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ADDRESSING BARRIERS TO PATIENT CARE:

Market Access Challenges With Anti-VEGF Therapies

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CONTENT SOURCE

This continuing medical education (CME) activity captures content from a live meeting.

ACTIVITY DESCRIPTION

The use of anti-VEGF therapies for retinal diseases raises numerous issues in today's health care environment when the cost of treatment is often as much a consideration as the efficacy and safety. The following content showcases the challenges faced by physicians, practice administrators, and payors in the journey to providing quality care of patients with retinal disease.

TARGET AUDIENCE

This certified CME activity is designed for retina specialists and ophthalmologists involved in the management of retinal diseases.

LEARNING OBJECTIVES

Upon completion of this activity, the participant should be able to:

- **Identify** and **implement** algorithms, decision-making tools, and patient communication approaches that can be used to determine the most appropriate treatment for the patient.
- **Identify** opportunities to advocate against prior authorizations and step policies and appeal them.
- **Discuss** the potential impact of the Drug Quality and Security Act and opportunities to advocate for continued access to compounded ophthalmologic drugs.
- **Describe** the impact of the Medicare Access and CHIP Reauthorization Act (MACRA) on ophthalmology and its potential impact on the prescribing of anti-VEGF agents.

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1. Please rate your confidence in your ability to engage patients in shared decision making (based on a scale of 1 to 5, with 1 being not at all confident and 5 being extremely confident).

a. Not at all confident
b. Not very confident
c. Neutral
d. Confident
e. Very Confident

2. Please rate your confidence in your ability to proactively avoid claim denials or late reimbursement (Based on a scale of 1 to 5, with 1 being not at all confident and 5 being extremely confident.).

a. Not at all confident
b. Not very confident
c. Neutral
d. Confident
e. Very Confident

3. Please rate your confidence in your ability to discuss approved and off-label drugs with patients (Based on a scale of 1 to 5, with 1 being not at all confident and 5 being extremely confident.).

a. Not at all confident
b. Not very confident
c. Neutral
d. Confident
e. Very Confident

4. How often do you use shared decision-making tools with patients who require anti-VEGF treatment (based on a scale of 1 to 5, with 1 = "Never" and 5 = "Always")?

a. 1
b. 2
c. 3
d. 4
e. 5

5, How often MUST YOU abide by a fail-first policy when using FDA-approved anti-VEGF agents (based on a scale of 1 to 5, with 1 = "Never" and 5 = "Always")?

a. 1
b. 2
c. 3
d. 4
e. 5

6. Step therapy is a policy requiring selection of a specific drug for a disease state for a treatment trial period prior to authorizing a drug of the physician's choice. The goal of step therapy is to:

a. Enhance the patient-physician relationship by removing pharmaceutical decision making from the prescriber's control.
b. Provide optimal patient results, since step therapy has been rigorously tested with good results in randomized controlled trial in common retinal diseases such as neovascular age-related macular degeneration.
c. Reduce third-payer party costs, since step therapy often requires generic or off-label drug selection, usually of lower cost than other FDA-approved alternatives.
d. Improve patient satisfaction, since there is a less-involved informed-consent process since there is not a variety of options available to newly diagnosed patients with step-therapy mandated insurance coverage.

7. A 52-year-old diabetic patient has started intravitreal anti-VEGF therapy after presenting with 20/50 vision and moderate intraretinal fluid with an SD-OCT central sub-field thickness of 552 μm. The patient shows only minimal change in vision and intraretinal fluid after 3 monthly injections of anti-VEGF agent (A). The physician treating the patient would like to switch the patient to intravitreal anti-VEGF agent (B) at this fourth visit. The patient and the physician's practice manager both have ongoing concerns about how to pay for the cost of the patient's intravitreal medication. The best option for the physician at this fourth visit is:

a. Have the technician pull a stock FDA-approved medication that the physician and the patient have elected to try from the physician's purchased inventory. Treat the patient with this medication and submit a claim to the patient's commercial insurance.
b. Discuss with the patient the cost of the new medication, explaining that the patient may be responsible for the cost if there is not coverage. Enroll the patient in copay assistance if the patient would like to participate in that program. Schedule the patient 1 to 2 weeks later for an injection and have the office staff perform an investigation of benefits. Verify that the patients' insurance is active when the patient returns for the next injection.
c. Have the patient pay in full at the time of service for the FDA-approved medication that the patient and physician agree to try. Explain that the patient will have the payment refunded if her insurance reimburses the office for the FDA-approved medication.
d. Use a sample of the newly elected FDA-approved medication, enroll the patient in copay assistance, if the patient would like to participate in that program. Schedule the patient to return at the next appropriate interval for assessment of response to the new medication and consideration of another injection. Have the office staff perform an investigation of benefits in the meantime. Verify that the patients' insurance is active when the patient returns for the next visit, since stock medication should have coverage available at this point. Collect the patient's copay and coinsurance at the time of service at both visits.
e. Both (b) and (d)

PRETEST QUESTIONS

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8. A patient with neovascular age-related macular degeneration (AMD) diagnosed 18 months prior is undergoing treatment with an FDA-approved agent and is doing well. The patient is monocular and has tolerated extension out to 8 weeks between injection visits. The patient is anxious to extend any further and is on fixed-interval 8-week treatment with this agent in his only centrally sighted eye. The patient has a Medicare replacement plan, and the injectable medication and all professional charges have been paid to date. The prescriber receives a phone call from a medical director at the Medicare replacement plan. The medical director has a discussion with the prescriber about the availability of off-label bevacizumab (Avastin) for neovascular AMD. The prescriber knows this conversation means the she needs to convert the patient from the successful FDA-approved agent to bevacizumab.

a. True
b. False

9. An established patient with a Medicare Advantage plan is scheduled for AMD treatment, but the patient is not responding to the current medication, and the physician would like to inject with a different medication on this visit.
What is the best approach to ensure appropriate treatment for the patient as well as reimbursement for the new medication?
Check which of the following statements are CONSISTENT or NOT CONSISTENT with your current clinical practice.

