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Retina Today

NAVIGATING COPAYS IN RETINA CARE

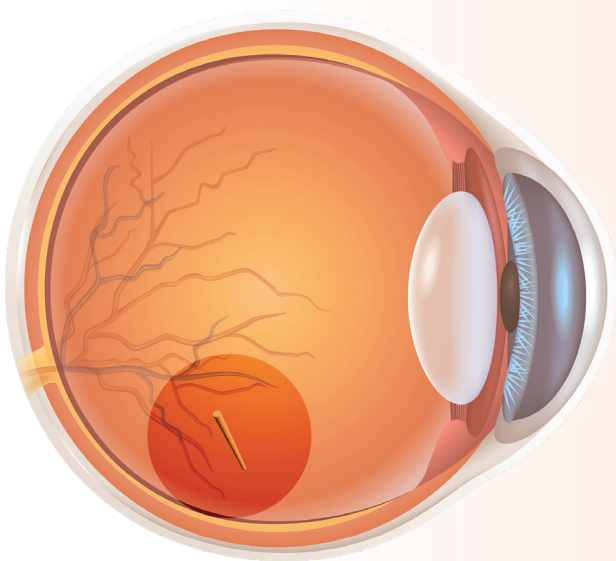
How assistance programs are changing and what you can do about it.





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THE ECONOMICS OF CARE



When we all set out to become surgeons, I bet none of us thought we would end up spending so much time talking to patients about money. However, as the treatment landscape for retinal diseases becomes increasingly complex with novel drugs, biosimilars, step therapy, changing reimbursement, and OR access issues, money is a big factor in our practices these days.

Nothing has made this clearer than the dwindling funding for copay assistance programs such as Good Days. Patients who never spent a dime on their anti-VEGF agents are being hit with bills—and they are confused. Our practices have been absorbing not only their emotions, but the long conversations that come with them. Now, physicians and staff are tasked with educating patients on various insurance plans, explaining what copay assistance programs are, and why patients have lost coverage.

To help, we sat down with Michael M. Lai, MD, PhD, to discuss what happened with our copay assistance programs, how it has affected our practices, and what we can do about it. He notes that the onslaught of patient education has paid off for his practice; his patients are better informed, and many are better equipped to manage their health care finances.

A nice companion article to that is our Practice Management column, which highlights the various issues with the prior authorization process for anti-VEGF therapies and potential solutions. If you want more on the economics of practice, we have an excellent article in the May/June issue of *Retina Today* that provides an update on the anti-VEGF step therapy process by Jennifer Adeghate, MD, PhD, and her team at the Medical College of Wisconsin.

When you're ready to focus on your own finances, check out Coding Advisor, which provides helpful tips for properly coding E/M and eye visit codes to maximize your reimbursement. Lastly, we have an article on life insurance to help you stay on top of important long-term goals.

We became retina specialists to save patients' vision. While we may not have expected so many financial hurdles to reach that goal, it's worth the effort to ensure patients get the care they need in a timely manner. ■

ALAN RUBY, MD

SECTION EDITOR



FURTHER READING

ANTI-VEGF STEP THERAPY: AN UPDATE

Despite ongoing advocacy efforts, this payer policy persists, putting vision at risk.

By Lucas McGuire, BS; Baseer Ahmad, MD;
and Jennifer Adeghate, MD, PhD



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LIFE INSURANCE: TERM VERSUS PERMANENT



This primer explains the different approaches and when one might work better than the other.

BY DAVID MANDELL, JD, MBA, AND JASON O'DELL, MS, CWM

Life insurance is part of nearly every retina specialist's wealth planning. This is not surprising, because those with dependents use it to protect future income for their family's well-being in case of an untimely death. However, life insurance can help achieve other planning goals, including asset protection, tax diversification, wealth creation, and estate tax planning. To achieve these goals and more, doctors have two types of life insurance policies to consider: temporary (term) and permanent (cash value). This primer outlines the basics of both life insurance options to help you use them appropriately for far more than protecting against a worst-case scenario.

TERM LIFE INSURANCE

Term insurance is the least costly type of life insurance; because you are only paying for death benefit, there is no accumulation element. Thus, term insurance offers peace of mind for a limited time. For those nervous about investing in something that follows them throughout their lives (an understandably daunting prospect), term insurance offers a compromise between providing something versus nothing for their loved ones in the event of death.

As the name implies, term coverage lasts a finite time—usually between 10 and 30 years—with the average policy having a 20-year term. During this time, premiums are an expense; the policy doesn't accrue any value, but the beneficiaries receive a payout if you pass while the policy is active.

For ophthalmologists, this can be a cost-effective way to ensure that, if they die, their families receive a short- or long-term (depending on the payout amount) income replacement. This gives the beneficiaries the time they need to mourn and regroup without worrying about finances.

PERMANENT LIFE INSURANCE

Looking at life insurance as an investment instead of a cost opens you up to a plethora of other long-term options that fall under the umbrella of permanent (or "cash value") life insurance.

Like term insurance, permanent life insurance policies offer a payout to the beneficiaries in the event of the covered person's passing. However, this category of insurance also carries cash value along with the death benefit. Provided the premiums are paid regularly, permanent insurance can last for the policyholder's entire life.

Although permanent life insurance premiums are higher than term policy premiums, this type of coverage will eventually move from an expense to an investment. As you pay your premiums, your policy should begin to accrue tax-free cash value, which is attractive to many physicians. After a pre-determined period (covered in your policy terms), you can access this cash value if you need funds.

Within the permanent life insurance umbrella are five different types of policies, three of which are more commonly used. The two types of policies not covered here, and used less frequently by physicians, are variable life and variable universal life insurance, both of which have greater downside risk and upside potential.

