DOB ☐

CONSENT IN CHART ☐

LAST DFE:_____

RIGHT EYE		LEFT EYE
LUC .5	LUC.3 DME	EYLEA
AVASTIN	OZURDEX	ILUVIEN
VABYSMO	KENALOG	BEOVU

OTHER: _____

☐ SAMPLE ☐ REGULAR DOSE

☐ BILLING APPROVAL ☐ PAP

☐ DRUG PHOTO ☐ PODIS

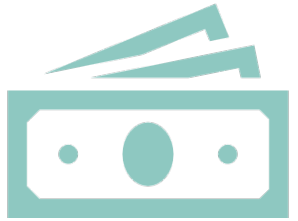
TECH:_____ SCRIBE:_____ NUMBING METHOD:_____

Drug management -Financial

Drug Management Tools

Dashboards

Inventory System Reports



Financial Statements

Dashboard

How often does your team want to review?

Who is the audience for the information?

What are the key items your team wants to review?

Drug Management Dashboard

- Completed monthly
- Tracks usage per MD monthly and YTD
- Tracks cost per vial/syringe
- Tracks Charges/Payments and cash for drugs

REVENUE & DRUG USAGE

REVENUE	JAN	FEB	MAR

PAYMENTS POSTED	JAN	FEB	MAR
MD 1			
MD 2			
MD 3			
MD 4			
TOTAL	$ -	$ -	$ -

PAID INVOICES	JAN	FEB	MAR

DRUGS USAGE	JAN	FEB	MAR
MD 1	$ -	$ -	$ -
MD 2	$ -	$ -	$ -
MD 3	$ -	$ -	$ -
MD 4	$ -	$ -	$ -
TOTAL	$ -	$ -	$ -

NET CHARGES LJC	JAN	FEB	MAR
MD 1			
MD 2			
MD 3			
MD 4			
TOTALS	$ -	$ -	$ -

Monthly Tabs

BILL CPT	PROCEDURE	USAGE		UNITS	Cost Per Unit	COST
J0178	INJECTION AFLIBERCEPT 1 MG		2	0	$0.00	$0.00
J0179	BEOVU		6	0	$0.00	$0.00
J2777	VABYSMO		60	0	$0.00	$0.00
J2778	LUCENTIS (3 UNITS)		3	0	$0.00	$0.00
J2778	LUCENTIS (5 UNITS)		5	0	$0.00	$0.00
J3299	XIPERE		36	0	$0.00	$0.00
J3301	KENALOG (4 UNITS)		4	0	$0.00	$0.00
J3490	SYFOVRE		1	0	$0.00	$0.00
J7312	OZURDEX (7 UNITS)		7	0	$0.00	$0.00
J7313	ILUVIEN 0.19MG IVT		19	0	$0.00	$0.00
J7314	YUTIQ		18	0	$0.00	$0.00
J7316	JETREA OCRIPLASMIN 2.5MG/ML		1	0	$0.00	$0.00
J9035	AVASTIN		1	0	$0.00	$0.00
MD1		0		0		$0.00

ENDING INVENTORY		COST
EYLEA		0
AVASTIN		0
LUC .5		0
LUC .3		0
BEOVU		0
OZURDEX		0
ILUVIEN		0
VABYSMO		0
SYFOVRE		0
XIPERE		0
YUTIQ		0
KENALOG		0
JETREA		0

BILL CPT	PROCEDURE	USAGE		UNITS	Cost Per Unit	COST
J0178	INJECTION AFLIBERCEPT 1 MG		2	0	$0.00	$0.00
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J2778	LUCENTIS (3 UNITS)		3	0	$0.00	$0.00
J2778	LUCENTIS (5 UNITS)		5	0	$0.00	$0.00

J Code Tab

J CODE CHARGES	JAN	FEB	MAR
MD1			
MD2			
MD3			
MD4			
TOTAL	$ -	$ -	$ -

J CODE PAYMENTS	JAN	FEB	MAR
MD1			
MD2			
MD3			
MD4			
TOTAL	$ -	$ -	$ -

J CODE GROSS PROFIT	JAN	FEB	MAR
MD1	$ -	$ -	$ -
MD2	$ -	$ -	$ -
MD3	$ -	$ -	$ -
MD4	$ -	$ -	$ -
TOTAL	$ -	$ -	$ -

Column1	JAN	FEB	MAR
CASH			
AR + INVENTORY			
AP			
REMAINING CASH	$ -	$ -	$ -

Productivity Dashboard

PROVIDER	CHARGES	PAYMENTS	LESS J CODES CHARGES	LESS J CODES PAYMENTS
MD 1				
MD 2				
MD 3				
MD4				
Grand Total				

DAYS WORKED		ENC/DAY TOTAL	ENC/DAY NP/DAY	ENC/DAY WI/DAY
MD 1	0	0	0	0
MD 2	0	0	0	0
MD 3	0	0	0	0
MD4	0	0	0	0

AUG TOTAL PATIENTS	Loc 1	Loc 2	Loc 3	Loc 4	Loc 5	OR	Grand Total
MD 1							
MD 2							
MD 3							
MD4							
Grand Total							

TOTAL NEW PATIENTS

NEW	Loc 1	Loc 2	Loc 3	Loc 4	Loc 5	Grand Total
MD 1						
MD 2						
MD 3						
MD4						
Grand Total						

SATELLITES	Loc 1	Loc 2	Loc 3
Ave Staff Wage			
Rent			
Total			
CHARGES LJC			
PAYMENTS LJC			

WORK IN	Loc 1	Loc 2	Loc 3	Loc 4	Grand Total
MD 1					
MD 2					
MD 3					
MD4					
Grand Total					

WI EST.	Loc 1	Loc 2	Loc 3	Loc 4	Grand Total
MD 1					
MD 2					
MD 3					
MD4					
Grand Total					

WI NEW	Loc 1	Loc 2	Loc 3	Grand Total
MD 1				
MD 2				
MD 3				
Grand Total				

Inventory Management Reports

- Units Mismatch
- Unassigned
- Unbilled

Claims

- AR Buckets
- Denials
- PM System Analytics

Profit & Loss

- Total Income
- Cost of Goods Sold
- Overhead

Audience Poll & Discussion

- Any digital solutions that have assisted with creating dashboards?
- Examples of how monitoring data has identified red flags in drug management
- Other?

Questions?

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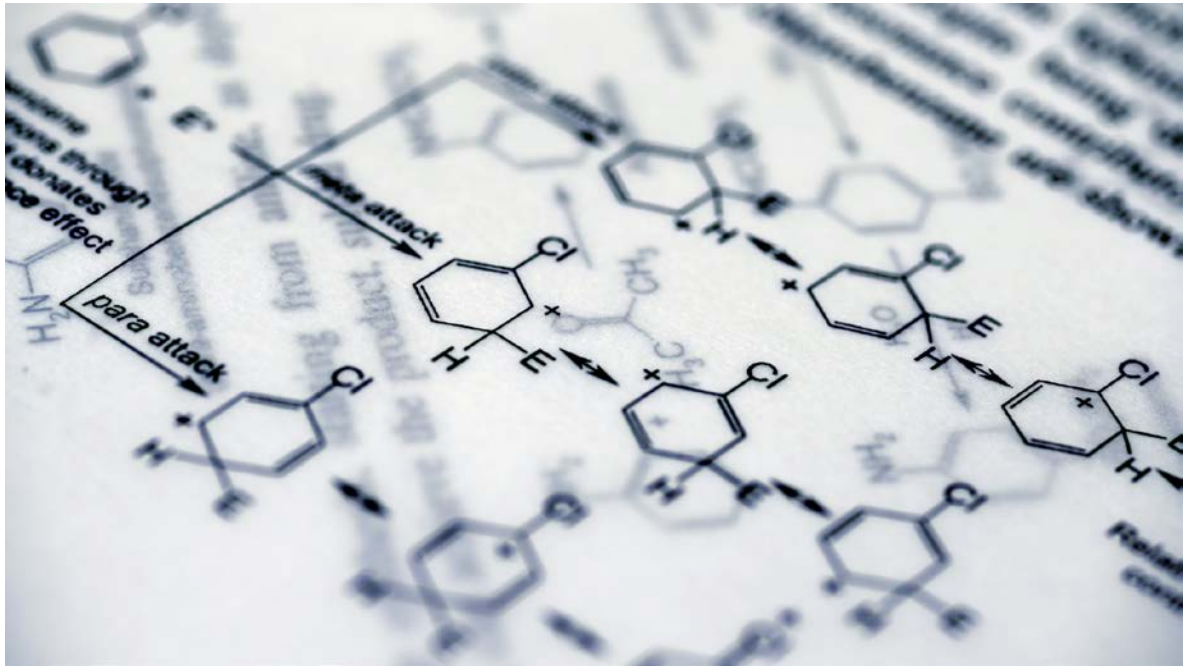
Anticipate the Journey: Retinal Therapeutics and Considerations

Ankoor R. Shah, MD

Commonly Utilized Therapeutic Options

Anti-VEGF and Steroidal Treatments



Retina Drugs

Drug	Drug Class	Drug Type	Indication (s)
Bevacizumab (Avastin)	Anti-VEGF	Reference - Repackaged	Non-FDA Approved – DR, DME, wAMD, RVO, mCNV
Aflibercept (Eylea)	Anti-VEGF	Reference	Diabetic retinopathy (DR), Diabetic Macular edema (DME), Wet AMD, Retinal Vein Occlusion (RVO)
Ranibizumab 0.3mg (Lucentis)	Anti-VEGF	Reference	DME, DR
Ranibizumab 0.5mg (Lucentis)	Anti-VEGF	Reference	RVO, Wet AMD, Myopic Choroidal Neovascularization
Ranibizumab-eqrn 0.3mg (Cimerli)	Anti-VEGF	Biosimilar	DME, DR
Ranibizumab-eqrn 0.5mg (Cimerli)	Anti-VEGF	Biosimilar	RVO, Wet AMD, Myopic Choroidal Neovascularization
Ranibizumab-nuna 0.5mg (Byooviz)	Anti-VEGF	Biosimilar	RVO, Wet AMD, Myopic Choroidal Neovascularization
Brolucizumab (Beovu)	Anti-VEGF	Reference	Wet AMD, DME
Faricimab (Vabysmo)	Anti-VEGF + Ang 2	Reference	Wet AMD, DME
Flucinolone Implant (Iluvien)	Steroid	Reference	DME, RVO, noninfectious uveitis
Flucinolone Implant (Yutiq)	Steroid	Reference	Non-infectious intermediate, posterior and panuveitis
Dexamethasone Implant (Ozurdex)	Steroid	Reference	DME, RVO, noninfectious uveitis