Action	Consistent	Not Consistent
Treat with a sample medication and perform a benefits investigation for the new medication for future treatments		
Treat with currently approved medication and schedule for a medication change once a benefits investigation is complete		
Treat with the newly recommended medication from inventory, bill for it, and perform a benefits investigation before next treatment		
Treat with a sample of newly recommended medication and bill the drug as stock to see if the carrier will pay for services rendered		
Reschedule and perform a benefits investigation with the pharmaceutical company's practice support program for the new medication		
Ask staff to contact the insurance carrier immediately to confirm and document that the new medication is covered, and then proceed with treatment		
Request that the patient signs an Advance Beneficiary Notice for the new medication and, collect from the patient the full allowable rate on the medication after treatment		
Check the carrier's published clinical policy to confirm the medication is covered for that diagnosis and the patient's plan type does not require an authorization or referral for the change in medication		

Addressing Barriers to Patient Care:
Market Access Challenges With Anti-VEGF Therapies

The use of anti-VEGF therapies for retinal diseases raises numerous issues in today's health care environment when the cost of treatment is often as much a consideration as the efficacy and safety. Thus, payors have become more involved in managing the use of these agents, potentially interfering with clinical decision making.

The information shared here captures the most relevant content from an interactive discussion held earlier this year among retinal physicians, practice administrators, and payors. The discussion among thought leaders in the retina field centers around the challenges retina providers face in obtaining access to anti-VEGF medications for their patients and how they overcome those challenges.

—Nathan Steinle, MD, Moderator

ACCESS TO TREATMENT

Q | NATHAN STEINLE, MD: Anti-VEGF agents for the treatment of age-related macular degeneration (AMD), diabetic retinopathy (DR), retinal vein occlusion (RVO), and myopic neovascularization transformed the management of these conditions.[1-5] When we are considering using these injections, we have three available products to choose from: bevacizumab, ranibizumab, and aflibercept. There is also an expanding array of investigative products. Although the clinical benefits of anti-VEGF compounds are well documented,[1-5] there are other important considerations that impact retina practices, including cost.

Let's begin our discussion with a typical patient seen in my practice. This patient has wet AMD and has now failed two attempts at extension to 6 weeks from 4-week intervals on bevacizumab. The decision is made to switch to an FDA-approved agent.

Whether switching from one FDA-approved anti-VEGF agent to the other, or switching from bevacizumab to an approved agent, how do you handle this situation in your practice? If a patient has been treated off-label and then is switched to an on-label treatment, what steps do you take?

SEAN GOODALE, CPA, MBA: Typically we'll visit with the doctor and the patient and have a discussion. Unfortunately, it always begins with questions like, "Can we do this?" "Are we allowed to do this?" "What's the financial ramification of that?" Working through those details is part of the challenge of the practice.

DR. STEINLE: In our practice, we obviously start with a long discussion with the patient. We talk about assistance programs for financial support. We enroll the patient in the manufacturer's payor support programs. And we try to get a quick reply for that. I usually turn over some of this discussion to my most knowledgeable technician simply as a time-saving measure.

Have you found the payor support programs from the manufacturers to be helpful for your practice? Do you think they are crucial?

AUDIENCE MEMBER: Yes. About 99% of our patients sign up for the payor programs.

DR. STEINLE: I agree. We sign up nearly 100% of our patients. Has anyone had patients who weren't interested in signing up for these payor programs?

AUDIENCE MEMBER: No.

AUDIENCE MEMBER: We have had patients say they do not want to disclose financial information.

DR. STEINLE: That's a fair point. There are a small handful of patients who do not want to disclose personal or financial information. But the vast, vast majority of patients appreciate the programs.

On the first day you examine the patient and determine anti-VEGF treatment is needed, do you start with a sample anti-VEGF? Or do you go ahead and treat during that first visit with stock drug? Or do you have the patient return once the benefits investigation is complete?

MR. GOODALE: We don't typically have the patient come back, because I haven't had a clinician yet who thinks that's okay. Most physicians will treat with a sample or we'll try to get instant approval if we can. With many of the payors, we're fine to inject on the first day. It's really just a few that end up being a challenge for us.

DR. STEINLE: What about members of the audience, what do you typically do? Do you use a sample that first visit? Or do you have the patient come back? Or do you treat on-label and hope you receive payment?

AUDIENCE MEMBER: We use a sample on the first visit.

DR. STEINLE: Are there any cases where you treat that same day? Does anyone wait a week or 2?

AUDIENCE MEMBER: In our practice, we always treat the same day.

AUDIENCE MEMBER: I never treat the same day. I used to treat the same day, but I've been in practice for 11 or 12 years, and I'm finding that it really doesn't matter if I treat the same day. They can go another week or 2 and the macula doesn't disintegrate. They actually do okay.[3,4,6,7]

DR. STEINLE: How do you explain this to the patient?