Whole Life Insurance

Within the scope of insurance, whole life is often compared with term. This coverage type has existed for decades, becoming a preferred policy in the 1940s and beyond. Whole life has evolved since its inception, but the original "til-death" policy continues to remain popular.

Whole life insurance premiums are fixed and do not

increase throughout your lifetime—as long as you pay them on time. The coverage pays a death benefit to the policy's beneficiary (named by you) and provides a cash value account into which you can invest part of your income while ensuring tax-deferred cash accumulation.

Whole life coverage is frequently used to complement a savings account once your emergency safety net is covered. If you don't need to access your funds and want them to grow faster than they would in savings, the whole life premium does the work for you, typically increasing with the insurance company's annual dividends.

Also, if you need to borrow from the cash value of your policy, you can. Provided you have structured the policy correctly, the earnings are accessible tax-free. Whole life insurance is ideal for those looking for benefits such as:

- Tax reduction
- Asset protection
- Estate planning
- Wealth accumulation
- Asset class tax diversification

However, whole life insurance is tied to the insurance company's investments. You don't get to diversify where your premium goes or move it between accounts. And once you've chosen a death benefit amount, you can't change it. If these factors are important to you, universal life insurance may be a better fit.

Universal Life Insurance

Universal life insurance works similarly to whole life coverage, but it provides flexibility in the premium and death benefit choices. With universal life, your cash value should grow as interest paid by the insurance company. If the company's investments do well, you'll reap the benefits of your policy's cash accumulation. However, should the company's investments do poorly, your interest return will likely reflect this. When that happens, less money is available to cover your death benefits, and you'll need to pay higher premiums to meet the gap. Another option for universal life policies may be to reduce the death benefit, a flexibility option not available with whole life insurance.

Equity-Indexed Universal Life

A subset of universal life coverage, equity-indexed universal life insurance (EIUL) provides the policyholder with premium and policy flexibility. You can choose from a list of stock market indices in which the insurance company will invest your premium and grow your cash value at the same rate as stock market returns, with a cap and a floor. There are numerous investment options and elements to select with EIUL policies, and they need to be managed closely. As such, it is essential to work with an insurance specialist when investing in this type of policy.

PLAN AHEAD FOR PEACE OF MIND

While life insurance is a fundamental planning tool for many retina specialists, there are a host of options in the marketplace, falling under two broad categories: term and permanent insurance. We both use term and permanent policies in our personal planning because we recognize that each category has its benefits, risks, and use cases. We encourage all physicians, including retina specialists, to become more educated on them as well. ■

*SPECIAL OFFER: Mr. Mandell and OJM Group partners are pleased to offer their latest book, *Wealth Strategies for Today's Physician: A Multi-Media Playbook*. The *Playbook's* innovative format features more than 90 links to videos and podcast episodes to enhance important financial topics for physicians. To receive a free print copy or ebook download, text RETINA to 844-418-1212, or visit www.ojmbookstore.com and enter promotional code RETINA at checkout.*

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MANAGING WITHOUT COPAY ASSISTANCE PROGRAMS

Here's what happened with Good Days, and how you can adjust in your clinic.

An interview with Michael M. Lai, MD, PhD



Patient copay assistance programs have been wonderful resources for patients who require chronic treatment with high-cost drugs such as anti-VEGF agents. However, these programs have recently experienced significant underfunding, leaving certain patients struggling to pay for their therapies. *Retina Today* (RT) sat down with Michael M. Lai, MD, PhD, to discuss what happened and how retina practices have been adjusting to ensure the best possible care for their patients.

RT: WHAT IS GOOD DAYS?

Dr. Lai: Good Days is a nonprofit organization that supports copays for patients with chronic conditions; in retina, the fund supports patients with chronic diseases such as AMD, diabetic retinopathy, retinal vein inclusion and, recently, geographic atrophy. Retina drugs are expensive and most patients require ongoing treatment for a long period

KEY TAKEAWAYS

- ▶ Copay assistance programs such as Good Days fill a gap to help patients who can't afford the copay or the deductibles to maintain their treatments. Donations to these copay assistance programs have dwindled over the years, leaving many patients without the needed financial support.
- ▶ The loss of copay assistance programs mostly affects patients with Medicare Advantage plans and other plans with high deductibles and copays.
- ▶ To address the financial strain on patients, clinicians have switched some patients to repackaged and off-label bevacizumab (Avastin, Genentech/Roche), used samples from manufacturers, and, in certain cases, try to extend the treatment interval.

of time, sometimes indefinitely. Programs like Good Days fill a gap to help patients who can't afford the copay or the deductibles to maintain their treatments.

These funds have been in existence for years to support patients, and the need for them has increased because there are more treatments available and the cost of these treatments have increased. At the same time, the health care system has been shifting more of those increased costs onto patients through insurance plans with high deductibles and copays, including Medicare Advantage plans.

With all these factors colliding—more treatments that cost more and insurance plans and payers shifting costs to the patient—copay assistance programs have become more important in supporting patients who now face increasing financial burden for their health care.

RT: WHY ISN'T GOOD DAYS AN OPTION NOW?

Dr. Lai: It takes more money now to support all the retina patients who have deductible and copay needs. However, donations to programs such as Good Days (typically from pharmaceutical companies) have dwindled over the years, leaving many patients without the needed financial support.

Due to complicated legal and compliance rules governing donations to charitable organizations and how such funds can be used to support drug costs, we don't have much visibility into why certain donors cut back on their contributions. Regardless of why, the result of this reduced funding is less money to support patients. Many patients currently enrolled in these programs must re-enroll periodically, and some of them are unable to do so. For newly diagnosed patients, these assistance programs aren't accepting new patients, leaving them with little help to cover their deductibles or high copays.