2022

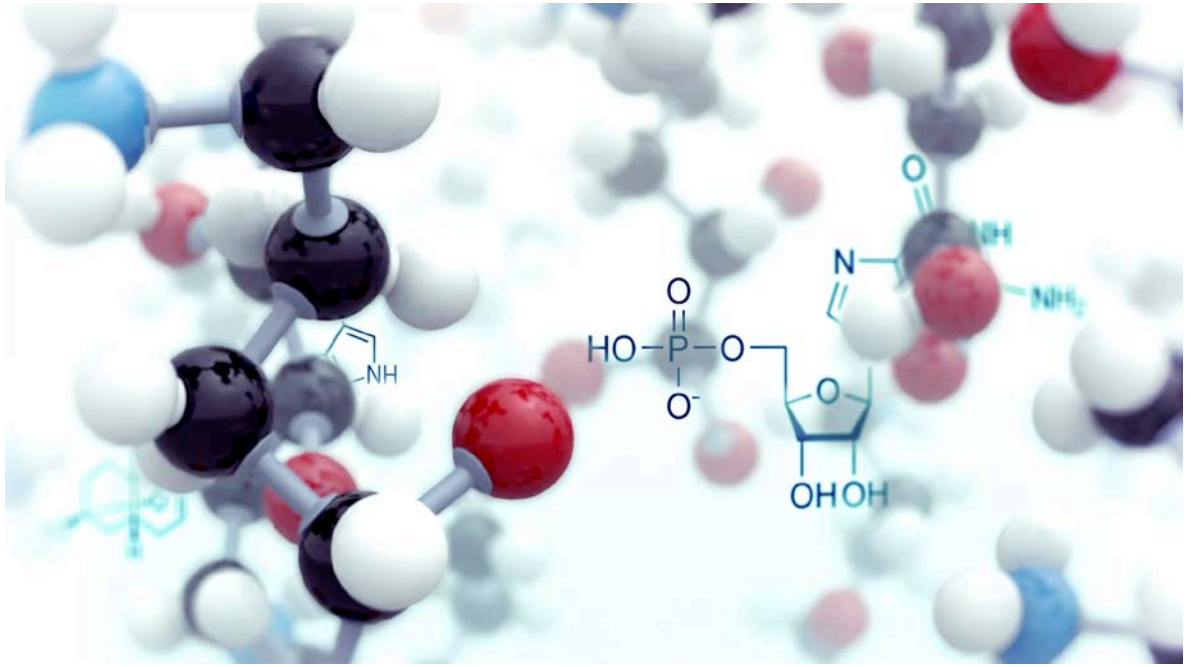
7

2023

12

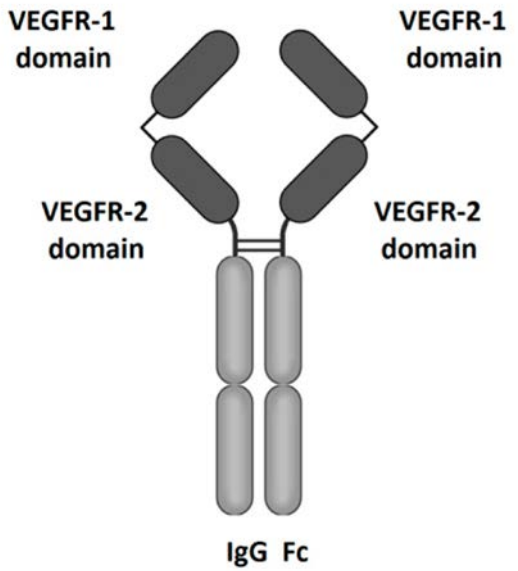
Novel FDA-Approved Medications

New Pharmacologic Entrants



Aflibercept 8mg (Eylea HD)

- Aflibercept is a soluble decoy receptor that binds vascular endothelial growth factor-A (VEGF-A), VEGF-B and placental growth factor (PIGF).[1]
- 4 times the concentration of the original in slightly higher volume (0.07ml vs 0.05ml)
- New J-Code coming
- Approved for wet AMD (PULSAR Trials) and DME (PHOTON) Approved for monthly x 3, then q7weeks or longer



[1]Sharma, Yog Raj, Koushik Tripathy, Pradeep Venkatesh, and Varun Gogia. "Aflibercept – How Does It Compare with Other Anti-VEGF Drugs?" *Austin J Clin Ophthalmol* 1, no. 3 (2014): 1016.

Pegcetacoplan (Syfovre)

- Pegcetacoplan is a pegylated complement C3 inhibitor peptide that inhibits the C3 convertase, preventing cleavage of C3 into C3a and C3b, which prevent an inflammatory response and opsonization, respectively[1,2]
- Can be administered up to every 25-60 days, typical patterns are monthly or every other month.

[1]Khan, H., Aziz, A. A., Sulahria, H., Ahmed, A., Choudhry, N., Narayanan, R., . . . Khanani, A. M. (2023). Emerging Treatment Options for Geographic Atrophy (GA) Secondary to Age-Related Macular Degeneration. Clin Ophthalmol, 17, 321-327.

[2]Liao, D. S., Grossi, F. V., El Mehdi, D., Gerber, M. R., Brown, D. M., Heier, J. S., . . . Francois, C. G. (2020). Complement C3 Inhibitor Pegcetacoplan for Geographic Atrophy Secondary to Age-Related Macular Degeneration: A Randomized Phase 2 Trial. Ophthalmology, 127(2), 186-195.

- A pegylated aptamer that inhibits the cleavage of C5, preventing formation of C5a and C5b, inhibiting the complement pathway
- Approved for monthly dosing

Avacincaptad Pegol (Izervay)

Biosimilar Space

Biosimilar Basics

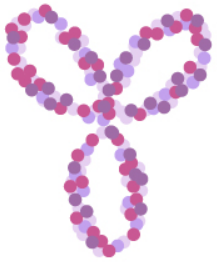
THE FDA'S CURRENT STANDARD FOR APPROVING BIOSIMILARS IS AS FOLLOWS:

"A BIOSIMILAR IS HIGHLY SIMILAR TO, AND HAS NO CLINICALLY MEANINGFUL DIFFERENCES IN SAFETY, PURITY, AND POTENCY (SAFETY AND EFFECTIVENESS) FROM AN EXISTING FDA-APPROVED REFERENCE PRODUCT. THE GOAL OF A BIOSIMILAR DEVELOPMENT PROGRAM IS TO DEMONSTRATE BIOSIMILARITY BETWEEN THE PROPOSED BIOSIMILAR PRODUCT AND THE REFERENCE PRODUCT, NOT INDEPENDENTLY ESTABLISH THE SAFETY AND EFFECTIVENESS OF THE PROPOSED PRODUCT."

- Biosimilars Reduce Costs typically 15-30% beyond reference product
- Have undergone smaller scale clinical trials
- Typically inherit the full spectrum of diseases covered by the reference drug

Current Biosimilars

- Ranibizumab-nuna –
  - 0.5mg Indications
- Ranibizumab-eqrn –
  - 0.5mg AND 0.3mg Indications



Reference product

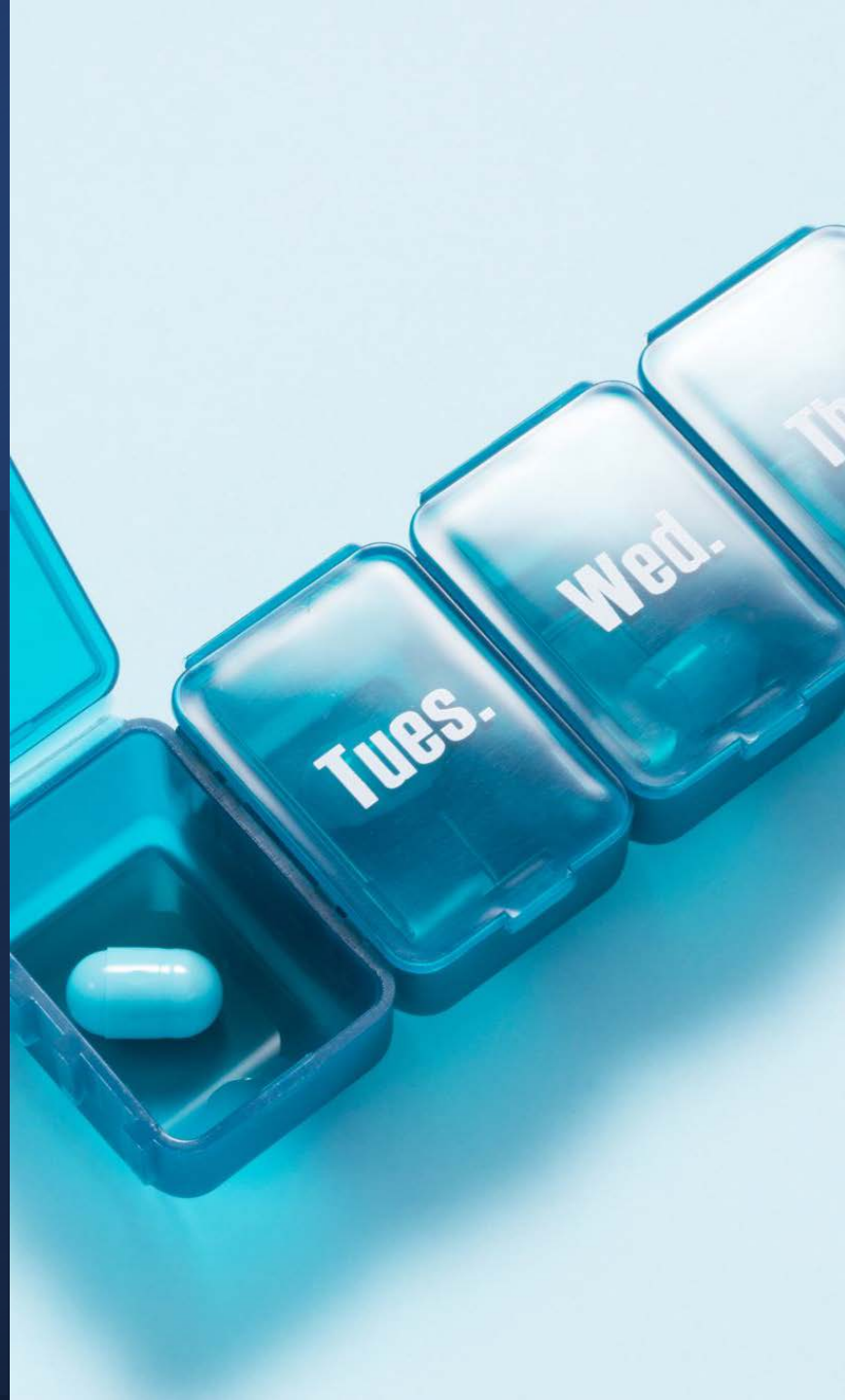
Biosimilar

Future Entrants

- Aflibercept Future Biosimilars:
- Was expected in Q4 2023, looking more like Q2, Q3 2024 as the base case, but potentially delayed to 2025

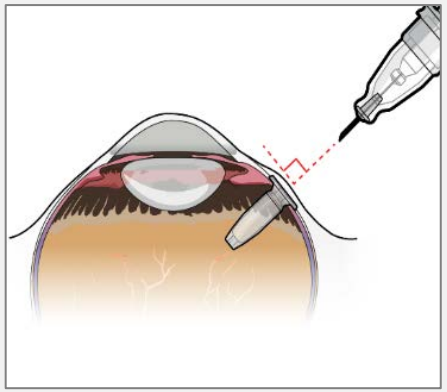
Suprachoroidal and Reservoir Devices

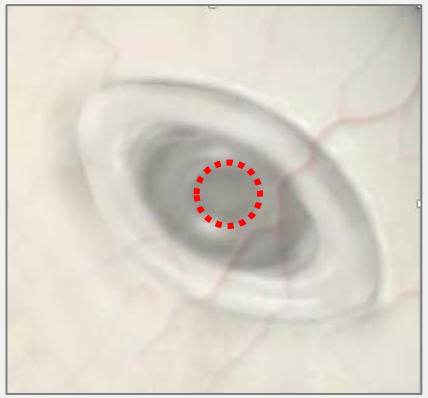
Novel Therapeutic Drug Delivery



Ranibizumab Injection (Susvimo Implant) and Refill

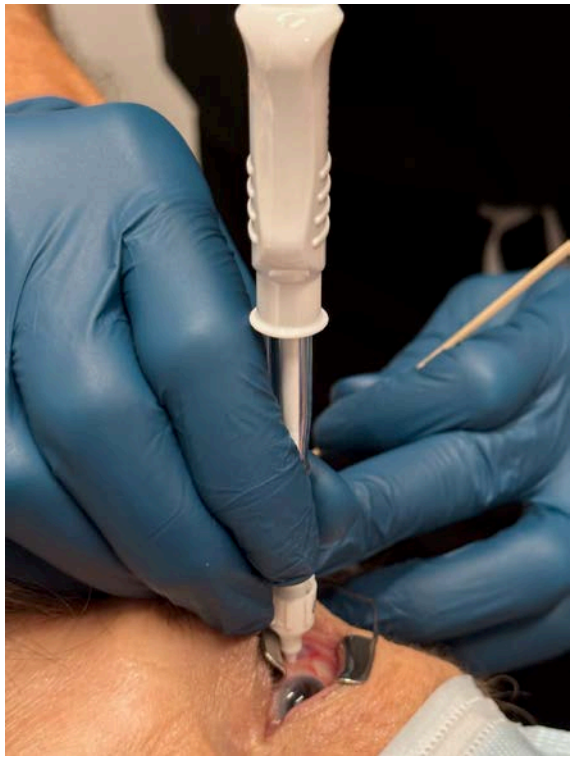
- Device Implanted in the Operating Room
- Refill Procedure Performed in Clinic Setting