AUDIENCE MEMBER: I explain to the patient that he or she has macular degeneration and there is an on-label drug I'd like to use. I explain that we need to have time to contact the insurance carrier, make sure they will pay for it, I tell he or see that I'll see them in a week and perform the injection at that time. Most patients are fine with that, because usually when you talk to them, it's been going on for a week or 2 or more, so there's nothing that can't wait a few days. Our clinic operates on a schedule that includes two days a week that are for injections only. If it's the end of the week when we have a situation like I described, the patient will back on Monday. At the beginning of the week, they come on Wednesday, so they delay isn't long. We've done some studies now with some of the newer drugs with which we have to wait to get the patients enrolled and we haven't had any problems. Watching those patients, they actually don't go downhill as quickly as you think they would.

DR. STEINLE: Do you base it on disease state? If it's AMD, are you more prone to treat quickly because you're worried about getting a subretinal bleed versus diabetic macular edema (DME) or RVO?

AUDIENCE MEMBER: No. I think most patients with retinal disease can wait at least a week.[3,4,6,7]

AUDIENCE MEMBER: I treat with a sample and then enroll the patient in the assistance program.

DR. STEINLE: Regarding the issue of whether patients can wait, when I first started in private practice, I always strived to treat the patient before they walked out the door on their first visit. Just for my own peace of mind more than the patient's peace of mind. Over time my perspective has shifted, because in my practice we are participating in about 25 clinical trials at any given time. If you look at most of our clinical trials, we almost always can wait 3 to 7 days until we receive the reading center results and for randomization to occur.[3,4,6,7]

Thus, if a patient presents with new wet AMD, DME, or RVO, and I am going to enroll that person in one of my practice's clinical trials, it takes a few days to obtain study images, and then the patient returns a few days later to receive treatment. Waiting several days before the first injection in clinical trials has taught me that the general population can also wait a few days before their first injection.[3,4,6,7]

A recent study[8] looked at these two approaches. Goldberg and colleagues looked at the HARBOR data,[9] specifically the patients who were treated very quickly in the HARBOR study versus those who had treatment delayed by several days. This study looked at the two extreme quartiles, those who were treated first, and those who were treated later within the treatment protocol. The study results indicate that in the end, basically both patient groups had the same outcome. So, to your point, most diseases can wait at least a few days for treatment. Thus, there's good data to support that you can actually defer treatment for a short period.[8]

Overall, the goal is to treat with the right agent, at the right interval, for the right patient at the right time. However, there are hurdles that get in our way, namely patient access issues and payor barriers. So, let's discuss first about initiating treatment. Injectable agents are expensive, and we obviously want to limit financial exposure for the practice itself. Thus, what steps do you take within the practice to ensure you receive payment when treating on-label for retinal disease?

AUDIENCE MEMBER: Verification.

AUDIENCE MEMBER: Once they agree to a patient assistance program, they have to be put into the actual program.

DR. STEINLE: How do you mark that in the chart, so the provider is aware the patient is covered?

AUDIENCE MEMBER: We include it on the charge ticket that is always pulled with each patient visit. The technicians know which insurance each patient has, and anytime a drug is given, we mark on the ticket that it's already approved.

DR. STEINLE: That is very similar to how we handle it in my practice. Does anyone verify insurance every time the patient comes into the office for a visit? Does the front desk staff verify it every time?

AUDIENCE MEMBER: Yes, we check each patient's insurance at each visit.

DR. STEINLE: We also strive to check each patient's insurance every single time they come in because you never know if something has changed. Patients often do not think to tell you that they got married or changed jobs, etc.

MR. GOODALE: We do the same thing. Every single time the front desk staff verifies insurance when the patient checks in for his or her appointment. You have to verify.

DR. STEINLE: Does insurance verification occur at the provider level in any practices represented in the audience? Or does they front desk staff handle it? I rely on my front desk.

AUDIENCE MEMBER: It's always done by the front desk staff.

DR. STEINLE: What about copays? Who collects copays and when do you collect it? Do you collect it when the patient checks in or as the patient is leaving?

MR. GOODALE: We typically collect it at the end of the visit.

AUDIENCE MEMBER: At the end.

AUDIENCE MEMBER: When the patient checks in.

DR. STEINLE: What if the patient doesn't have the copay money? What if a patient has $20, but not the entire $50 copay. What would you do?

AUDIENCE MEMBER: We take whatever the patient can offer us: $5, $10, $20, etc. If they don't have any payment to offer, we tell them that at the next visit they will owe for two copays and it must

be paid up front. In a situation like this, we never let a patient go more than two visits without payment before services are rendered.

DR. STEINLE: Does anyone use Care Credit or a similar health care financing option?

MR. GOODALE: We have it, but we don't utilize it very often.

DR. STEINLE: In our practice we probably underutilize these financing options, too. Does someone have any good tips to share?

AUDIENCE MEMBER: To me, Care Credit and similar financial programs are expensive. They charge a lot, so we decided not to use them. And we check eligibilities with the patient all the way through. There are programs that require a credit card swipe to check in for an appointment. This way, if there are any past fees owed, the patient pays outstanding fees when they arrive to the facility.

AUDIENCE MEMBER: We get patients' eligibilities first and then again before they come to the appointment.

DR. STEINLE: That's a good idea to educate them ahead of time. That way there are no surprises, and the front desk staff can avoid an interaction with an angry patient.

AUDIENCE MEMBER: In my experience, Care Credit goes out of its way to make it difficult for you to comply with the rules and regulations. First of all, they pay you 20% less. And then the patient ends up paying nearly three times what they would pay without Care Credit. So, we have made a decision not to deal with that company. I would rather use samples on a patient than to tell patients to use Care Credit. That's my personal opinion.

NAVIGATING THE INSURANCE MAZE

Q | **MR. GOODALE:** I grew up loving puzzles and I love mazes. Well, clinical and utilization management is like a complicated maze but it is not fun. This is what you've got to go through, and utilization management is kicking into high gear now.