RT: WHO DOES THIS AFFECT?

Dr. Lai: It's easier to say who this doesn't affect. It doesn't affect patients with traditional Medicare plus supplemental insurance, because they are fully insured and have minimal out-of-pocket costs. This does not affect patients with commercial insurances because almost every drug company has its own copay assistance program to support patients with commercial insurance. Pharmaceutical companies cannot offer copay assistance programs to patients with federal insurance plans because doing so may violate Anti-Kickback Statute.

Patients who are not in one of those two categories

How Has Your Treatment Approach Changed for Patients Who Have Lost Copay Assistance? (Select 3 Most Common)

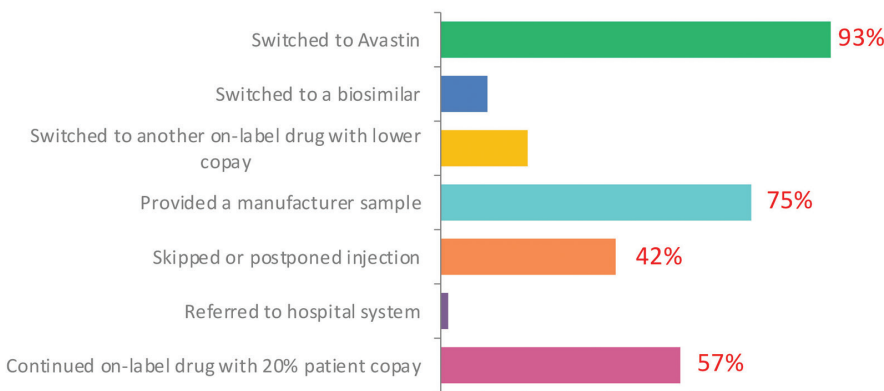


Figure 1. As part of an ASRS survey, respondents were asked to share how their treatment approach has changed for patients who lost their copay assistance. Nearly all the 455 respondents (93%) switched patients to bevacizumab.

need some type of copay assistance or must pay out of pocket. The most likely patients to be affected by the funding shortage of Good Days and other programs are those covered by Medicare Advantage plans. Many patients who signed up for these insurance plans, which have become very popular over the years are not aware of the copay and deductible requirements that come with them. Due to Anti-Kickback Statute, independent charitable organizations like Good Days remain the only legal mechanism to support these patients.

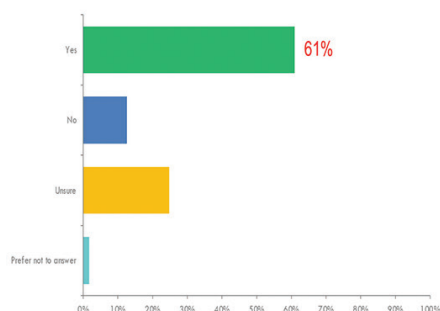
RT: WHAT CAN RETINA PRACTICES DO TO HELP PATIENTS WHO HAVE LOST THIS ASSISTANCE?

Dr. Lai: In the short term, many retina specialists have switched some patients to repackaged and off-label bevacizumab (Avastin, Genentech/Roche). We've also tried to use samples from manufacturers when we can, and, in certain cases, we try to extend the treatment interval (Figure 1). We've even had some patients ask to skip doses because they are struggling to afford the drug. Now more than ever, we find ourselves having to balance preserving vision with the patient's financial burden.

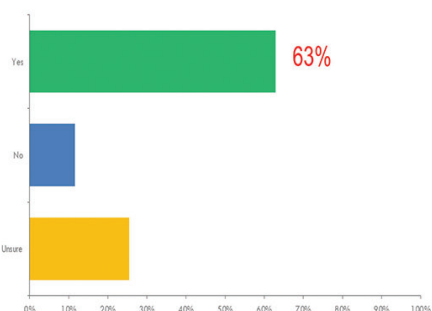
Unfortunately, none of these short-term solutions are sustainable. For example, the bevacizumab supply chain is fragile; there are fewer compounding pharmacies available and there have been reported issues of contamination or quality-control concerns with repackaged bevacizumab.

Within my own practice, some patients haven't done as well, clinically, after switching to bevacizumab—some have more fluid, experience vision loss, and/or require more frequent injections. In a 2025 American Society of Retina Specialists' (ASRS) survey, many clinicians reported similar

Have You Observed Patients Who Have Experienced Vision Loss Due to Cost-Related Delays in Treatment?



Have Any Patients Been Lost To Follow-Up Due To Financial Hardship?



Have You Noticed a Disproportionate Effect on Lower Income or Underserved Communities?

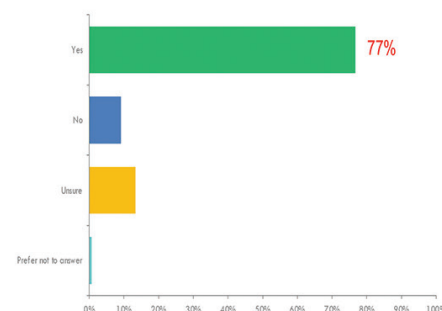


Figure 2. The ASRS survey further revealed negative visual consequences, increased loss to follow-up, and disproportionate effects on lower-income patients.

experiences with their patients (Figure 2).

Our practice has also devoted resources to counseling patients, and staff are educating patients on their copays and deductibles and why they have a balance. In this process, we realized that many patients weren't aware that they had deductibles as part of their health plan because they never needed to pay; that deductible was picked up by a copay assistance program such as Good Days. As more patients are becoming aware of their own financial responsibility, some of them are incorporating this deductible into their budget.

In addition, we have engaged third-party entities to educate patients on the different types of health insurance plans and guide them on selecting a plan that better supports the costs of treating their chronic retinal diseases. Over time, these educational efforts have paid off, and patients are better informed and many—but not all—can manage their deductibles and copays.