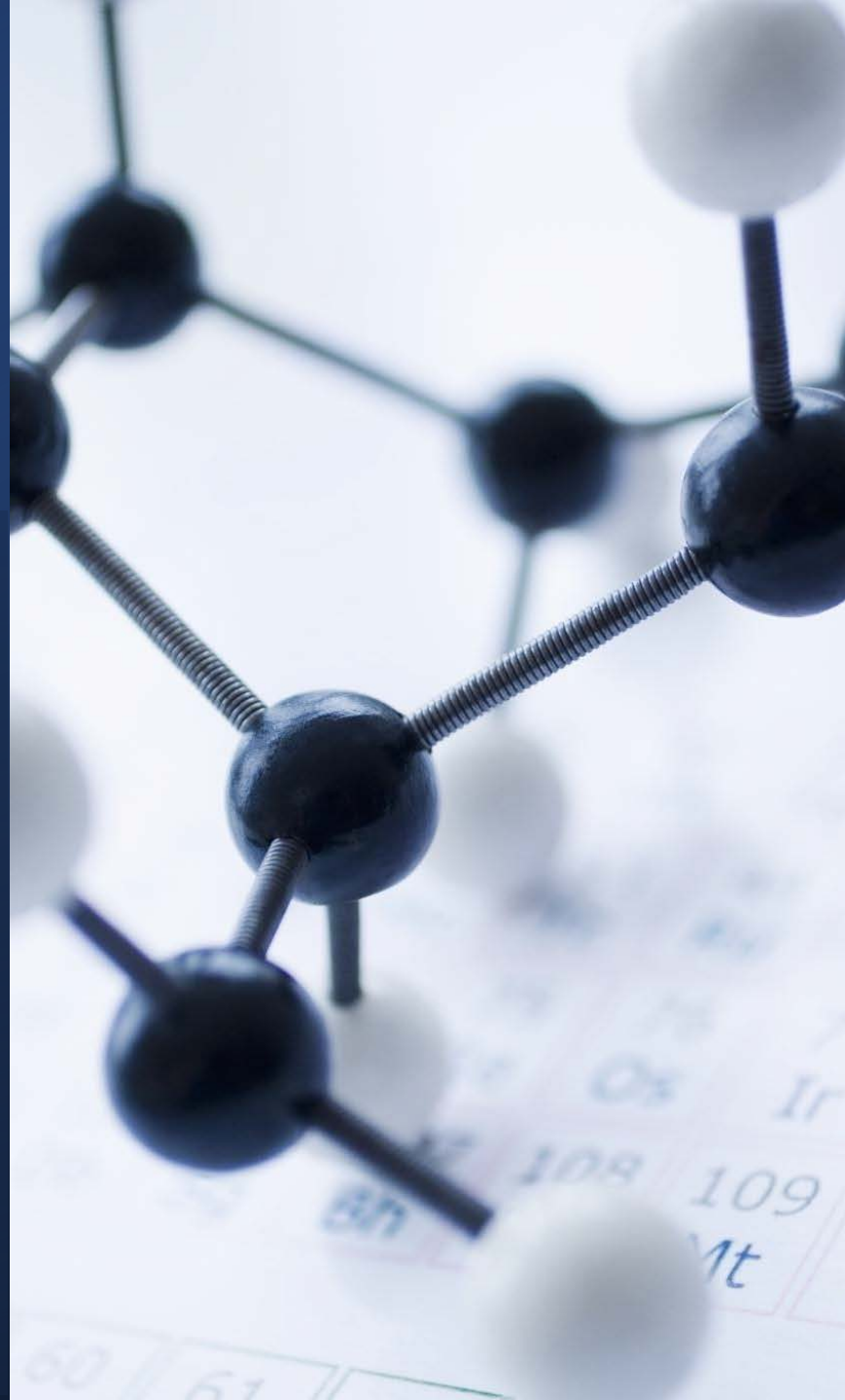
Triamcinolone acetate (Xipere)

- Suprachoroidal Steroid Injections
- Peachtree, Magnolia, and Azalea Trials – lead to approval
- Benefits of Durability and Reduced Adverse Reactions in Suprachoroidal space
- NEW CPT code **67516**



Gene Therapy and Dry AMD

Next Generation Treatment Options



Targeting GA in Dry AMD

- Current strategies target the inflammatory pathway – specifically the compliment cascade.

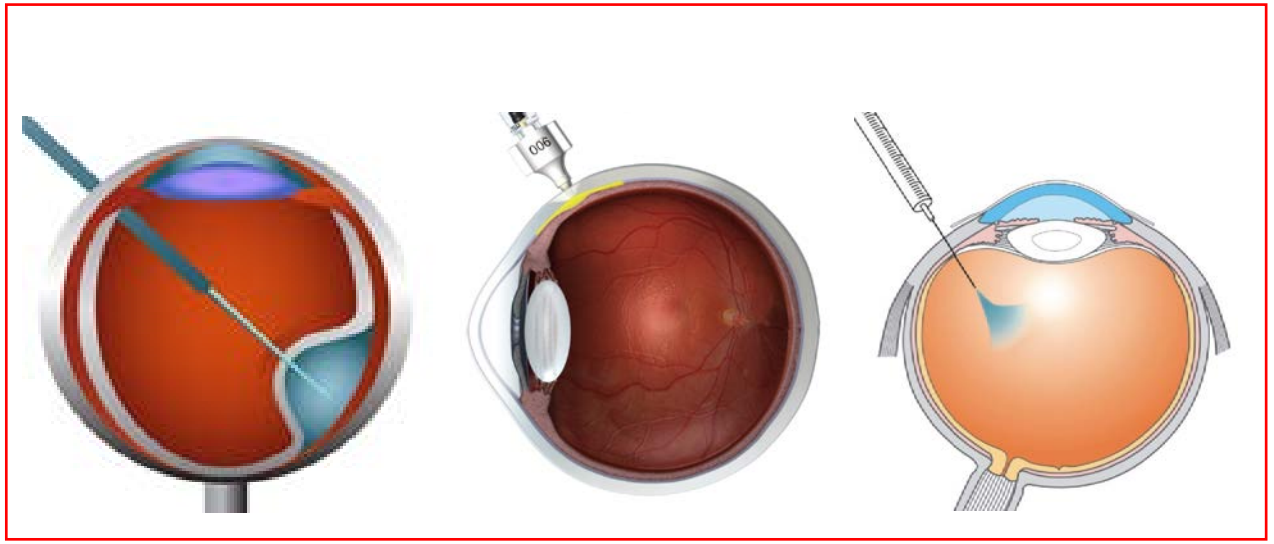
Eye (2022) 36:294 – 302

Table 2. Potential complement pathway therapeutic targets for dry AMD [35, 44, 45].

Target	Molecule(s)	Company	Type/MOA	Pathway	Comments
Complement factor B	IONIS-FB-L_{Rx}	Roche/Ionis	Subcutaneous ligand-conjugated (LICA) antisense therapy	Alternative pathway	Phase II GOLDEN trial ongoing
Complement factor I	GT005	Gyroscope	Subretinal AAV2 vector; gene therapy designed to induce expression of CFI	Alternative pathway	Phase I/II FOCUS trial showed GT005 to be well tolerated; phase II EXPLORE and HORIZON studies are ongoing
Complement factor H	GEM103	Gemini	IVT recombinant human CFH	Alternative pathway	Phase 2a ReGAtta trial enrollment complete
Complement factor I	GEM104	Gemini	IVT full-length recombinant human CFI	Alternative pathway	In preclinical development
Complement factor D	ALXN2040	Alexion/ AstraZeneca	Oral factor D inhibitor	Alternative pathway	IND application submitted; phase II study planned
Complement C3	NGM621	NGM Bio	IVT humanized IgG1 monoclonal antibody	Classical pathway	Phase II CATALINA study currently recruiting
Complement C3	Pegcetacoplan	Apellis	IVT cyclic peptide-bound polyethylene glycol polymer	Classical pathway	Phase II FILLY trial showed reduction of GA growth; phase III DERBY and OAKS trials ongoing
Complement C5	Avacincaptad pegol	Iveric Bio	IVT pegylated RNA aptamer	Classical pathway	Phase II GATHER1 trial showed decrease in GA lesion size; phase III GATHER2 trial ongoing

Desai, D., Dugel, P.U. Complement cascade inhibition in geographic atrophy: a review. *Eye* **36,** 294–302 (2022). https://doi.org/10.1038/s41433-021-01765-x

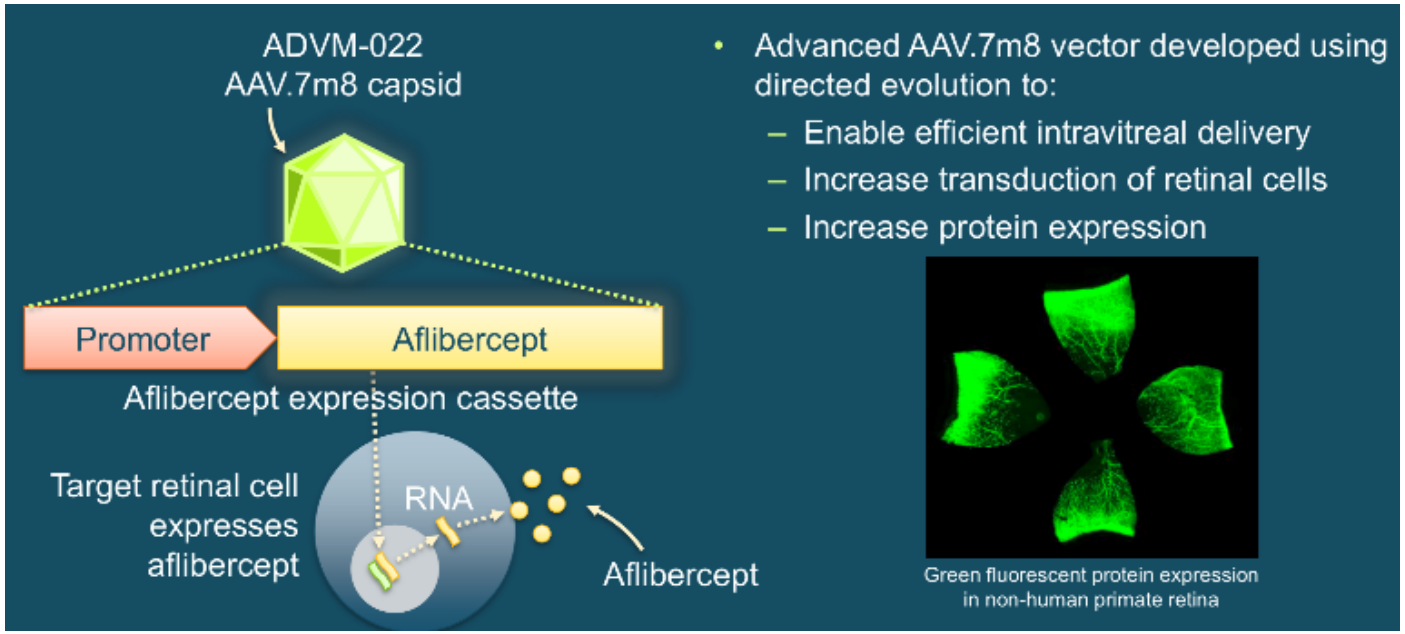
Establish an intraocular biofactory to produce an anti-VEGF agent