It appears from the audience response that many of you have issues with prior authorization. How many of you have a dedicated person on staff to handle prior authorization? And how many get rejections on prior authorizations?

AUDIENCE MEMBER: Step edits have become a real burden in our region.

MR. GOODALE: Some of the issues we're seeing include step edits, prior authorizations, and drug formularies. Those barriers are just beginning to become prevalent in retina and will continue to become more prevalent.

Step edits are relatively new. Step therapy is a type of prior authorization for drugs that initiates medication for a medical condition with the most preferred drug therapy and progresses to other therapies only if necessary.[10] Carriers have widely used step therapy in the retina space to drive first-line use of bevacizumab.[11]

We know that barriers to payment are increasing for anti-VEGF reimbursement. Requests to send patient charts before we can be reimbursed are becoming common, along with other requests like preauthorizations. Policies are constantly fluctuating, practitioners don't always know when they will be released, and some are released in mid-year. That's why we suggest you check your patients' eligibility at every visit because it is not uncommon for a carrier to change a given policy in May, and you don't even know it's changed. Sometimes they don't really know their own policies and they'll try to initiate new programs, especially with step therapy.

The insurance provider will say they want one of our physicians to switch drugs. And we say that we can't do that. And we also have seen some other things, too. You should keep an eye on your reimbursement levels. Insurance providers have been known to change reimbursement in the mid-stream as well. We have seen issues, for example, with bevacizumab coming in at lesser than the cost, which is hard to believe. But it happens. And then you also see the other side where they try to incentivize you to use off-label drug, especially bevacizumab. And when they're doing that, you're not always getting paid at that level either. You think you are. They tell you will. But that doesn't always happen. You must keep looking at those types of things. They send out those letters that read, "So, here's your Medicare Advantage plan."

ASRS knows this is happening and they're working with us on that.[12] The ASRS has good resources on their website to help fight these types of battles. That way you do have to reinvent the wheel. Always look at the ASRS website as they have likely encountered your specific issue before.

DR. STEINLE: Who else has seen incentivizing letters like this, in which they're paying $250 for bevacizumab injection, for the cost of the drug? We have not in our practice area in California. I know that in New York carriers are doing it.

AUDIENCE MEMBER: I haven't physically seen a letter but for our practice, instead of the J-9035 they want you to use a C code and bill 5 units, which equals $300; this is significantly different than the J-9035 for that insurance company.

MR. GOODALE: And if you bill the wrong code, they deny it.

AUDIENCE MEMBER: So, just to be fair, let's remember that the CATT trial[13] tells us that ranibizumab and bevacizumab have the same efficacy and the same side effect profile. Incentivizing us to use bevacizumab, is bad. Incentivizing us to use ranibizumab, with a rebate program, is not bad. And we never talk about that. Thoughts on that?

DR. STEINLE: Thank you for your comments. I would respectfully disagree that these two drugs are the same molecule. The molecules are quite different (ranibizumab versus bevacizumab),[14,15] and the packaging and delivery method is different. We will soon discuss some different reasons why you might use one agent versus another.

AUDIENCE MEMBER: In the CATT trial, bevacizumab was handled much differently than it is in the real world.[16]

DR. STEINLE: That is a great point, as the bevacizumab used in CATT[13] had unique compounding requirements that were very stringent. Real-world bevacizumab is not compounded in the same manner typically. Thus, the bevacizumab that we receive in private practice is much different than what is used in national clinical trials.[16]

AUDIENCE MEMBER: I've seen so many patients for whom I've used bevacizumab, and then switched to ranibizumab or aflibercept and the branded drug works two to three times better. It's amazing how much better the branded drug is compared with nonbranded drug, in my opinion.

STEP THERAPY

MR. GOODALE: We have discussed just some of those barriers to drug access. And that's where we're seeing step therapy come into play, too, in all our practices.[10] It's a payment model and insurance providers are saying "you have to do 'this' before 'that,'" and it varies. It can be a preference from that formulary. It is not always cost driven, although most of us think it is. Some have other reasons for why they do it. Can there be savings? Possibly. Can it drive utilization of a preferred brand? That's another reason why it would exist. And the policies don't always make sense, but you've got to play by the rules. It's like Merit Based Incentive Payments System (MIPS) and Medicare Access and CHIP Reauthorization Act (MACRA).[17] You do it because you have to do it. We've seen step therapy come into play in recent years in retina, but it's much more prevalent in other specialty medicine areas.

October 2018, the beginning of Medicare Open Enrollment last year, was the deadline for notifying patients of plans to institute step therapy.[18] Several plans, but not all, have attempted to implement this change. No clear definition of "failure" exists, yet some commercial plans have tried defining with strict nonpatient-care focused definitions. Overall, defining "failure" is often ambiguous. Has anyone in the audience found that as well? Have you seen any insurance companies try to implement it mid-stream? It is wrong, but they're trying, and you have to educate them.

AUDIENCE MEMBER: Very much so.

WINSTON WONG, PHARMD: For those of you who said you have step therapy, are the insurance companies requiring you to go through bevacizumab first before going to a branded product? Or is it between the two branded products?

AUDIENCE MEMBER: Almost always the step edit requires bevacizumab use first-line treatment.

DR. STEINLE: And do they define how many injections you must to give before you can classify a given patient as a bevacizumab "failure?"

AUDIENCE MEMBER: No.

DR. STEINLE: We, too, have found that it's very ill-defined.