RT: COULD EXTENDED DURATION DRUGS HELP?

Dr. Lai: There are some exciting therapies in the pipeline—such as tyrosine kinase inhibitors, gene therapies, and sustained delivery devices—that may potentially allow extended treatment durations. But what's unknown at this point is how much those new therapeutics will cost. If

they cost more than our current options, that won't help much. Also, some of these treatments under development are surgical, which brings in all of the issues we currently face regarding OR access and declining reimbursement for retinal surgery in the ambulatory setting.

RT: DO BIOSIMILARS PLAY A ROLE IN THIS?

Dr. Lai: It's helpful to have biosimilars because they are less expensive than the reference drug, but the cost is still high enough that if someone cannot afford the copay for the reference drug, chances are there they cannot afford the copay for the biosimilar either.

A CALL FOR MORE COLLABORATIVE CARE

The treatment landscape has become quite complicated in retina, and the loss of Good Days funding has put a strain on our clinics, staff, and patients. With careful patient education, advocacy, and creative treatment approaches, we can still meet our patient's needs. Because independent charitable organizations like Good Days constitute the only legal means to support copays and deductibles for the large number of patients covered by federal health insurance plans, protecting access to these programs and supporting their funding should be the highest priorities for all of us. I remain hopeful that we will have better therapies and policies in the future to protect our patients' vision. ■



**FURTHER
READING**

ASRS RESOURCES

Patient Assistance Programs



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USING E/M AND EYE VISIT CODES WHEN SURGICAL REIMBURSEMENT DECLINES



These strategies can help supplement your practice revenue.

BY MATTHEW BAUGH, MHA, COT, OCS, OCSR

At the start of 2026, CMS made policy changes on facility-based surgical reimbursement. Several months into the year, the effects of these changes have already become evident, as retina practices have observed declining surgical reimbursement.¹ Whether from relative value unit (RVU) adjustments, policy changes, or ongoing valuation pressure, revenue generated from retina surgeries is tighter than it was last year.

While surgical cases remain essential to patient care, their reimbursement is subject to payment constraints that are outside of a practice's control. Examination code selection, however, is not. Under the 2026 Medicare Physician Fee Schedule (MPFS), and a combined increase of the conversion factor and RVUs, office visit reimbursement has increased from 2025. This shift presents an opportunity: By appropriately selecting between evaluation and management (E/M; 992XX) and eye visit (920XX) codes based on documentation and payer policies, retina practices can compliantly and strategically help offset declines in surgical revenue.

2026 NATIONAL AVERAGE MPFS FOR OFFICE SETTING

The 2026 national average Medicare allowables (Table) show meaningful differences between E/M and eye visit codes that directly affect retina practices.² For example, for established patients, 99214 reimburses \$135.61 compared with \$127.26 for 92014. While an \$8 difference per visit

may seem modest, it can compound quickly in a high-volume, injection-based practice. The difference is even more significant for new patients: 99204 reimburses \$177.36, while 92004 reimburses only \$149.64—a nearly \$28 Medicare differential per encounter.

It's important to note that these figures reflect national average MPFS rates; actual reimbursement will vary by region. Medicare Advantage, commercial, and Medicaid payer fee schedules vary, and some plans may have frequency limitation for eye visit codes. However, by selecting the appropriate E/M or eye visit codes, retina

KEY TAKEAWAYS

- ▶ By appropriately selecting between evaluation and management (E/M; 992XX) and eye visit (920XX) codes, practices can help offset declines in surgical revenue.
- ▶ For established patients, 99214 reimburses \$135.61 compared with \$127.26 for 92014; while the difference per visit may seem modest, it compounds quickly in a high-volume, injection-based retina practice.
- ▶ When an E/M and an eye visit code are both supported, selection should be based on documentation, payer rules, and allowable—not habit.

SELECTING BETWEEN E/M AND EYE VISIT CODES IS NO LONGER JUST A DOCUMENTATION EXERCISE. FOR RETINA PRACTICES NAVIGATING SURGICAL REIMBURSEMENT DECLINE, IT IS A STRATEGIC DECISION THAT DIRECTLY AFFECTS FINANCIAL PERFORMANCE.

practices can appropriately maximize reimbursement. Multiplied across thousands of encounters, appropriate examination code selection becomes a critical strategy for stabilizing revenue, especially in a year when surgical reimbursement has already declined.

E/M VERSUS EYE VISIT CODES: UNDERSTANDING THE DIFFERENCE

E/M Codes (99202–99215)

E/M codes require a medically relevant history and examination as determined by the physician. Since 2021, E/M codes are selected based on either medical decision making (MDM) or total physician/qualified professional time. MDM is based on the following:³

- Number/complexity of problems addressed
- Data reviewed/analyzed
- Risk of complications/morbidity

Eye Visit Codes (92002–92014)

Eye visit codes require:

- History
- General medical observation
- Chief complaint
- Examination elements (ie, intermediate vs comprehensive)
- Initiation or continuation of diagnostic/treatment program

Eye visit codes are not leveled by complexity; rather, they are determined by examination requirements. Comprehensive eye visit codes (92004 for new patients, 92002 for established patients) require all 12 examination elements (ie, visual acuity, visual fields, motility, conjunctiva, adnexa, pupil/iris, cornea, anterior chamber, lens, IOP, optic nerve, and retina/vessels), while intermediate eye visit codes (92014 for a new patient, 92012 for established patients) require three or more examination elements.