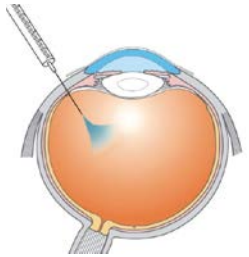


*Slide Credit: Charles Wykoff, Retina Consultants of Texas

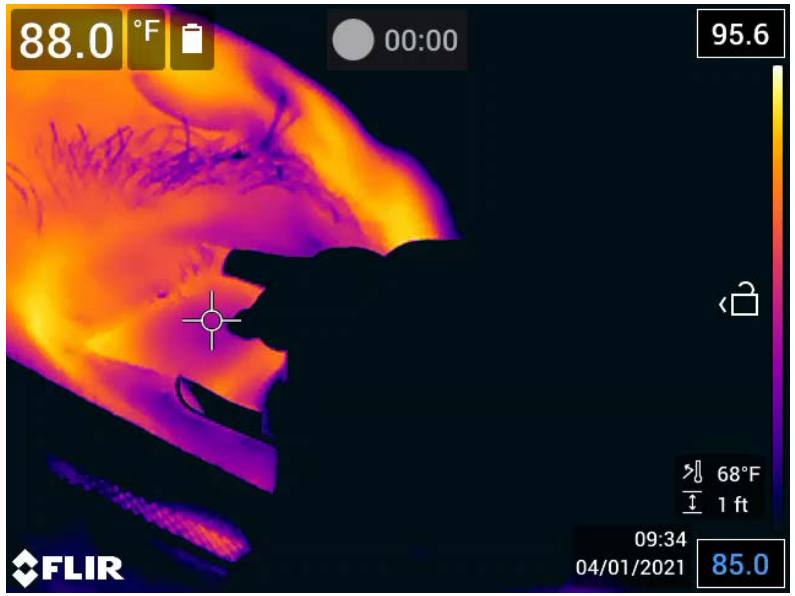
More Durable Therapeutics

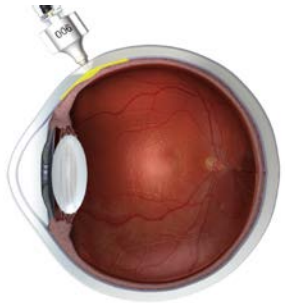
Could be a Tremendous Step Forward for DR Management





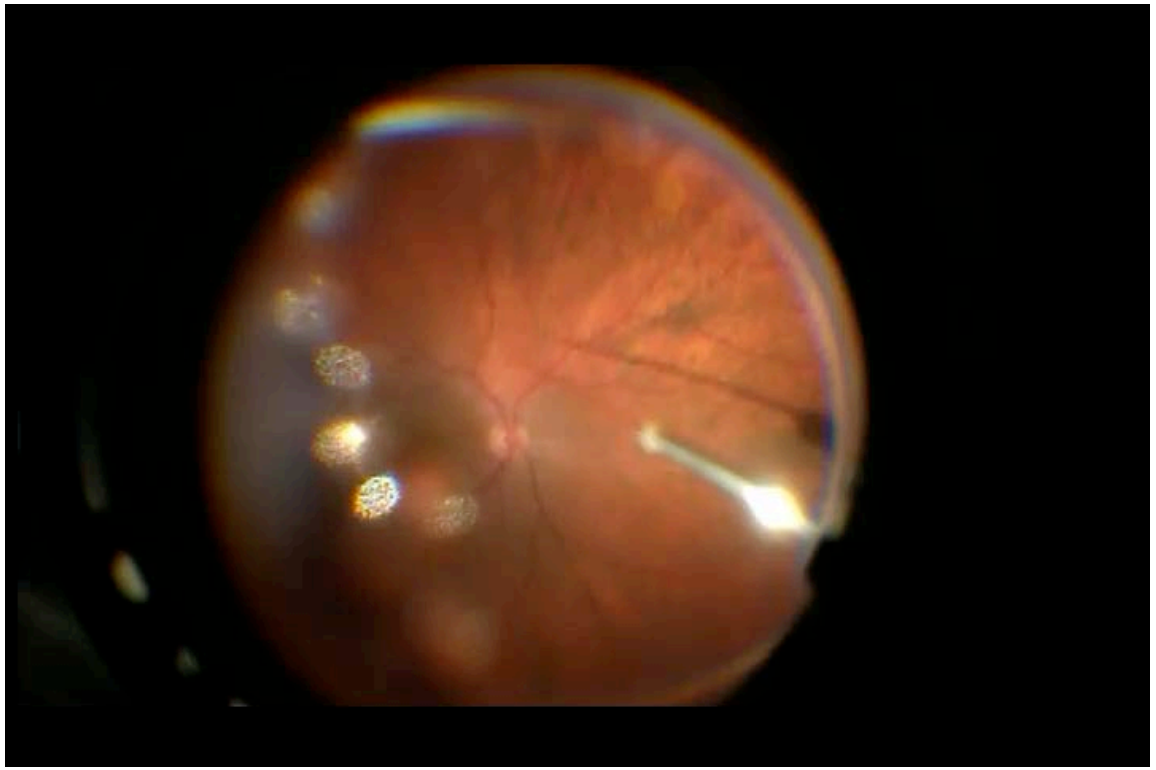
Suprachoroidal Injection and Thermal Imaging





*Video Credit: Charles Wykoff, Retina Consultants of Texas

Subretinal Delivery of Gene Therapy



NEW Category III code: 0810T - effective 7/1/2023

*Video Credit: Charles Wykoff, Retina Consultants of Texas

Biosimilars

Policy Implications

Adoption Rates

- Glean information from Oncology: Rituxan, Avastin, Herceptin
- Slow initial adoption as oncologists learned about biosimilars
- First mover advantage tends to be present
- Second reference drug with biosimilars (ie Eylea in eye space) tend to have faster adoption

Step(s) Therapy

- Avastin → Biosimilar Lucentis → Lucentis/Eylea/Beovu/Vabysmo
- Aetna notable national carrier with Avastin → Byooviz → Medication of Choice
- Expectation is that more will follow

Refrigerator Management

- Now need to carry a number of different options in your fridge
- Space and inventory management more important now than ever
- Awareness of quirks of payor policy more important now than ever: disease states, frequency edits, etc.

Audience Poll & Discussion

- Specific payer policy challenges related to new drug treatments?
- PA or step-therapy implications?
- Practice implementation strategies that have been succesful?

Questions?

Journey to Reimbursement

Joy Woodke, COE, OCS, OCSR

Prepare for New Drugs

New Drug Treatment Checklist

Review	• Review FDA label for indications and frequency
Identify	• Identify any published payer policies
Report	• Report with NOC HCPCS code, (J3490 or J3590) until assigned a permanent code

Include	• Include on CMS-1500:
	  • Item 19: medication name, dosage in mg/mL
	  • Item 24a: NDC in 5-4-2 format and unit of measurement (UOM) (e.g. ML0.05)

Monitor	• Monitor remittance advices for appropriate payment

New FDA-Approved Drugs and CPT codes

Drug	HCPCS	NDC 5-4-2 Format **Report in item 24a**	CPT code	Indication(s)
Eylea HD 8 mg/0.07 mL	J3490, J3590 or C9399 - JZ	61755-0050-01 61755-0050-**51(sample)**	67028	Neovascular age-related macular degeneration, diabetic macular edema, diabetic retinopathy
Izervay (avacincaptad pegol) 2 mg/0.1 mL	J3490, J3590 or C9399 -JZ	82829-0002-01	67028	Geographic atrophy (GA) secondary to age-related macular degeneration
SYFOVRE (pegcetacoplan) 15 mg/0.1 mL	C9151-JZ (facility), 15 units eff 7/1/23 **J2781, 15 units eff 10/1/23**	73606-0020-01	67028	Geographic atrophy (GA) secondary to age-related macular degeneration
XIPERE (triamcinolone acetonide injectable suspension) 0.9 mL (40 mg/mL) **Suprachoroidal use**	J3299, 4 units J3299-JW, 32 units#	71565-0040-01	**0465T**	Macular edema associated with uveitis **Procedure note should include dose and wastage**: 4 mg/0.1 mL was injected, and 32 mg/0.8 mL was wasted from the single-dose vial labeled as 0.9 mL (40mg/ml) of medication from one tray included in the Xipere carton.

Visit aao.org/retinapm for updates.

Subretinal Drug Delivery Injection (0810T)

Category III Codes

- 0810T Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies

  ▶(Report medication separately)

  ▶(Do not report 0810T in conjunction with 67036, 67039, 67040, 67041, 67042, 67043)◀

Medication: Luxturna

GA: Prepare for the Journey

New drugs report with NOC HCPCS code

Dry AMD ICD-10 codes linked to injections

CPT code 67028 has a medically unlikely edit (MUE) of 1

28-day rule may apply

Prepare for the Journey

Payer challenges

- Unique policies and/or PA, step policies
- Delayed implementation of permanent HCPCS codes

NOC HCPCS codes

- Clean claims, ready to appeal

New indications

- GA, Eylea HD does not include ME following RVO or ROP

Variance to "28-day rule"

- Eylea HD initial every 28 days +/- 7 days
- Syfovre every 25-60 days
- Izervay every 28 days +/- 7 days

New Drug: Practice Implementation

Review NOC HCPCS Checklist

- Research payer policies, FDA indications, frequency, PA and/or step therapy

Update EHR and PM systems

- Library setup, new code
- Usual and customary fee
- Scrub edits
- Chart templates, macros
- Encounter types, schedule changes
- Electronic consents

Implementation Strategies

PRACTICE STRATEGY

PREPARE TO APPEAL

UTILIZE PATIENT ASSISTANCE PROGRAMS

PHASED IMPLEMENTATION

MONITOR PAYER POLICIES

Got JZ?

Master JZ and JW Modifiers

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JW Modifier

- Effective January 1, 2017
- Single-dose containers
- Report on all claims that bill for unused and discarded drugs
- Documentation must include amount of drug injected and wasted
- Units reported must match chart note

JZ Modifier

Required July 1, 2023

Single-dose vials, containers and packages

Report when no discarded amount of drug or when less than 1 unit

Pop Quiz

- Do not report JW or JZ modifier for:

A. Multi-dose vials or containers

B. Sample drugs

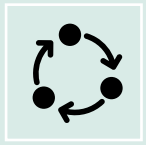
C. Specialty pharmacy drugs

D. All of the above

Single-Use vs Multi-dose Vials

Vials are designated as single-dose or multi-dose

Check labeling, some distributed either way (eg Kenalog)



Single-Dose:

Report units injected and reportable wastage, 1 unit or greater (JW)

No wastage or less than 1 unit (JZ)

Multi-dose:

Reports units injected

No JW or JZ modifier

Multidose: Kenalog

HCPCS descriptor:

- J3301, Injection, triamcinolone acetonide, NOS, 10 mg

Multidose, 10 mg or < = 1 unit

- Multiple dose vial

Documentation

- Dosage given
- Do not report wastage or modifiers JW, JZ

Single-dose: Kenalog

HCPCS descriptor:

- J3301, Injection, triamcinolone acetonide, NOS, 10 mg

Single-dose, 10 mg or < = 1 unit

- 40 mg vial

Wastage as documented

- 4 mg injected, 36 mg wasted
- J3301, 1 unit
- J3301 –JW, 3 units

JW Modifier

- Incorrect ✗

D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES
J3396			Charge $$
J3396	JW		Zero Charge

No charge second line

D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS
J3396	JW		Charge $$	150

Total units billed one line

- Correct ✓

D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS
J3396			Charge $$	130
J3396	JW		Charge $$	20

JZ Modifier

- Incorrect ✗

D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES
J0178			Charge $$
J0178	JZ		Zero Charge

Billed on two lines

- Correct ✓

D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS
J0178	JZ		Charge $$	2

Billed on one line with modifier JZ, 2 units

JW or JZ?