MR. GOODALE: It's all very ambiguous. And I've actually had instances in which it's not bevacizumab first; it might be a competing product but the insurance company has a preference product. And I don't think that's going away. I think it will increase, and you've got to be aware of it.

"If a payor is forcing you to treat your patient differently than you would treat your own family members, a moral dilemma exists."

—Nathan Steile, MD

DR. STEINLE: The reason why step therapy is an issue, especially given the increasing prevalence of this policy in southern California where I practice, is because it's a barrier between me and the patient. Suddenly you have this payor in between what I want to do for the patient, what the patient wants to do for themselves, and what we can actually do for the patient. And also, many times it leads to noncompliance because we're giving a medication that's not efficacious, and the patient is getting more injections. Sometimes patients will say that the situation just isn't working for them, so they fail to return for care at all. There are also ethical concerns with step therapy. If a payor is forcing you to treat your patient differently than you would treat your own family members, a moral dilemma exists.[19,20,21]

So, what is the medical community doing about it? Several states have passed or introduced legislation to protect consumers against such policies by setting a maximum duration for a step therapy protocol, ensuring consumers can appeal the decision; or prohibiting the use of step therapy for some conditions.

Some states have passed legislation that is trying to minimize step therapy.[22] For example, Texas passed a law trying to minimize or at least specifically defining "step therapy" so insurance companies can't just have this ambiguous step therapy plan out there without a well-defined plan as far as when you can move to another agent. But many states have no legislation considered during the last session. It's really complicated across the United States.

DR. STEINLE: To help retina specialists handle some of these challenging situations, the ASRS has some problematic payor policies (Figure 1).[11] If you want a good watchdog who's hopefully working for all of us, I think the ASRS has done a really great job. In our practice, we use their forms and letters considerably. The ASRS has good advocacy letters you can send to your local congressman, state congressman and at the national level. And ASRS has drafted several good letters to fight payors as well. One of the things the ASRS is fighting against is the "28-day rule" regarding injection frequency.

AUDIENCE MEMBER: We have had to appeal when injections are performed less than 28 days, whether due to patient travel schedules or due to insufficient responses with longer durations. And we got paid.

AUDIENCE MEMBER: We treated them with samples.

AUDIENCE MEMBER: We don't treat with samples. We have someone checking the next appointment and making sure that it's 28 days or more. If a patient ends up coming in a day early, we ask them to return in 1 to 2 days.

DR. STEINLE: Samples can be used to bridge gaps. What if, for example, a patient comes in early because they're going on a vacation to Europe for 2 months, and they want to get one last injection before they go away. What do you do?

AUDIENCE MEMBER: We ask the patient to take us to Europe with them! But then we use a sample if it has been less than 28 days since their last injection.

AUDIENCE MEMBER: Talking about sampling, we seem to get very few samples from our drug representatives. Several audience members have said they treat with samples but we don't have enough in our stocks to do that.

DR. STEINLE: What do you do when you're running low on samples?

AUDIENCE MEMBER: We call the pharmaceutical representative.

AUDIENCE MEMBER: Our representative doesn't provide enough samples either.

AUDIENCE MEMBER: You've got to phone your rep. Call them again if they are unresponsive.

MR. GOODALE: We use a sample if we have to in order to do what's best for the patient. You just have to work through it and do what you can.

ADMINISTRATOR'S PERSPECTIVE

Q | **DR. STEINLE:** Let us now shift to drug access from an administrator's perspective. To reduce the risk of denials or unexpected bills for the patient, our front desk and back office staff confirm that the insurance is active at each visit. Our staff connects patients with entities that provide financial assistance if necessary. We ask the vast majority of our injection patients to register with those entities as a precaution. For instance, it may appear that the patient is covered with Medicare and that they have a good secondary, but there are still issues with copays, whether it's through deductibles or other problems. Those assistance programs and funds can be very helpful.

So, let's examine a practice with 10 retina specialists. In a practice with 10 retina physicians, they are required to hire nine full-time billers, of whom three do nothing but interact with payors (acquiring authorizations, filing claims, following up on claims, etc.), and one employee is dedicated to nothing but verifications. What do you think is the biggest challenge each day from an administrator's perspective?

THE ASRS:

Opposes prior authorization for FDA-approved drugs covered by Medicare Part B
Opposes step therapy and urges payors to allow retina specialists and their patients to make clinically driven, patient-centered, judicious choices based on each patient's risk factors, clinical appearance, availability of compounded drugs, and financial needs
Opposes arbitrary treatment-interval policies, such as the "28-day rule"
Encourages payors to notify physicians when they develop new or modify existing policies designed to control costs and improve quality

Figure 1. The ASRS's stance on problematic payors.

AUDIENCE MEMBER: Acquiring authorizations.

AUDIENCE MEMBER: Insurance changes among patients. We deal with verification but sometimes patients think they are approved for Medicare but then find out in the small print that they actually have Medicare Advantage. And occasionally our staff will miss it.

DR. STEINLE: Mr. Goodale, how many patients in your practice know what insurance they have?

MR. GOODALE: Patients don't always know because they think they have Medicare, but it's Medicare Advantage and they're confused. That is a big challenge. It's also hard to tell what the issue of the day is going to be. Whether it's the inventory issue, or supply, or payment, it all has to do with attention to detail. Is your chart accurate? Did you bill it appropriately? All those things come into play. When you have a high injection volume, you're going to have these challenges that all have to do with detail and accuracy.

DR. STEINLE: There is a study by Prenner and colleagues that provides some clinical data of how much time our staff spend dealing with these issues that are all related to patients with AMD.[27] The study revealed about 25% of all staff time in a typical week is dedicated to getting authorizations, making sure the patients are covered, handling billing, and all the paperwork that comes with these tasks. It's an amazing amount of time for your clinic staff.