RETINA-SPECIFIC CASE EXAMPLES FOR 2026

Case No. 1: Stable Dry AMD

An established patient with intermediate dry AMD in each eye presents for routine 5-month follow-up. Their OCT is stable, and they're compliant with AREDS2 vitamins

TABLE. 2026 NATIONAL AVERAGE MEDICARE ALLOWABLES		
Code	Allowable	Total Relative Value Unit
New Patient		
99202	\$75.15	2.25
99203	\$117.57	3.52
99204	\$177.36	5.31
99205	\$236.81	7.09
92002	\$84.84	2.54
92004	\$149.64	4.48
Established Patient		
99212	\$59.45	1.78
99213	\$95.19	2.85
99214	\$135.61	4.06
99215	\$192.39	5.76
92012	\$90.52	2.71
92014	\$127.26	3.81

and home Amsler monitoring. No changes are made to the treatment plan, and the patient will return in 6 months.

The documentation for this case shows:

- One stable chronic illness
- Minimal data
- No prescription drug management

This documentation supports a low MDM, consistent with 99213. However, the physician performed and documented a problem-focused examination (less than 12 examination elements), which also supports the intermediate eye visit code 92012.

Under 2026 Medicare averages, 99213 reimburses \$95.19 and 92012 reimburses \$90.52. Either code may be appropriate depending on documentation and payer policy. When both are supported, selection should be based on documentation, payer rules, and allowable—not habit.

Case No. 2: Stable Dry AMD With Coexisting Glaucoma

A commercially insured patient with bilateral dry AMD presents for a 6-month follow-up. A comprehensive examination (ie, all 12 examination elements, including dilation) is performed and documented. The assessment reveals



FURTHER READING

Certain scenarios favor or require evaluation and management coding. These include systemic disease management (eg, diabetes with ocular manifestations), payers that restrict eye visit codes to routine examination, frequency edits by commercial carriers, and when prolonged services are appropriate, which can only be used for time-based selection. Understanding payer restrictions is essential to prevent denials and protect revenue. For more information, check out this article:

WHEN TO USE AN EVALUATION AND MANAGEMENT OR EYE VISIT CODE



These strategies can help you determine which code to use.

By Joy Woodke,
COE, OCS, OCSR



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intermediate dry AMD in the right eye and dry AMD with geographic atrophy in the left eye, both stable. The patient is scheduled to return in 2 months for monitoring. The patient also has glaucoma and continues using drops prescribed by their referring physician.

The electronic health record (EHR) suggests 99214 based on “two stable chronic illnesses” and prescription drug management. However, two ICD-10 codes for AMD in the right and left eye do not necessarily represent two separate chronic illnesses—rather, it is one disease process affecting both eyes. Additionally, prescription drug management only counts if the retina specialist is managing the medication; in this case, the patient’s glaucoma drops are prescribed elsewhere.

Because two of the three MDM elements do not meet moderate complexity, 99214 is not supported, so the appropriate E/M level is 99213. The documented comprehensive examination also supports 92014.

Under 2026 Medicare averages, 99213 reimburses \$95.19 and 92014 reimburses \$127.26. The physician—not the EHR—is responsible for ensuring the documentation supports the selected code.

Case No. 3: Diabetes Follow-Up With Chemotherapy-Related Dry Eye

An established patient with diabetic retinopathy presents for follow-up and reports worsening dry eye

symptoms while undergoing chemotherapy. A comprehensive examination is performed, revealing stable mild nonproliferative diabetic retinopathy without diabetic macular edema. Severe dry eye is diagnosed, and cyclosporine ophthalmic emulsion 0.05% (Restasis, Abbvie) is prescribed. The visit was initially coded as 99215, citing severe exacerbation and high-risk drug therapy. The claim is denied. Why?

The reason is that although the patient is receiving chemotherapy, the ophthalmologist is not prescribing or monitoring that therapy, so it cannot be used to elevate risk. Prescribing drops for dry eye qualifies as prescription drug management—moderate risk, not high. To support 99215, two of the three MDM elements must meet high complexity, typically involving threat to life or bodily function requiring emergency surgery or hospitalization.

In this case, 99214 is appropriate. (The comprehensive examination would also support 92014, but E/M level 4 generally reimburses higher under Medicare.)

Common pitfalls include labeling disease as “severe” without meeting high-risk criteria, using future risk of blindness to justify high MDM, and overreliance on software rather than thorough documentation with oversight.

CODE CAREFULLY TO MAINTAIN STABLE REVENUE

Every encounter should prompt three questions:

1. What E/M level of MDM is supported?
2. Does the documentation meet eye visit code requirements?
3. What are the payer’s reimbursement rates and policy restrictions?

Selecting between E/M and eye visit codes is no longer just a documentation exercise. For retina practices navigating surgical reimbursement decline, it is a strategic decision that directly effects financial performance.

Decreased surgical reimbursement is real in 2026; however, office-based examination reimbursement—when coded accurately and compliantly—offers retina practices a meaningful opportunity to stabilize revenue despite these changes. ■

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PRIOR AUTHORIZATION BURDEN FOR ANTI-VEGF THERAPIES



The prior authorization process can be costly and time-consuming for patients and retina specialists.

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The concept of prior authorizations (PAs) originated in the 1960s, when insurers began requiring physicians to pre-certify medical necessity for hospitalizations.¹ In the 1980s, PAs became a management tool to limit the costs of advanced imaging and newer therapies.¹

The use of PAs has grown substantially since their inception, with almost 50 million PA requests submitted for Medicare Advantage insurers in 2023.²

PAs incur approximately \$35 billion annually in administrative costs.³ In a recent study comparing five Medicare Advantage plans with 30.5 million beneficiaries, 93% of Medicare Part B medication spending would have required PAs from at least one insurer; for ophthalmology, an estimated 26% of spending would have been for PAs.⁴ The current PA process for anti-VEGF therapies places unnecessary burdens on both patients and providers; while PAs increased by 30% in 2023, their use outpaced the potential 8% cost-saving opportunity.⁵

QUANTIFYING THE PRIOR AUTHORIZATION BURDEN ACROSS MEDICAL SPECIALTIES

Traditional Medicare (Parts A and B) plans do not require PAs for most procedures, including anti-VEGF injections. Medicare Advantage (Medicare Part C) and commercial insurance plans, however, frequently require prior authorizations.² (Medicare Advantage plans are subsidized by the government but are often managed by private insurers.)