- Access the Table of Common Retina Drugs
  - aao.org/retinapm

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Table of Common Retina Drugs

DESCRIPTION	UNITS	INDICATION(S)	HCPCS	JW/JZ MODIFIER
Cimerli™ (Biosimilar)	3 units	Diabetic retinopathy, diabetic macular edema (0.3 mg/0.05 mL)	**Q5128**	JZ
Cimerli™ (Biosimilar)	5 units	Neovascular age-related macular degeneration, macular edema following RVO, myopic choroidal neovascularization (0.5 mg/0.05 mL)	**Q5128**	JZ
EYLEA™	2 units	Diabetic retinopathy, diabetic macular edema, wet age-related macular degeneration, macular edema following retina vein occlusion	**J0178**	JZ
Methotrexate (MTX)	Total 10 units Report 1 unit injected Second line with -JW modifier, 9 units	Off-label use for ophthalmology** Used for specific ocular inflammatory conditions, including uveitis secondary to systemic disease	**J9250**	JW

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JZ FAQs

- Is JZ Modifier just for Medicare Part B claims?
- Medicaid denied our claim with JZ modifier, what do we do?
- There is “wasted” drug in pre-filled syringes, do we report JZ?
- What is the correct order of modifiers if reporting other modifiers with JZ?
- Does JZ Modifier apply to impacts like Ozurdex, YUTIQ and Illuvien?
- What about ASCs, hospital outpatient facilities?

Prepare for Your Next Audit

SMRC Audits

INTRAVITREAL INJECTIONS

- 29% FAILURE

SMRC: Common Reasons for Denial

Non-response to the Documentation Request

Insufficient Documentation

Billing and Coding

Intravitreal Injections: https://noridiansmrc.com/completed-projects/01-309/

Audit Realities

Yes, we failed

- How?
  - Stories from the crypt
- What can we expect?
  - Increased scrutiny
- What should we do now?

Pop Quiz

- My EHR specializes in ophthalmology, but this does not ensure complete documentation and correct coding

A. True

B. False

Pop Quiz

- In recent SMRC audits of intravitreal injections, examples of insufficient documentation included the following, *except*:

A. Dosage injected in mg and mL

B. Wastage was discarded

C. Off-label indication

D. Lack of a procedure note

Intravitreal Injection Documentation

Medical necessity

- Treatment plan, why the specific medication was chosen, changed or continued
  - Video: How to Document Why a Specific Drug is Chosen*
- Diagnosis per FDA label and/or payer policy
- Physician order

Procedure note

- Diagnosis
- Site of injection, route of administration, eye(s)
- Dosage in mg and mL, document wastage

Inventory log

- Medication used linked to patient, date of encounter
- Available in the event of an audit

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Access the checklist for more details at aao.org/retinapm

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- https://www.aao.org/practice-management/multimedia-detail/how-to-document-specific-intravitreal-injection

Proactively Prepare

- Work Smarter, Not Harder
  - Customize reports to automatically highlight coding and billing mistakes
  - Quick reference guides (appendix)
- Preventative Practice Management
  - **Internal chart audits**
  - Find errors before the auditors
  - Take corrective action
- Learn from mistakes
  - What else can we do to prevent?

Audience Poll & Discussion

- Experience any JZ or JW denials or challenges?
- Any audit experiences to share?
- How do you monitor reimbursement for new drugs?

Questions?

Rapid Fire Retina

- Other topics for the panel?

Better Together

Connect with retina colleagues now and during AAO 2023!

Final Thoughts

Learn More!

2023 Retina Coding Summer Symposium

(Recording)

Join the most knowledgeable retina coding experts in ophthalmology for three hours of professional coding education. They'll map out the latest coding updates impacting the retina practice, review key competencies, test your knowledge and steer you towards successful solutions for preventing claim denials.

Instructors: Ankoor R. Shah, MD, Retina Consultants of Texas, Academy health policy committee, AAOE board and medical director of coding products; and **Joy Woodke**, COE, OCS, OCSR, Academy director of coding and reimbursement

Topics include:

- New Retina Treatments and How to Prepare Your Practice
- Identify Strategies to Improve Reimbursement for Geographic Atrophy
- Understand the Appropriate Use of Modifiers JW and JZ
- Resolve and Prevent Intravitreal Injection Claim Denials
- Protect Your Revenue and Take Action to Combat Audits
- Poll the Audience: Retina Coding Competency Challenge

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Coding Camp | 23CODE2 ($/C)
Level: Intermediate — Advanced

Equip your entire ophthalmic team with the most current coding and reimbursement guidance at Coding Camp 2023, the trusted source for accurate and up-to-date knowledge for more than 20 years. This interactive, three-hour intermediate coding session will provide you with the latest coding updates and empower your practice to navigate variable payer requirements that securely maximize reimbursement. Early registration is recommended as seats sell out quickly. This year's course will cover:

- Myth-busters 2.0: We will debunk the top coding and reimbursement myths from this past year and provide you with correct guidance.
- Compliance matters: Learn about the current hot topics and how compliance is essential in preparing for audits and avoiding investigations.
- Name that modifier: Review challenging examples to develop proficiency and confidence in applying modifiers.
- Code this Op report: Apply your knowledge of surgical coding to real-world cases and level-up your skills in coding complex surgical procedures.
- Coding competency challenge: Get answers to the most frequently asked coding questions.

Moderator: Joy Woodke, COE, OCS, OCSR, Academy Director, Coding & Reimbursement
Panelists: Matthew Baugh, MHA, COT, OSC, OCS, OCSR; Heather Dunn, COA, OCS; Ankoor Shah, MD. With a special presentation on the 2024 coding updates by Michael X. Repka, MD, MBA

Nov. 3, 1:30 to 4:30 p.m. | Moscone South, 207-208

aao.org/practice-management/annual-meeting-courses/coding-sessions

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Academy Resources

aao.org/retinapm

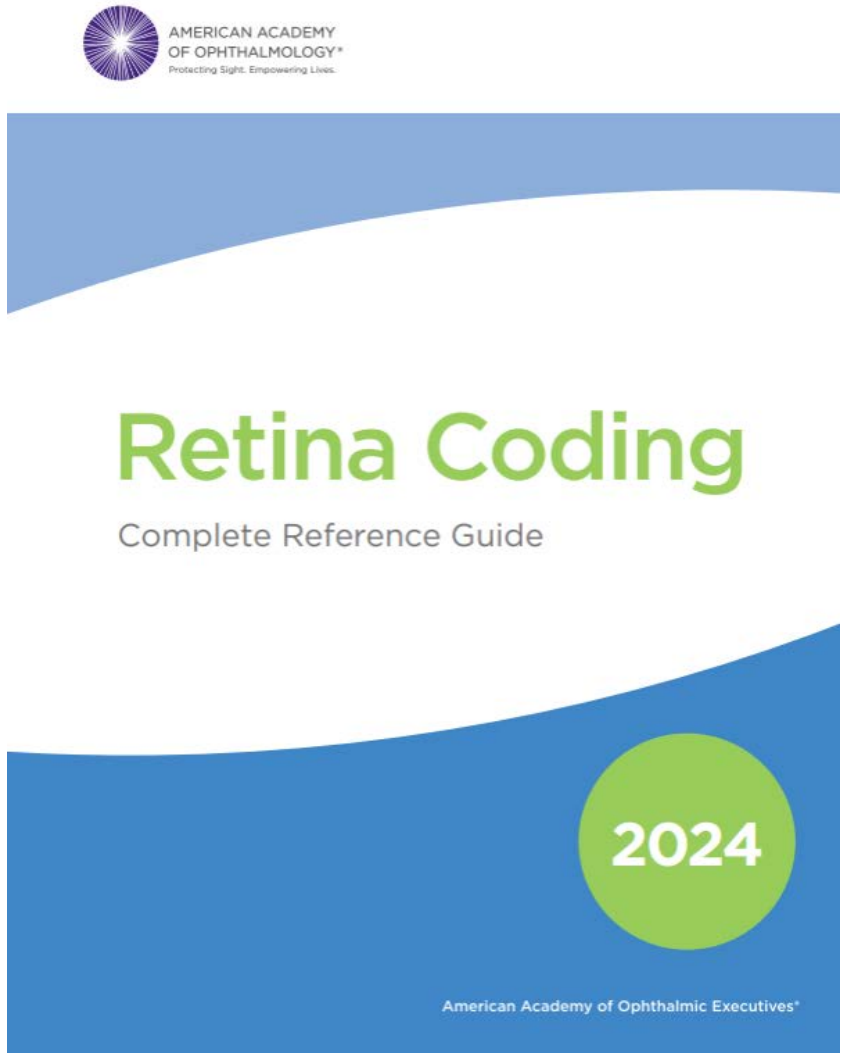
aao.org/audits

aao.org/coding

aao.org/em

aao.org/lcds

aao.org/consulting



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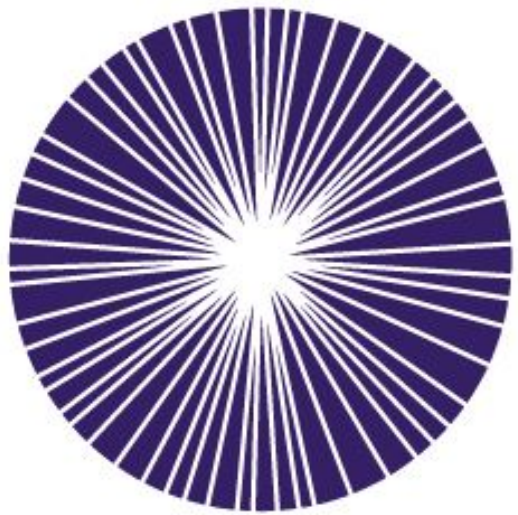

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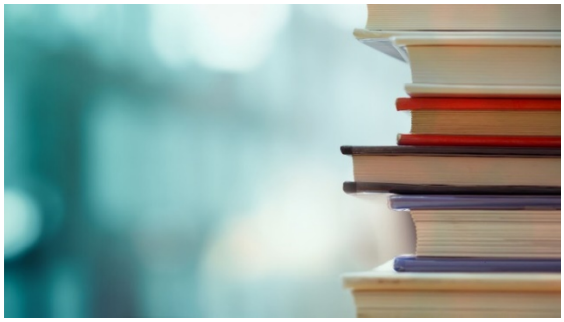

APPENDICES

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Anticipate the Journey: Advancing Retina Practice
AAO 2023, San Francisco

Drug Calculation Template

Courtesy of: Jessica Schroeder, MPH, CPC, OCS

PROCEDURE TIME OUT

VERIFIED PATIENT NAME AND DOB ☐

CONSENT IN CHART ☐

LAST DFE:_____

RIGHT EYE		LEFT EYE
LUC .5	LUC.3 DME	EYLEA
AVASTIN	OZURDEX	ILUVIEN
VABYSMO	KENALOG	BEOVU

OTHER: _____

☐ SAMPLE ☐ REGULAR DOSE

☐ BILLING APPROVAL ☐ PAP

☐ DRUG PHOTO ☐ PODIS

TECH:_____ SCRIBE:_____ NUMBING METHOD:_____

PROVIDER	CHARGES	PAYMENTS	LESS J CODES CHARGES	LESS J CODES PAYMENTS
MD 1				
MD 2				
MD 3				
MD4				
Grand Total				

	DAYS WORKED	ENC/DAY TOTAL	ENC/DAY NP/DAY	WI/DAY
MD 1	0	0	0	0
MD 2	0	0	0	0
MD 3	0	0	0	0
MD4	0	0	0	0

AUG TOTAL PATIENTS	Loc 1	Loc 2	Loc 3	Loc 4	Loc 5	OR	Grand Total
MD 1							
MD 2							
MD 3							
MD4							
Grand Total							

TOTAL NEW PATIENTS

NEW	Loc 1	Loc 2	Loc 3	Loc 4	Loc 5	Grand Total
MD 1						
MD 2						
MD 3						
MD4						
Grand Total						

SATELLITES	Loc 1	Loc 2	Loc 3
Ave Staff Wage			
Rent			
Total			
CHARGES LJC			
PAYMENTS LJC			

WORK IN	Loc 1	Loc 2	Loc 3	Loc 4	Grand Total
MD 1					
MD 2					
MD 3					
MD4					
Grand Total					

WI EST.	Loc 1	Loc 2	Loc 3	Loc 4	Grand Total
MD 1					
MD 2					
MD 3					
MD4					
Grand Total					

WI NEW	Loc 1	Loc 2	Loc 3	Grand Total
MD 1				
MD 2				
MD 3				
Grand Total				

Monthly Productivity Dashboard Example

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Checklist: Intravitreal Injections Documentation and Coding Guidelines

Revised September 2023

Reminder: This checklist should be updated per payer guidelines.