In Practice: Scenario #1

DR. STEINLE: Let's review some situations that many practices likely encounter and discuss how to handle them. For example, what do you tell the medical director at the insurance company who asks why you aren't using more bevacizumab?

For me, we have a clinic in Bakersfield, CA, and in that area there are numerous advertisements for malpractice lawyers. So it's not uncommon for a DME patient to arrive for an injection and mention a radio or television advertisement they heard or saw about bevacizumab. This is never a good situation, and the malpractice lawyers have really been going after the angle related to silicone oil droplets in compounded bevacizumab. A quick internet search for "bevacizumab + malpractice" will reveal 10 different lawsuits against

providers who are using bevacizumab, especially regarding endophthalmitis and silicone oil bubbles. These little silicone oil bubbles do collect in patients over time.[23,24] Especially if you have a young diabetic patient who is maybe age 42. In response to this, we wrote a paper featuring our case series in our practice.[25] Has anyone seen these silicone bubbles? What do you do about them? Do you think they're innocuous? Do you change sources of your bevacizumab at all? And from where do you get your branded bevacizumab?

AUDIENCE MEMBERS: We get our bevacizumab from Avella Specialty Pharmacy.

DR. STEINLE: Do you switch the syringes if you see silicone oil bubbles after injections? Did it make a difference if you switch syringes for your bevacizumab injections?

AUDIENCE MEMBER: We do try to switch syringes. There does not seem to be one universal go-to bevacizumab syringe/supplier.
AUDIENCE MEMBER: I've had several syringes in which It is a completely plugged needle with compounded bevacizumab. Then I have to stick the patient twice, which increases endophthalmitis rates.
AUDIENCE MEMBER: Have you heard of successful lawsuits regarding silicone oil bubbles with bevacizumab use?

MR. GOODALE: I've received requests from law offices, and they're starting to send medical records requests and requests for depositions, or at least conversations from attorneys. There are advertisements on television about it. The lawyers are trying to draw patients to that.

AUDIENCE MEMBER: But in order for the patient to win the lawsuit, they would have to show that the silicone oil bubbles are significantly impacting their life. And in somebody who has 20/400 vision, that's probably not a very reasonable claim.

MR. GOODALE: I agree with you completely. But I can tell you that we're still getting the requests and even after we send the records, the lawyers are still following through. Even though everything points to this as not an issue, somebody wants to make it an issue.

DR. STEINLE: Has anyone gone through a lawsuit for silicone oil bubbles? We've gotten a couple letter requests so far.

AUDIENCE MEMBER: We have gotten a few letters.
AUDIENCE MEMBER: Isn't it required that your patient must have seen a subsequent practitioner who has detected oil droplets in the vitreous?

DR. STEINLE: But if you look, they are there. I am guessing most chronic bevacizumab injection patients have silicone oil droplets in the vitreous.[23,24]

AUDIENCE MEMBER: That's why we all have a malpractice carrier.

DR. STEINLE: Has anyone performed a vitrectomy yet for silicone oil bubbles? I have not.

AUDIENCE MEMBER: I explain to the patient that the floaters are a common thing and it's not harmful.
AUDIENCE MEMBER: Ophthalmic Mutual Insurance Company (OMIC) actually has added a statement about the silicone oil to their consent form.[26] Patients only see it when they look down because when their head is upright the bubbles float superiorly. In my experience, patients mostly want to know that this is harmless. They want to make sure they don't have a retinal tear. And, again, everything is a matter of odds, right? So, we haven't had any issues in terms of patients being upset even, never mind asking for medical records. And I can tell you that I probably use more bevacizumab than anybody else, and it hasn't really been an issue.

DR. STEINLE: Who's your supplier for bevacizumab?

AUDIENCE MEMBER: We get it from Pine Pharmaceuticals. We used to use Avella Specialty Pharmacy, now we use Pine. The only problem was, and I don't know if it's still happening, but with Avella the syringes used to get stuck and we do not have the problem with the product from Pine. In terms of the silicone oil bubbles, both products were the same.
AUDIENCE MEMBER: Avella is cheaper.

DR. STEINLE: And to the question earlier about bevacizumab, the volume you purchase matters too. So, how many people buy the syringes with 0.1 mL of bevacizumab?

AUDIENCE MEMBER: We buy 0.1 mL.
AUDIENCE MEMBER: We buy 0.05 mL.

DR. STEINLE: Do you find air bubbles in either 0.1 or 0.05 mL compounded syringes? I find there are always air bubbles in all compounded syringes regardless of supplier or type of syringe. So, you really don't know what dose you're giving to patients. If you perform enough of these injections over time, it's really hard to know consistently what dose of bevacizumab you're giving to patients due to the volume loss secondary to air bubbles.

In Practice: Scenario #2

DR. STEINLE: Moving on to the next scenario we may encounter in our practices, let's say there is a 67-year-old teacher who is recently diagnosed with wet AMD. She is covered by Medicare Advantage. How do you handle her treatments?

MR. GOODALE: Typically that's going to be a conversation with the doctor. Our doctors are all educated on what Medicare Advantage plans allow for, unless it's an odd one. If it's a patient being seen for the first time, it always goes through billing first in our office. They authenticate what insurance will cover on benefits investigation. If we get a quick response, we will treat using stock drug. If not, we'll use a sample, if possible, or the doctor will treat anyway, and we try to get payment. That happens a lot. We have in-house billing and they're always engaged, and that's a little cumbersome, but it's just the way we do it. We have some plans that require prior authorization for bevacizumab and not FDA approved drugs.