In a 2024 survey of the American Medical Association, 93% of physicians reported that PAs delayed necessary care, 94% reported that PAs negatively affected patient outcomes, 82% reported that PAs could lead to abandonment of treatments, and 29% reported that PAs led to a serious adverse event.⁶ Approximately 88% reported that PAs resulted in higher overall use of health care resources, with 77% using ineffective initial treatments due to step therapy requirements, and 73% reporting that PAs increased office visits. About 80% of physicians were concerned that PAs may lead to higher patient out-of-pocket costs, and 58% thought they may adversely affect the workforce. Physicians and their staff spent approximately 13 hours per week processing an average of 39 PAs weekly.⁶ The majority of PA requests were performed manually, with 59% via phone calls and 45% via fax⁷; only 23% of physicians reported they were able to submit their PAs electronically.⁶

Even after the claims are submitted, some PAs may be denied. The Office of the Inspector General previously found that Medicare Advantage insurers had inappropriately denied 13% of PAs for medical services that should have been covered.⁴ There is also a rising concern that the use of AI may lead to increased denials.⁵

PRIOR AUTHORIZATIONS FOR ANTI-VEGF AGENTS

A PA request for an anti-VEGF injection takes approximately 100 minutes to process.⁸ Medical staff must

identify which insurers require PAs, what prerequisites are required for each specific insurer, and which clinical notes and documentation are necessary to receive approval.⁶ In studies of two different large electronic medical databases, approximately 96% to 98% of PA requests for anti-VEGF agents were ultimately approved,^{8,9} indicating that the majority of physicians were using the therapies for approved conditions. However, only 2% of PA requests were approved on the same day.⁹ There was a mean delay of 1.5 days for Medicare Advantage plans, 5 days for commercial carriers, and 4 days for Medicaid,⁹ which means that patients often must return on a different day for treatment. Of the few PAs that were denied, the reasons were unknown, but they may have included PA requests for off-label but clinically effective and evidence-based indications.

Costs to Society

While the physician's office and insurers are the most actively involved in the PA process compared with patients,³ each group, and society as a whole, can be adversely affected by the PA process due to delays and denial of care. In a theoretical model based on the average demographics of a patient receiving anti-VEGF therapy and using average employment rates and salaries, average number of patients with a caretaker/driver, and average life expectancy, each PA request increased the total societal costs by approximately \$640 (range: \$25 to \$4,100), amounting to an increased cost of approximately \$11,000 over a patient's lifetime (range: \$230 to \$90,000).⁹ These estimates included direct and indirect health care and non-health care sector costs, including patient and caretaker lost wages, patient out-of-pocket costs, transportation costs, staffing, the weighted proportion of additional imaging and clinical examinations for delayed return visits beyond 30 days, material costs associated with submitting and processing the PA requests, lost patient and caretaker productivity due to missing work, and lost patient productivity at work due to an undertreated visual impairment. A variety of clinical scenarios were evaluated, with variables ranging from least to most expensive in the probability sensitivity analyses.

It should be noted that these calculations of increased societal costs included only the submitted PA costs and not the PAs that were never submitted because the physician was deterred by the lengthy and costly PA process. They also did not include the baseline patient insurance premiums and deductibles. The direct savings from denying one PA for an anti-VEGF agent was only about \$27 per injection (range: \$3 to \$50).⁹ Because PAs do not confer any direct clinical benefit to patients, the cost-utility of PAs for anti-VEGF injections could not be calculated.

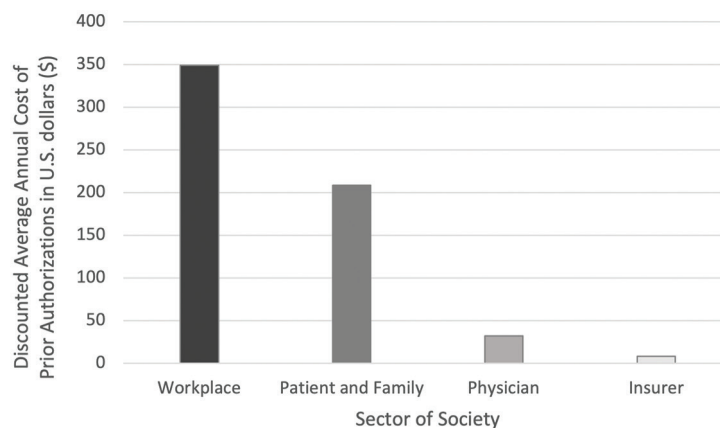


Figure. In the average case, PAs increased costs for the workplace, patients and their family, physicians, and insurers, with the workplace and the patients and family the most affected. The costs were discounted 3% annually to account for future costs being valued less than current costs.

The workplace was found to experience the greatest economic burden, followed by the patient and family, and the medical practice (Figure).⁹ If a solo or small practice physician does not have sufficient staff to help process a PA request or has to undergo a time-consuming peer-to-peer review to appeal a denial, the time and opportunity costs for the physician may exceed the reimbursements for the injection.