Chart Documentation

- ☐ Visual acuity, chief complaint and appropriate history of present illness (HPI)
- ☐ Treatment plan
  - For new patients, document why the specific medication was chosen.
  - For established patients, document their response to the current medication and the reason for continuing it.
  - When changing medications, document the reason.
- ☐ Diagnosis supporting medical necessity and appropriate indication for use per payer policy and/or FDA indication
- ☐ Any relevant diagnostic testing services, with interpretation and report
- ☐ Risks, benefits and alternatives discussed
- ☐ Documentation showing that the patient desires surgery
- ☐ Physician's order that includes:
  - Date of service
  - Medication name and dosage in mg and mL
  - Diagnosis
  - Physician signature
- ☐ Interval of administration is appropriate per the 28-day rule
- ☐ Procedure record that includes:
  - Diagnosis
  - Route of administration (intravitreal injection) and medication name
  - Site of injection (which eye(s) treated)
  - Dosage in mg and volume in mL, (eg, Avastin 1.25 mg/0.05 mL) and lot number
  - For single-dose vials or syringes, record of wastage of 1 unit or greater (eg, Visudyne)
  - For wastage of less than 1 unit document: *"Any residual medication less than one unit has been discarded"* (eg, EYLEA)
  - Consent completed for injection, medication and eye(s) on file and updated annually
  - For initial treatment involving off-label use of a medication (eg, Avastin), a complete informed consent form with that notification
  - A completed Advanced Beneficiary Notice of Noncoverage (ABN) for Medicare Part B beneficiaries or a waiver of liability all other patients, if applicable (eg, diagnosis not indicated, exceeds frequency)
- ☐ Medical record that is legible and has patient identifiers (eg, patient's name, date of birth) on all pages
- ☐ A legible physician's signature
- ☐ Paper medical records with a signature log
- ☐ Electronic Health Record with a secure electronic physician signature and a related practice policy that is readily available for audits
- ☐ Abbreviations that are consistent with an approved list and are readily available for audits
- ☐ Well-maintained, legible inventory logs and medication administration records (MARs)

Coding Injections

- ☐ CPT 67028, eye modifier appended (-RT or -LT)
  - Bilateral injections billed with modifier -50- per payer guidelines (Medicare Part B claims billed with 67028 -50 on one line, fees doubled and 1 unit)
- ☐ A HCPCS code for the medication
  - Append JZ modifier to the HCPCS code for single-dose vials and no wastage
- ☐ Appropriate units administered (ie, EYLEA 2 units)
- ☐ A HCPCS code with modifier -JW appended on the second line for wasted medication, if appropriate
- ☐ Medically necessary ICD-10 code appropriately linked to 67028 and HCPCS code(s)
- ☐ On the CMS-1500 claim form **in** item
  - 24a or Electronic Data Interchange (EDI) loop 2410: 11-digit NDC code in 5-4-2 format, preceded by N4 qualifier followed by unit of measurement (UOM), ML and appropriate amount. (eg,ML0.05)
    - Example, Avastin: N450242006001 ML0.05
  - 19 or EDI equivalent: Description of administration method, medication and dosage per insurance guidelines and when reporting a miscellaneous HCPCS code (eg, Avastin)

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Fact Sheet: JW and JZ Modifiers

Published June 5, 2023

HCPCS Modifiers

-JW Drug amount discarded/not administered to any patient

-JZ Zero drug amount discarded/not administered to any patient

Policies

JW Modifier

Effective January 1, 2017, physicians must report the JW modifier on all claims that bill for drugs with unused and discarded amounts from single-dose containers, vials and packages. Chart documentation must state the amount of drug injected and wasted, which is consistent with the units reported on the claim submission.

JZ Modifier

Effective January 1, 2023, Medicare will use JW and JZ modifiers to calculate discarded drug refunds.

Effective July 1, 2023, physicians are required to report JZ modifier on all claims that bill for drugs supplied as single-dose vials, containers and packages based on FDA-approved labeling with no discarded amounts.

Exclusions

The use of JW or JZ modifiers are not appropriate when:

- Drugs are labeled as multidose vials or containers.
- The physician does not purchase the drug and it is not payable under Medicare Part B. This includes:
    - Specialty pharmacy drugs or “white bag” distribution
    - Sample medications

Single-dose and Multidose

Many commonly used ophthalmic drugs are distributed as pre-filled syringes (eg, Eylea), while others may be purchased in single-dose (eg, Vabysmo, Cimerli, Byooviz) or multidose vials (eg, Kenalog).

Read the medication vial label to identify and confirm the corresponding specific National Drug Code (NDC) for the product being administered. This is the NDC number to report on the CMS-1500 in item 24a or EDI equivalent. The type of vial would confirm if JZ/JW should be reported (single-dose) or if no modifier is required (multidose).

Report JZ modifier when the actual dose of the drug from a single-dose vial is less than the billing unit based on the HCPCS descriptor. JW modifier is reported only when the discarded drug is one unit or greater.

When the dosage is less than one unit, round up to the nearest unit.

Case Studies

JW Modifier

Example 1:

- 12 mg of Visudyne (verteporfin) used and 3 mg discarded
- HCPCS code J3396 injection, Verteporfin, 0.1 mg
- Single-dose vial 15 mg, 150 units
- J3396, 120 units
- J3396 –JW, 30 units

Example 2:

- 30 units of Botox (onabotunlinumtoxinA) injected, and 70 units discarded
- HCPCS code J0585 injection, onabotunlinumtoxinA, 1 unit
- Single-dose vial 100 units
- J0585, 30 units
- J0585 -JW, 70 units

Example 3:

- 2 mg of Kenalog (triamcinolone) injected and 38 mg discarded
- HCPCS J3301, triamcinolone acetonide, 10 mg
- Single-dose vial 40 mg (appropriate NDC reported)
- J3301, 1 unit
- J3301 –JW, 3 units

JZ Modifier

Example 1:

- 6 mg of Vabysmo (faricimab-svoa) injected
- HCPCS J2777, faricimab-svoa, 0.1 mg
- Single-dose vial 6 mg
- J2777 – JZ, 60 units

Example 2:

- 10 mcg of Durysta implanted
- HCPCS J7351, injection, bimatoprost, intracameral implant, 1 microgram
- Single-use implant, 10 mcg
- J7351 –JZ, 10 units

Example 3:

- 5 mg of fluorouracil injected
- HCPCS J9190, fluorouracil, 500 mg
- Single-dose vial 500 mg (appropriate NDC reported)
- J9190 -JZ, 1 unit

No JZ or JW Modifier

Example 1:

- 2 mg of Kenalog (triamcinolone) injected
- HCPCS J3301, triamcinolone acetonide, 10 mg
- Multi-dose vial 40 mg (appropriate NDC reported)
- J3301, 1 unit

Example 2:

- 5 mg of fluorouracil injected
- HCPCS J9190, fluorouracil, 500 mg
- Multi-dose vial 500 mg (appropriate NDC reported)
- J9190, 1 unit

Additional Resources

Visit the Coding for Injectable Drugs webpage at https://www.aao.org/practice-management/coding/injectable-drugs to learn more and to download these articles and tables: "Correct Coding for Single-Use Vials," "How to Get Reimbursed for Multidose Vials," Table of Common Drugs and Table of Common Retina Drugs.

Sources

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Retina Testing Services **NCCI 29.2** **Effective 7/1/2023**	**EO peripheral retinal disease 92201**	**EO posterior pole 92202**	**FA 92235**	**ICG 92240**	**FA/ICG 92242**	**FP 92250**	**Posterior Segment OCT 92134**	**Optic Nerve OCT 92133**
EO peripheral retinal disease 92201		**Mutually Exclusive**	Billable same day	Billable same day	Billable same day	**Mutually Exclusive**	Billable same day	Billable same day
EO posterior pole 92202	**Mutually Exclusive**		Billable same day	Billable same day	Billable same day	**Mutually Exclusive**	Billable same day	Billable same day
FA 92235	Billable same day	Billable same day		**Mutually Exclusive**	**Mutually Exclusive**	Billable same day	Billable same day	Billable same day
ICG 92240	Billable same day	Billable same day	**Mutually Exclusive**		**Mutually Exclusive**	**Bundled**	Billable same day	Billable same day
FA/ICG 92242	Billable same day	Billable same day	**Mutually Exclusive**	**Mutually Exclusive**		**Bundled**	Billable same day	Billable same day
FP 92250	**Mutually Exclusive**	**Mutually Exclusive**	Billable same day	**Bundled**	**Bundled**		**Bundled**	**Bundled**
Posterior Segment OCT 92134	Billable same day	Billable same day	Billable same day	Billable same day	Billable same day	**Bundled**		Mutually Exclusive
Optic Nerve OCT 92133	Billable same day	Billable same day	Billable same day	Billable same day	Billable same day	**Bundled**	Mutually Exclusive	

Retina—Biosimilars, Dual Inhibitors, and Coding for New Drugs

BY **JACOB GOODMAN,** ACADEMY MANAGER, REIMBURSEMENT & REGULATORY POLICY, **ANKOOR R. SHAH, MD,** ACADEMY HEALTH POLICY COMMITTEE MEMBER, AND **JOY WOODKE, COE, OCS, OCSR,** ACADEMY DIRECTOR OF CODING AND REIMBURSEMENT.

It is an exciting era in retina. Physicians and patients have become accustomed to anticipating the next big change in clinical interventions—and practices have had to be nimble in keeping up with evolving reimbursement policies. New therapies, including biosimilars and dual inhibitors, have brought new challenges related to reimbursement and step therapy.

Biosimilars. According to the FDA, a biosimilar is "a biologic that is highly similar to and has no clinically meaningful differences in terms of safety, purity, and potency (safety and effectiveness) from an existing FDA-approved biologic, called a reference product."[1] And what are biologics? Biologics are biological products, such as vaccines, blood products, tissues, gene therapies, and—in the case of aflibercept (Eylea), bevacizumab (Avastin), and ranibizumab (Lucentis)—VEGF inhibitors.

Unlike generics, a proposed biosimilar needs to go through clinical trials to demonstrate its biosimilarity with the reference drug. Biosimilars that succeed in these smaller scale clinical trials inherit the coverage for diseases that the FDA approved for the reference product. The biosimilars are typically priced in a manner that can reduce overall costs.

Two FDA-approved biosimilars for Lucentis. Currently, two biosimilars of ranibizumab are FDA-approved based on good safety profiles and similar efficacy. Cimerli (ranibizumab-eqrn) has approval for all indications of the reference drug ranibizumab, as it comes in both the 0.3 and 0.5 mg/0.05 mL formulations. Byooviz (ranibizumab-nuna) has approval for all indications of ranibizumab 0.5 mg/0.05 mL.

Dual inhibitors. Dual inhibitors act on two different molecular targets. Vabysmo (faricimab-svoal), for example, is a dual inhibitor that blocks both VEGF-A and angiopoietin-2. The FDA approved it in early 2022 for the treatment of neovascular age-related macular degeneration (AMD) and diabetic macular edema (DME). In the AMD trials (TENAYA and LUCERNE) as well as the DME trials (YOSEMITE and RHINE), many patients were able to have their treatment intervals extended to 16 weeks, providing a durability advantage over existing medications. Reduced treatment burden and improved control of fluid within the retina are some of the primary advantages for patients.

Two Ranibizumab Biosimilars

Biosimilar	Byooviz (ranibizumab-nuna)	Cimerli (ranibizumab-eqrn)	
Dosage	0.5 mg/0.05 mL	0.3 mg/0.05 mL	0.5 mg/0.05 mL
Indications	Neovascular AMD, macular edema following RVO, myopic choroidal neovascularization	Diabetic retinopathy, DME	Neovascular AMD, macular edema following RVO, myopic choroidal neovascularization

Coding for New Drugs

First steps when coding for a new drug. First, you will need to check whether your payer has a step therapy policy that precludes initial use of a new drug (see "Step Therapy," next page). Then to facilitate timely reimbursement with limited denials, you will need to identify the appropriate coding.