AUDIENCE MEMBER: Rarely do we treat on the first visit. We perform a thorough benefits investigation and the patient returns on another day for treatment.

AUDIENCE MEMBER: I do both: injection clinics in which you have time to preauthorize treatment, and same-day injections. On the same-day injections, I don't inject in the exam room where the patient is examined. They are sent to an additional room where a technician prepares the patient for injection, which includes all of the insurance preauthorization process. At the end of my exam, the patient is not expecting treatment in 5 seconds. So, there is time allotted to move to a different room for the treatment, and allows a pause in the process. The office staff is there to help with these other important but time-consuming steps.

DR. STEINLE: That's a smart, professional tip. The movement of the patient allows your staff time to perform all the steps necessary for authorization, and yet your clinic continues to flow.

In Practice: Scenario #3

DR. STEINLE: We have a 67-year-old patient with DME. We start her on an FDA-approved agent, and her insurance benefits are investigated. Authorization is obtained, and the drug is pulled from stock and injected. Ninety days and three injections later, there's no reimbursement despite properly filed claims. It's time for the patient to return for the next injection. How do you handle this? The patient still has DME, and she still requires more injections.

AUDIENCE MEMBER: It wouldn't have gone that far in my practice. In my office, we would have realized sooner that the reimbursement hadn't been received.

DR. STEINLE: It sounds like you have an ideal system in place. Tell us how we can learn from your process.

AUDIENCE MEMBER: We have a full-time medication coordinator who prints the injection schedule and reviews at each appointment. First, she looks at billing and if a payment is still pending, they will use a sample, or she notifies the physician. We have another insurance person who could call. But it would not go that far into the process.

MR. GOODALE: We have a very similar process. We obviously run practice management reports, and we're looking at approvals before the patient visit. But we see it happen, and the patient will still be treated, but it tells us we have a bigger problem in our own billing process. Sometimes it's a practice problem and not an insurance problem. It's something we're not doing right.

DR. STEINLE: What do you do for that patient who's coming in for their next visit but not approved quite yet?

MR. GOODALE: We'll treat the patient because we know we'll fix it. If we know they're authorized and it's moving forward, we try to identify what the problem is, but we'll treat and bill.

"If you're not being paid in 30 days, you should go back to the insurance company to find out why."

—Winston Wong, PharmD

AUDIENCE MEMBER: If the billing coordinator sees a balance on the ticket, they alert me.

AUDIENCE MEMBER: I do my research to find out where it is in the insurance process, and if it looks like it's going forward, we treat. If not, we use bevacizumab.

DR. WONG: I believe everyone said earlier they usually call the insurance company to get their authorizations. And I'm assuming you're getting the authorization before you give the injection. Because, if the authorization is in the system, and the claim that is submitted is a clean claim, meaning everything is there, you should be paid in 30 days with every insurance company.

If you're not being paid in 30 days, you should go back to the insurance company to find out why. Referring to what Mr. Goodale said, it my experience, most of the time when there's delayed payment, it is because the claim is incomplete. And generally, from what I've seen, it's the fault of the practice management systems that have allowed the claim to fall through the cracks. The claim may be out to 90 or 120 days, simply because you just don't know it. You must tighten up your tracking system, but if you have that authorization, then you should be paid in 30 days.

DR. STEINLE: Dr. Chan is in the audience, so I'm going to ask his opinion. Because I have never personally gone through the exercise of obtaining an authorization myself, can you tell me, as a clinician, how much time it takes to pick up the phone and do it yourself?

DR. CHAN: I try to avoid getting authorization the same day. I treat with samples. But, to get authorization, I will call the carrier and they usually tell me to fill out a form. They fax me a form, I fill it out, and I fax it back. It usually takes about 3 to 5 days at most. But sometimes I'll get it back within 24 hours.

AUDIENCE MEMBER: Mr. Wong mentioned that practices should be getting paid within 30 days. Blue Cross is one of the insurance providers with which I have issues. No prior authorization is needed, but they've been doing prepayment reviews. I have to send the

record, then I have to wait so it ends up being 60 or 90 days. So, that would be a real-world scenario leading to 3 months of treatment in which you're not getting paid.

DR. WONG: Are they saying there's an official precertification process that's required?

AUDIENCE MEMBER: There's no preauthorization. We are given a list of diagnoses that are treatable with this drug, say aflibercept, so we treat based off of that.

MR. GOODALE: They're possibly doing a record review to stall the payment.

DR. WONG: If that's a Blue Cross plan in Louisiana, they just started doing that within the past 6 months.

CHANGING TIMES

MR. GOODALE: Value-based reimbursement is coming, but it's a challenge. I remember 4 or 5 years ago when we first heard about MIPS and MACRA.[17] The physicians in our practice came back from the American Academy of Ophthalmology Annual Meeting saying, "Sean, we have to get on this! We've can have a 25% increase in payment if we do everything right." They talked about how we were going to get a 25% increase and we were going to be the ones who do it right. And I told them that was never going to happen! That's not the way it works.

I can see from a show of hands in the audience that no one got a 25% bonus this year. Some of you may have gotten something, maybe 3%, but nowhere near that 25%. That's because this is budget neutral and this was created to eliminate the sustainable growth rate formula.[28] If you remember, that's what we would get all excited about every year. Medicare made the announcement that it would cut our reimbursement 25% and we would all panic. Then Medicare would come back and say they would only cut it 5% and suddenly we were all thrilled that our reimbursement was cut by 5%. It was this game we played for a number of years with the sustainable growth rate.[17,28,29,30,31]

That's gone and we now have MIPS/MACRA. We have a bunch of hoops to jump through to get our so-called bonus payment. Which, if you do everything right, last year was about 2.08%, right?