Effects on Insurers

Even the insurers had increased costs from PAs. Insurers had to pay an extra \$5 per year in the average case to process anti-VEGF PA claims,⁹ similar to the estimated \$2 to \$4 costs per PA in other medical specialties.¹⁰ However, insurers were the only sector of society that could potentially save money from anti-VEGF PA requests in the least expensive clinical scenarios, where the PA denial rates were high, the delays for approval were the longest, and the physician had manufacturer-supplied drug samples available to use. Medicare Advantage and commercial carriers can gain interest from undistributed funds from delayed and denied care.¹¹

Potential Solutions

While eliminating PAs would remove a barrier to patient care, some ways to help mitigate the PA burden in the future may include transitioning to electronic PAs, using AI programs, and training staff on the latest rules and regulations for each insurer. Starting January 1, 2026, CMS required that insurers implement electronic PA requests, and Medicare Advantage and Medicaid plans must respond to urgent requests for care within 3 days and routine requests within 7 days, but those requests excluded medications such as anti-VEGFs agents.¹²

Approximately 65% of insurers are considering the use of AI programs to expedite the PA process. While there is

HOW TO GET INVOLVED

Advocate for prior authorization reform through your federal representatives.

You can also contact the American Society of Retina Specialists at monica.horton@asrs.org if an insurer is imposing a new policy that restricts access to Medicare Part B drugs or other treatments.



physician concern about increased denials, AI may also help combat the administrative work of PAs.^{1,10}

ADVOCACY EFFORTS

Although most PAs for anti-VEGF therapies were ultimately approved by insurance companies, the majority were approved only after delays, increasing the costs for patients and society. It can take a total of 4 to 6 weeks from the initiation of the PA request until the physician receives reimbursement from the insurers.¹⁰ The current PA process increased the total costs of anti-VEGF therapies for patients, the workplace, the physician, and society without conferring a clinical benefit. PAs were not cost saving in the average case; the potential savings to the insurance companies did not offset the increased costs to the rest of society.

A proposed bipartisan bill, titled Improving Seniors Timely Access to Care Act (H.R. 3514), would not eliminate PAs, but it would expand beneficiary protections, implement a standardized electronic PA process, increase transparency, and require plans to report on their use of PAs. Insurers, lawmakers, and physicians should continue to work together to try to minimize the current burden of PA requirements and remove barriers to patient care. ■

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BRIEF SUMMARY OF PRESCRIBING INFORMATION
This Brief Summary does not include all the information needed to use XIPERE® safely and effectively. See full Prescribing Information for XIPERE®.

XIPERE® (triamcinolone acetonide injectable suspension), for suprachoroidal use
Initial U.S. Approval: 1957

INDICATIONS AND USAGE

XIPERE® (triamcinolone acetonide injectable suspension) 40 mg/mL is indicated for the treatment of macular edema associated with uveitis.

CONTRAINDICATIONS

4.1 Ocular or Periocular Infections XIPERE® is contraindicated in patients with active or suspected ocular or periocular infections including most viral diseases of the cornea and conjunctiva, including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases.

4.2 Hypersensitivity XIPERE® is contraindicated in patients with known hypersensitivity to triamcinolone acetonide or any other components of this product.

WARNINGS AND PRECAUTIONS

5.1 Potential Corticosteroid-Related Effects Use of corticosteroids may produce cataracts, increased intraocular pressure, and glaucoma. Use of corticosteroids may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses. Corticosteroids should be used cautiously in patients with a history of ocular herpes simplex. Corticosteroids should not be used in patients with active ocular herpes simplex.

5.2 Alterations in Endocrine Function Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and hyperglycemia can occur following administration of a corticosteroid. Monitor patients for these conditions with chronic use. Corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Drug induced secondary adrenocortical insufficiency may be minimized by gradual reduction of dosage. This type of relative insufficiency may persist for months after discontinuation of therapy; therefore, in any situation of stress occurring during that period, hormone therapy should be reinstituted. Metabolic clearance of corticosteroids is decreased in hypothyroid patients and increased in hyperthyroid patients. Changes in thyroid status of the patient may necessitate adjustment in dosage.

ADVERSE REACTIONS

6.1 Clinical Trials Experience Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. XIPERE® was studied in a multicenter, randomized, sham-controlled, double-masked study in patients with macular edema associated with uveitis. Table 1 summarizes data available from the clinical trial for XIPERE® treated patients and control patients. The most common ocular (study eye) adverse reactions occurring in ≥ 2% of patients and nonocular adverse reactions occurring in ≥ 5% of patients are shown in Table 1.

Adverse Reaction	XIPERE® (N = 96) n (%)	Control (N = 64) n (%)
Ocular		
Increased intraocular pressure, non-acute ^{a,b}	13 (14%)	9 (14%)
Eye pain, non-acute ^b	11 (12%)	0
Cataract ^c	7 (7%)	4 (6%)
Increased intraocular pressure, acute ^{a,d}	6 (6%)	0
Vitreous detachment	5 (5%)	1 (2%)
Injection site pain	4 (4%)	2 (3%)
Conjunctival haemorrhage	4 (4%)	2 (3%)
Visual acuity reduced	4 (4%)	1 (2%)
Dry eye	3 (3%)	1 (2%)
Eye pain, acute ^d	3 (3%)	0
Photophobia	3 (3%)	0
Vitreous floaters	3 (3%)	0

Uveitis	2 (2%)	7 (11%)
Conjunctival hyperaemia	2 (2%)	2 (3%)
Punctate keratitis	2 (2%)	1 (2%)
Conjunctival oedema	2 (2%)	0
Meibomianitis	2 (2%)	0
Anterior capsule contraction	2 (2%)	0
Chalazion	2 (2%)	0
Eye irritation	2 (2%)	0
Eye pruritus	2 (2%)	0
Eyelid ptosis	2 (2%)	0
Photopsia	2 (2%)	0
Vision blurred	2 (2%)	0
Non-ocular		
Headache	5 (5%)	2 (3%)