What if a drug doesn't yet have a permanent HCPCS code? When you bill for drugs, you use a five-character alphanumeric code that is known as a HCPCS code (Healthcare Common Procedure Coding System). If a drug hasn't yet been assigned its own HCPCS code, you would use an unlisted or not other classified (NOC) code. For example, payers would typically recognize codes J3490 *Unclassified drugs* and J3590 *Unclassified biologics* if the service was provided in an office and C9399 *Unclassified drugs or biolog-*

ics if provided in a facility.

After a HCPCS code is assigned. You can no longer use an unlisted or NOC code to bill for an item once a specific HCPCS code is assigned to that item. At this point, CMS usually adds the medication to the average sales price (ASP) quarterly payment files, which is the fee schedule for medications. Prior to this assignment, the medication is carrier-priced by your region's Medicare Administrative Contractor, and the price is typically based on wholesale acquisition cost.

Step Therapy

An ongoing problem. Retina practices have become familiar with payer policies that require step therapy. These "fail first" policies require clinicians to use the payer's preferred drug therapy (typically involving a lower-cost drug) and then document a failed response before alternate drugs are covered. Payers have, for example, applied step therapy policies to the use of anti-VEGF agents in treating proliferative diabetic retinopathy, retinal vein occlusion (RVO), and AMD (see "Step Therapy: Clinicians' Concerns and Challenges," April 2022, *EyeNet*). Aside from being an administrative burden, step therapy can delay patients' access to optimal treatments.

Hurdles added. With the introduction of the latest retina drugs, some payers have revised their step therapy policies. These changes, unfortunately, have added new steps. For example, some policies now require the use of biosimilars after failure with bevacizumab before more expensive drugs are covered.

Furthermore, some policies inappropriately require off-label indications prior to the use of preferred brand medications—such as the use of Byooviz prior to aflibercept for diabetic retinopathy. The Academy has successfully addressed some of these flawed policies.

Has step therapy harmed your patients? If you observe adverse reactions or patient harm because of a step therapy requirement, email healthpolicy@aao.org to help guide the Academy's ongoing work with CMS.

Introducing a New Drug Into Your Retina Practice

Before implementing new drugs into your practice, review this checklist:

1. Review the FDA label and confirm indications for and frequency of treatments, as this may vary from other medications currently used in the practice.

2. Identify any published payer policies for the new drug and any unique documentation guidelines or required HCPCS codes. Also review any step therapy policies.

3. Report with an NOC HCPCS code, J3490, J3590, or C9399, until a permanent code is assigned (see "Coding for New Drugs," previous page).

4. Check your CMS-1500 form to ensure that you have entered the required information, including the following:

- Item 19, or its Electronic Data Exchange (EDI) equivalent, should include the medication name and dosage (in mg/mL), as well as the invoice amount.
- Item 24a, or EDI loop 2410, should include the "N4" qualifier followed by the unique national drug code (NDC) for the medication in 5-4-2 format and the unit of measure (UOM). For Cimerli (0.5 mg/0.05 mL), for example, this would be N470114044101 ML0.05. (Note: On the claim form, don't include hyphens in the NDC and put uppercase "ML" before the UOM.)

5. Monitor remittance advice notices to ensure that you are being reimbursed appropriately, and create audit reports to monitor correct coding and payer allowables.

6. Watch for a permanent HCPCS code and make sure your practice updates its coding procedures. When a drug is assigned a permanent HCPCS code, there is an effective date. Additionally, the new code descriptor will include the size of each dosage unit, which enables you to calculate how many units to report. For example, effective for dates of service on or after April 1, 2022, Byooviz was assigned HCPCS code Q5124, *injection, ranibizumab-nuna, biosimilar (Byooviz), 0.1 mg.* As a result, when reporting an intravitreal injection of Byooviz, 0.5 mg, you would code Q5124, 5 units.

Tip: Create a cheat sheet. You can make your practice's coding more efficient and accurate by creating a quick reference guide for all your retina medications—but each quarter may bring new coding guidance (e.g., a new HCPCS code), so keep it up to date.

Quick Reference for New Retina Drugs

Drug	HCPCS	Descriptor	Units	NDC in 5-4-2 format
Byooviz, 0.5 mg	Q5124	*Injection, ranibizumab-nuna, biosimilar (Byooviz), 0.1 mg*	5	64406-0019-07
Cimerli, 0.3 mg	Q5128*	*Injection, ranibizumab-eqrn (Cimerli), biosimilar, 0.1 mg**	3*	70114-0440-01
Cimerli, 0.5 mg	Q5128*	*Injection, ranibizumab-eqrn (Cimerli), biosimilar, 0.1 mg**	5*	70114-0441-01
Vabysmo, 6 mg	J2777	*Injection, faricimab-svoa, 0.1 mg*	60	50242-0096-01

* Effective April 1, 2023.

1 www.fda.gov/drugs/biosimilars/review-and-approval. Accessed March 8, 2023.

MORE ONLINE. For more on step therapy, see this article at aao.org/eyenet. For documentation and coding guidance for intravitreal injection, including documentation checklists and the Table of Common Retina Drugs, visit aao.org/retinapm.

How to Add a New Retina Drug to Your Practice—11 Steps to Get You Started

Are you about to adopt a new retina drug into your practice? Rigorous planning and careful attention to detail will be key, because mistakes can be costly. The implementation process may seem daunting, but the steps below will help you get started.

1. Know when (and how) to use the NOC HCPCS codes. When submitting claims, you bill for drugs using HCPCS codes (Healthcare Common Procedure Coding System). But if a HCPCS code hasn't yet been assigned to the drug, you would use one of the Not Otherwise Classified (NOC) HCPCS codes.

2. Research payer policies and FDA indications. Understanding payer policies (aao.org/lcds) is key. But in the absence of a published payer policy, the FDA label may provide some guidance for coverage. The drug will not be reimbursable if you are using it inappropriately, so make sure you research the drug's FDA label for its indications and frequency of treatment.

3. Update your EHR and practice management systems. Add the new drug(s) to your systems' libraries.

Add codes for billing and tracking. For each new drug, set your system up with the following: appropriate NOC HCPCS code (e.g., J3490, J3590); National Drug Code (NDC); claim notes (e.g., medication name, dosage, and invoice amount) for item 19 of form CMS-1500 or its Electronic Data Interchange (EDI) equivalent; "usual and customary fees"; and, once it is assigned, permanent HCPCS code.

You should also set up your practice's own internal "pseudocode" for a drug and link it to the NOC HCPCS code. This will help you track a drug's utilization, reconcile its inventory, and audit its reimbursement, even if you have to use the same NOC HCPCS code for more than one drug.

Update templates and processes. Update the following: automated scrub edits, chart templates and macros, encounter types, and scheduling templates. Implementing electronic consents can help streamline the process for administering new drugs. (For sample consent forms, see www.omic.com/risk-management/consent-forms/.)

4. Rethink workflow. Adjust workflow to accommodate the new drug. Streamlining the process for ordering and administering drugs can help reduce errors and save time.

5. Educate staff and physicians. Training clinical staff on the use and administration of new drugs is important for ensuring patient safety and efficacy, and all staff members should be aware of new treatments and indications. Staff should also know about prior authorization and step therapy requirements, and billing staff should know the fee schedules, payer contracts, and what codes to use.

6. Establish ordering amounts and monitor inventory. Determining the appropriate amount of drug to order and monitoring inventory levels can help prevent shortages or overstocking. Establish a system for tracking drug usage and reordering drugs when needed. For tips, see "IVT Drugs: How to Control Costs and Survive an Audit" (Practice Perfect, July 2014).

7. Monitor claims and denials. Ensure that claims are submitted correctly and in a timely manner. Monitor denials and take corrective action when necessary. Audit payer reimbursements to confirm that you are paid the right amount.

8. Take advantage of patient assistance programs. Confirm with the vendor any eligible patient assistance and copay programs for the new drug. Identify the process for participating in such programs, train the staff on it, and make sure physicians know about it.

9. Don't forget your satellite offices. All offices should be equipped to handle new drugs, and staff at satellite offices should be trained on the new drugs. Confirm the process of delivery or transportation to all locations.

10. Educate your patients. Educating patients on the benefits and potential side effects of drugs is important for patient care and adherence to treatment plans. Providing instructions for administration and any necessary precautions will also help prevent adverse events.

11. Bookmark aao.org/retinapm. Visit the page frequently for updates on the latest resources and regulations.

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Meet Modifier –JZ: A Quick Guide to –JW's New Counterpart

Do you administer drugs that come in a single-dose container, vial, or package? Since Jan. 1, 2017, your practice should have been using modifier –JW *discarded drug not administered* to report unused and discarded amounts from single-dose containers. This enabled you to be reimbursed for all the drug in the container, not just the portion that was administered to the patient. But what if there is no wastage? This year, CMS introduced a new modifier: –JZ *zero drug amount discarded/not administered to any patient.*

Why the new modifier? In some circumstances, drug manufacturers that produce single-dose vials must refund CMS for part of the cost of discarded drugs. However, CMS found that modifier –JW was often omitted from claims, and the agency worried that this was often due to incorrect coding rather than an absence of discarded drugs. CMS believes that the new modifier will reduce errant coding and provide more accurate data for when the agency calculates the discarded drug refunds that some manufacturers must pay.

Timeline for using modifier –JZ. When CMS published the modifier –JZ in late 2022, it announced an extended timeline for its full implementation. Although the new modifier went into effect Jan. 1, 2023, you weren't required to use it for the first six months of the year. Starting with dates of service on or after July 1, you must use modifier –JZ for claims involving single-dose containers in which there is no wastage. Failure to do so could result in audits. The next key date is Oct. 1, when CMS contractors will start returning claims as unprocessable if they don't use modifiers –JZ and –JW appropriately.

Use of modifier –JZ. Append modifier –JZ to the Healthcare Common Procedure Coding System (HCPCS) code that represents the drug used.

Don't use modifiers –JW and –JZ when using multidose containers. Drugs in multidose containers can be administered to more than one patient. If you administer a drug from a multidose vial, you will be reimbursed only for the amount administered to the patient, not for any discarded amounts, and this means that modifiers –JW and –JZ don't apply. Report only the dosage and units used per patient.

How can you tell that a container is single-dose? Review a drug's FDA-approved labeling to confirm whether the container is considered single-dose or multidose. Some drugs—such as triamcinolone acetonide (Kenalog) and fluorouracil—can be distributed as either single-dose or multidose, so you should always confirm what type of container you are using. Additionally, the national drug code (NDC) may vary depending on whether the drug is in a single- or multidose container.

Only use for drugs that are "separately payable." Don't use modifiers –JW and –JZ for drugs that aren't separately payable under Medicare Part B. You wouldn't, for example, use them for sample drugs or for "white bagged" drugs, which is when a payer has a third-party specialty pharmacy fill the prescription and send the drug to you.

Not just for retina practices. Although the use of modifiers –JW and –JZ mostly impacts retina practices, they should be considered when any medication is used and reported.

Code This Case

How are the modifiers used in practice? Cases 1 and 2 demonstrate the use of modifier –JW, while cases 3 and 4 show the use of modifier –JZ.

Case 1: Visudyne. An intravenous infusion of Visudyne (verteporfin for injection) is performed for photodynamic therapy in the left eye. Based on the patient's weight, 12 mg of Visudyne was used and 3 mg wasted.

Key details:

- 12 mg of Visudyne used and 3 mg discarded.
- Relevant HCPCS code: J3396 *Injection, verteporfin, 0.1 mg.* (The code description indicates that 1 unit of the drug = 0.1 mg.)
- Single-dose vial contains 15 mg (150 units).
- Relevant CPT code: 67221 *Destruction of localized lesion of choroid (e.g., choroidal neovascularization); photodynamic therapy.*

What to report:

- 67221–LT.
- J3396, 120 units.

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Coming in the next EyeNet®

Feature
Nanotechnology The tiniest of technologies is changing ocular drug delivery, reaching cells in the back of the eye.

Clinical Update
Comprehensive Having trouble staying on top of all the dry eye treatments? Let cornea experts help. Part 2: aqueous deficiency.
Uveitis Evaluating and managing noninfectious uveitis can be complex. Aiming to clarify, Part 1 of a roundtable focuses on initiating treatment.