^aIncludes intraocular pressure increased and ocular hypertension ^bDefined as not occurring on the day of the injection procedure, or occurring on the day of the injection procedure and not resolving the same day ^cIncludes cataract, cataract cortical, and cataract subcapsular ^dDefined as occurring on the day of the injection procedure and resolving the same day

USE IN SPECIAL POPULATIONS

8.1 Pregnancy Risk Summary There are no adequate and well-controlled studies with XIPERE® in pregnant women to inform drug-associated risks. In animal reproductive studies from the published literature, topical ocular administration of corticosteroids has been shown to produce teratogenicity at clinically relevant doses. There is negligible systemic XIPERE® exposure following suprachoroidal injection [see Clinical Pharmacology (12.3)]. Corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. **Animal Data** Animal reproduction studies using XIPERE® have not been conducted. In animal reproductive studies from the published literature, topical ocular administration of corticosteroids to pregnant mice and rabbits during organogenesis has been shown to produce cleft palate, embryofetal death, herniated abdominal viscera, hypoplastic kidneys and craniofacial malformations.

8.2 Lactation Risk Summary It is not known whether ocular administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for XIPERE® and any potential adverse effects on the breastfed infant from XIPERE®. There are no data on the effects of XIPERE® on milk production.

8.4 Pediatric Use Safety and effectiveness of XIPERE® in pediatric patients have not been established.

8.5 Geriatric Use No overall differences in safety or effectiveness have been observed between elderly and younger patients following XIPERE® administration.

NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis No information is available on the carcinogenic potential of triamcinolone acetonide.

Mutagenesis No information is available on the mutagenic potential of triamcinolone acetonide.

Fertility No information is available on the effect of triamcinolone acetonide on fertility.

Manufactured for: Clearside Biomedical, Inc.
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XIPERE[®]
(triamcinolone acetonide
injectable suspension) 40 mg/mL

For treatment of uveitic macular edema

CONTAINED & SUSTAINED.

With proven durability supported by clinical trials
and real-world evidence,* **ONLY XIPERE[®]**
delivers treatment via the suprachoroidal space¹⁻⁴

In pivotal trial PEACHTREE, XIPERE[®]
SIGNIFICANTLY IMPROVED
BCVA BY ≥15 ETRS LETTERS
AND REDUCED CST at Week 24^{1,2,5}

In extension study MAGNOLIA
and in the IRIS[®] Registry*
ELEVATION IN IOP WAS LOW
OVER THE 48-WEEK PERIOD^{2,6}

~88% of XIPERE[®]-treated
patients in the IRIS[®] Registry had
NO NEED FOR RESCUE
BY WEEK 24^{2*}

PEACHTREE was a Phase 3 masked, randomized trial including 160 patients. MAGNOLIA was a multicenter, non-interventional extension study including 33 patients.

*The results of real-world studies should be considered in the context of the limitations of this type of evidence. While these findings provide insights into the real-world performance of XIPERE[®], they may not be directly comparable to results from randomized controlled trials.

BCVA=best-corrected visual acuity; CST=central subfield thickness; ETRS=Early Treatment Diabetic Retinopathy Study; IOP=intraocular pressure; IRIS=Intelligent Research in Sight.

Indication

XIPERE[®] (triamcinolone acetonide injectable suspension) for suprachoroidal use is a corticosteroid indicated for the treatment of macular edema associated with uveitis.

Important Safety Information

Patients should be monitored following injection for elevated intraocular pressure. See Dosage and Administration instructions in full Prescribing Information.

- XIPERE[®] is contraindicated in patients with **active or suspected ocular or periocular infections** including most viral diseases of the cornea and conjunctiva, including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases.
- XIPERE[®] is contraindicated in patients with known **hypersensitivity to triamcinolone acetonide** or any other components of this product.
- Use of corticosteroids may produce cataracts, increased intraocular pressure, and glaucoma. Use of corticosteroids may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses, and should be used cautiously in patients with a history of ocular herpes simplex.

- Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and hyperglycemia can occur following administration of a corticosteroid. Monitor patients for these conditions with chronic use.
- In controlled studies, the most common ocular adverse reactions were increased ocular pressure, non-acute (14%), eye pain, non-acute (12%), cataract (7%), increased intraocular pressure, acute (6%), vitreous detachment (5%), injection site pain (4%), conjunctival hemorrhage (4%), visual acuity reduced (4%), dry eye (3%), eye pain, acute (3%), photophobia (3%), and vitreous floaters (3%), and in 2% of patients: uveitis, conjunctival hyperaemia, punctate keratitis, conjunctival oedema, meibomianitis, anterior capsule contraction, chalazion, eye irritation, eye pruritus, eyelid ptosis, photopsia, and vision blurred.
The most common non-ocular adverse event was headache (5%).
- Corticosteroids should be used during pregnancy or nursing only if the potential benefit justifies the potential risk to the fetus or nursing infant.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see brief summary of Prescribing Information on adjacent page.

References: 1. XIPERE[®] [prescribing information]. Alpharetta, GA: Clearside Biomedical, Inc. 2. Singer M, et al. Presented at: 57th Annual Retina Society Scientific Meeting. September 11-15, 2024; Lisbon, Portugal. 3. Rai Udo J, et al. *Drug Discov Today*. 2015;20(4):491-495. 4. Chiang B, Jung JH, Prausnitz MR. *Adv Drug Deliv Rev*. 2018;126:58-66. 5. Yeh S, et al. *Ophthalmology*. 2020;127(7):948-955. 6. Khurana RN, Merrill P, Yeh S, et al. *Br J Ophthalmol*. 2022;106(8):1139-1144.

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