Pearls
Cornea A primer—and a case report—on how to spot and treat mpox.

Savvy Coder
Nd:YAG Tips to improve documentation and maintain reimbursement.

Blink
Take a guess at the next issue's mystery image. Then find the article at aao.org/eyenet and report your diagnosis.

For Your Convenience
These stories also will be available online at aao.org/eyenet.

- J3396–JW, 30 units.

Case 2: Botox. Botox (onabotulinumtoxinA) is injected to treat blepharospasm. A diagram of the injection sites on both sides of the face is documented, along with 40 units used, and 60 units wasted.

Key details:
- 40 units of Botox were injected and 60 units discarded
- Relevant HCPCS code: J0585 *injection, onabotulinumtoxinA, 1 unit*
- Single-dose vial 100 units
- Relevant CPT code: 64612 *Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (e.g., for blepharospasm, hemifacial spasm)*

What to report:
- 64612–50
- J0585, 40 units
- J0585–JW, 60 units

Case 3: Vabysmo. An intravitreal injection of Vabysmo (faricimab-svoa) is performed in the right eye. The dosage is documented as 6 mg/0.05 mL from a single-dose vial. Any residual medication less than 1 unit, or overfill, was discarded.

Key details:
- 6 mg of Vabysmo injected
- Relevant HCPCS code: J2777 *faricimab-svoa, 0.1 mg*
- Single-dose vial 6 mg
- Relevant CPT code: 67028 *intravitreal injection of a pharmacologic agent*

What to report:
- 67028–RT
- J2777–JZ, 60 units

Case 4: Fluorouracil. From a single-dose vial, a subconjunctival injection of 5 mg of fluorouracil in the left eye is performed. The vial is 500 mg/10 mL and remaining medication is discarded.

Key details:
- 5 mg of fluorouracil injected
- Relevant HCPCS code: J9190, *fluorouracil, 500 mg*
- Single-dose vial 500 mg
- Relevant CPT code: 68200 *Subconjunctival injection*

What to report:
- 68200–LT
- J9190–JZ, 1 unit

Note: Although medication was discarded in case 4, the descriptor for code J9190 indicates that the billing unit is 500 mg. The –JW modifier is not appropriate when the discarded dose is less than the HCPCS billing unit.

Is Your Practice Using These Resources?

Make the most of the following Academy and AAOE resources.

The Coding for Injectable Drugs webpage. For guidance on billing for injectable drugs, visit aao.org/practice-management/coding/injectable-drugs.

The Practice Management for Retina webpage. For coding resources, including the Table of Common Retina Drugs, visit aao.org/practice-management/coding/retina.

The AAOE's coding products. Visit aao.org/codingtools to learn about the AAOE's coding products, including the following:
- *Ophthalmic Coding Coach: Complete Reference*
- *Retina Coding: Complete Reference Guide*
- *Fundamentals of Ophthalmic Coding*
- *2023 ICD-10-CM for Ophthalmology: The Complete Reference*
- *2023 CPT: Complete Pocket Ophthalmic Reference*
- *2023 Coding Assistant for Subspecialties*
- *2023 HCPCS Level II Professional Edition*

Practice Management Express. The weekly e-newsletter that alerts AAOE members to the latest developments in coding.

AAOE-Talk. AAOE members can join this online community to crowdsource solutions to their billing dilemmas. Learn more at aao.org/practice-management/aaoe-talk-overview.

Not an AAOE member? Learn about the AAOE member benefits at aao.org/member-services/join-aaoe.

Geographic Atrophy—How to Get Paid for New Treatments

Whenever a new treatment emerges, the path to reimbursement is rarely smooth. For example, even after a drug receives FDA approval, Medicare Administrative Contractors (MACs) and other payers may delay coverage and be slow in publishing their policies for it. The new treatments for geographic atrophy (GA) face all those usual hurdles, plus a few unique bumps in the road.

A New Era for GA Treatment

Earlier this year, Syfovre (pegcetacoplan) was the first FDA-approved drug to treat GA, followed more recently by Izervay (avacincaptad pegol). Both drugs target the complement pathway and must be injected on an ongoing basis.

More GA drugs in the pipeline. Over the next few years, pharmaceutical companies are expected to release more GA drugs, targeting different parts of the complement pathway. Once these are approved, their FDA labels may list different indications and limitations, and each drug may have its own unique route to securing payer coverage. When you submit claims for new GA drugs, you can boost your success rate by following the tips below.

Which HCPCS Code?

The Healthcare Common Procedure Coding System (HCPCS) provides alphanumeric codes that are used to bill for items, supplies, and nonphysician services that aren't covered by the CPT codes. For example, the HCPCS codes for Eylea (aflibercept) and Lucentis (ranibizumab) are J0178 and J2778, respectively.

What if CMS *has not* yet assigned a HCPCS code to a new drug? If a new drug doesn't yet have its own permanent HCPCS code, you could use one of the following not otherwise classified (NOC) codes:

- J3490 *Unclassified drugs*
- J3590 *Unclassified biologics*
- C9399 *Unclassified drugs or biologics*

Each payer may have its preferred NOC code for a particular treatment, and the preferred code may vary depending on the circumstances. For example, the two J-codes above would typically be used for a service that is provided in an office, while C9399 would be used for a facility.

Determine payers' preference and submit clean claims. When using NOC HCPCS codes to bill for a new drug, the first key step is to identify which of the codes the payer would prefer you to use. It also is critical to check that your claim is clean, especially for the new GA treatments, given the problems discussed below.

What if CMS *has* assigned a HCPCS code? Even after a permanent HCPCS code is assigned by CMS, other payers may delay the implementation for a few months. However, once a payer implements a HCPCS code, it will insist that you use that code, when applicable, rather than a NOC code.

HCPCS codes for Syfovre. A permanent HCPCS code was assigned to Syfovre for facility use (C9151) effective July 1, 2023, followed by a code for the office setting (J2781) effective Oct. 1, 2023. For both codes, the dosage unit is 1 mg. Since the recommended dose is 15 mg, you would report 15 units.

CMS form 1500. On CMS form 1500, be careful when filling out items 19 and 24A—or their Electronic Data Interchange (EDI) equivalents. Report the medication name and dosage in item 19 and the national drug code (NDC) in item 24A. (For more specific guidance, go to aao.org/retinapm and click "Coding for Injectable Drugs.")

Which ICD-10 Code?

When you submit CPT code 67028 for performing an intravitreal injection, you also need to submit an ICD-10 code to indicate why the service was medically necessary.

No ICD-10 code for GA. Currently, there is no ICD-10 code that is specific for GA. Instead, use H35.31-, which is the code for nonexudative age-related macular degeneration (AMD), and add a sixth character to indicate which eye(s) underwent treatment, and a seventh character to indicate disease stage. The FDA label may state what stage of GA the drug can be used for.

Don't be surprised by initial denials. Historically, nonexudative AMD was a noncovered diagnosis for intravitreal

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injections. Indeed, submitting that diagnosis when billing for anti-VEGF drugs could have triggered a claims review or audit. When you submit a claim that links ICD-10 code H35.31- to CPT code 67028, you may initially receive denials. This is a typical challenge when the FDA approves a treatment for a previously untreatable disease state, but it is less likely to be an issue once payers update their coverage policies.

Wet and Dry AMD in Same Eye?

Patients with GA could also have exudative AMD in the same eye, which you might be treating with anti-VEGF medications. You may want to treat both conditions on the same day, which would require two separate intravitreal injections and may involve—at least initially—reimbursement problems.

MUE problems. Under the CMS Medically Unlikely Edit (MUE) program, CPT code 67028 has long been assigned a MUE value of 1. This means that CMS believes that, in the vast majority of cases, a patient shouldn't receive more than one intravitreal injection in the same eye on the same date of service. Consequently, only one injection per encounter will be paid.

CMS form 1500. With these combined treatments and different indications, it is critical that you link the ICD-10 codes to the CPT and HCPCS codes appropriately in CMS form 1500's item 24E (or its EDI equivalent):

- Link both the nonexudative and exudative AMD ICD-10 codes to CPT code 67028;
- link only the exudative AMD ICD-10 code to the HCPCS code for the anti-VEGF drug; and
- link only the nonexudative AMD ICD-10 code to the HCPCS code for the GA medication.

Payers Need to Update 28-Day Rule for CPT Code 67028

Intravitreal injections of anti-VEGF drugs have frequency limitations. This is typically every 28 days, which means that if you inject an anti-VEGF drug fewer than 28 days after injecting the same eye, either your claim for the second injection will be denied or, if paid, the payer is likely to try to recoup the money in an audit. Some retina drugs, per the FDA label, may extend this window after a certain number of doses.

Because of what is often called the "28-day rule" for CPT code 67028, a payer may initially reject the claim when an intravitreal injection for GA is performed sooner than 28-days after an intravitreal injection in the same eye. Payers will need to update their policies to account for this alternate class of medications—the complement inhibitors—which is distinct from the anti-VEGF treatments.

Getting Started With the New GA Treatments

The process of implementing a new treatment will be more manageable if you break it down into steps, as described in "How to Add a New Retina Drug to Your Practice—11 Steps to Get You Started" (*EyeNet*, July 2023).

Take a phased approach. Because of the varied payment obstacles described above, it may be best to implement the new treatment in phases, provided that such an approach is medically appropriate for individual patients. You could start with the treatment that involves the most straightforward claim—therapy for GA alone—rather than combined therapy for both GA and exudative AMD. Once payer cov erage has been confirmed for that first scenario, start alternating the two treatments at intervals of at least 28 days. Finally, try submitting a claim for two injections on the same day.

Be ready to appeal a denied claim. Prepare a strategy for prompt and appropriate appeals and educate your staff on those procedures. The first step is to confirm that the drug information was reported appropriately on the claim. Then, if appropriate, submit an appeal letter that explains the medical necessity for the intravitreal injection. As payers publish policies and update their claims processing systems, and as more drugs are introduced, there should be fewer denials.

Keep up with payer policies. The new GA treatments have been met with varied coverage from Medicare, commercial payers, and other payers. Most MACs have responded positively and have paid ophthalmologists' claims. A few national Medicare Advantage and commercial plans—including Humana and United Health Care—have published policies for GA treatment. Although some of these policies were initially flawed or overly stringent, they also were promptly revised. Policies will continue to evolve; policies of different payers will vary; and there is a risk that some payers may introduce prior authorization requirements. Key to minimizing denied claims: diligently and regularly access and review the policies of your payers.

MORE ONLINE. For tips on staying current with your MAC's policies, see this article at aao.org/eyenet.

Introducing a New Drug Into Practice

Before implementing new drugs into your practice, review this checklist:

☐ Review the FDA label.

☐ Identify any published payer policies for the new drug and any unique documentation guidelines or required HCPCS codes.

☐ Report with an NOC HCPCS code until a permanent code is assigned.

☐ Check your CMS-1500 form to ensure that you have entered the required information, including in items 19 and 24A (or their EDI equivalents).

☐ Monitor remittance advice notices to ensure that you are being reimbursed appropriately, and create audit reports to monitor correct coding and payer allowables.

☐ Watch for the drug's permanent HCPCS code, review its descriptor (including its dosage unit), and note the date that it goes into effect.

For a more detailed version of this checklist, see "Retina—Biosimilars, Dual Inhibitors, and Coding for New Drugs" (*EyeNet*, May 2023).

Stay Current on Your MAC's LCDs

Know your local rules. MACs have the discretion to set their own coverage policies for GA treatments. They can publish this as a local coverage determination (LCD), sometimes accompanied by an explanatory article (LCA). The Academy posts these at aao.org/lcds.

See if your MAC offers weekly updates. Many payers have listservs that provide weekly e-mails notifying you about any updates. Go to your MAC's website and sign up to receive these emails.

Join the AAOE-Talk community. AAOE members can get an early heads-up on changes in reimbursement policies by monitoring the messages on AAOE-Talk: aao.org/practice-management/listserv. Not an AAOE member? You can join at aao.org/member-services/join-aaoe.