There's a lot of work that goes into that, too. And I think if you do the math, you might not be really excited about how much you spent to put those programs into play versus what you got back.[31] So, how are you guys dealing with this? Who does MIPS/MACRA in your practice? Do you have a dedicated individual? Or is it all automated? How do you deal with it?

AUDIENCE MEMBER: Our practice is in Ohio. My director and I work hand-in-hand with one another getting through things. We have the IRIS registry, too, which is a huge benefit to our practice.

MR. GOODALE: Is everybody on the IRIS registry? Anybody do anything different? I have heard stories about a lot of people doing a lot of different things. Some are filing a hardship exemption, and some are filing their MIPS/MACRA reports. They're using IRIS registry. They're doing everything they can. Because we just don't know how this thing really works. But yet, it's how we're judged.

Have you seen another impact on this as far as the way you're practicing medicine? Is anyone doing anything different in your practice because of MIPS/MACRA?

AUDIENCE MEMBER: There is more documentation.

MR. GOODALE: And that can be challenging, I know. It creates a challenging communication with your patients. You're talking about influenza shots and things of that nature. And they want to know if you can give them one. I see that no one in the audience administers influenza shots in their practice, yet we wrestle with that because it comes up in the conversation as soon as you ask about it.

There are a few retina-specific quality measures associated with MIPS/MACRA, including adult primary rhegmatogenous retinal detachment surgery: no return to the operating room within 90 days of surgery, and visual acuity improvement within 90 days of surgery.[32] These are just a couple, and we know they don't always make sense. And it seems that if we do really well on them, then Medicare eliminates them. That's what we saw this year. The problem is that in this specialty there is a finite number of quality measures we can use. And these things keep changing. You need to be aware of what's changed, and don't do what you did last year. If you do what you did last year, you're probably missing something.

AAO and ASCRS have some good resources, and ASRS also has resources available to stay updated on the annual changes.[33,34] Make sure you're doing the quality measures that count, because as this goes forward, we will continue to be evaluated based on these quality measures. We don't have to like it, but this is how insurers are going to measure you.

NAVIGATING THE PAYOR MAZE

DR. WONG: My role in this discussion is to present the payor perspective. I have spent 17 years working in large, regional insurance companies, the Blue Cross Blue Shield companies. I know the "Blues" well, and I know Louisiana pretty well. I'm the guy who everybody hates. I started out managing the pharmacy benefits and because my supervisor thought I did a good job controlling costs there, he pulled me over to the medical benefits. So, I'm the guy who actually set utilization review programs for medications across the entire plan.

My goal is not to defend what insurers do; I only want to provide you with our perspective. As an industry, payors are right there with you as stakeholders. We're trying to aim for the Triple Aim (Figure 2).[35] We're trying to improve outcomes, and we're trying to improve the patient experience. Many, many years ago it was to lower our costs. Now we just want to control our costs. But as we're going to find, as more stakeholders come to the table, when we take a look at the outcomes versus the patient experience versus cost, each one of us stakeholders have different weightings in terms of how the Triple Aim Framework should actually work.

As a payor, our goal is to balance clinical outcomes and the cost of care. In other words, we have a bucket of money that we have, which is limited, to pay for all those, pay for you providing all the services and your professional knowledge. When we take a look at what we have

to do, we have a lot of limitations from our side. One of these limitations is that we don't absolutely understand all the time the metrics that you use to determine your outcomes. The biggest challenge for us is when we're looking at clinical trials. We don't always realize how different the criteria are for measurements and metrics in the clinical trial versus the real-world practice setting. In other words, we're good readers, we're good analyzers, but we're bad practice people. We have no idea what the real-world experience is. What you're going to find is that we are getting more and more into real-world evidence. It's my feeling that as we start talking, the real-world evidence is what you're going to start needing to present to payors, because that will be key in terms of what's going to be put together and incorporated into your reimbursements and prior authorization criteria.

The new buzzword that we're hearing today is *value*. So, what is value? You've got the three stakeholders: patients, payors, and providers. Each one of those stakeholders views value from a different perspective. So, as we start talking as an industry about value-based payments (MACRA/MIPS), the framework may not actually fit into one of these three perspectives. So, as we have those dialogues with our patients, it's going to be much more difficult to truly drive that patient discussion into the value discussion. As the payor, I've got to show the dollar side, ie, why are we here, and why are we talking about this? In 2017, an estimated $338 billion spent just on medications, which is a $10 billion increase over 2016. Express Scripts said that specialty medications account for 40% of those. Of that $338 billion, if we include drugs from the medical side, which includes all the injectable oncology agents, to a very, very small degree the intravitreal injections that retina specialists use, that number goes up to 43%. And if we start taking a look at where we are on the trends, in terms of medication trends, specialty medications are still in double digit. These numbers were going in before the checkpoint inhibitors came in for oncology, before the chimeric antigen receptor (CAR) T-cell therapy, and now before the gene fusion therapies. So, the specialty trend is going to be continually increasing during the next 10 years or so, to where we are probably going to have at least 50 to 60% of our costs for medications coming out of the specialty realm (Figure 3).[36]

Retina treatments represent a very small part of that specialty cost, but as a payor, every penny counts. From a payor perspective, the cost of the medication is going to be driven by three things. First, you have the cost of the medication, which may or may not include a rebate, the bad word of the day. Second, the benefit design that's going to drive the patient liability, the copay or the coinsurance. Lastly, the utilization management. The cost of the medication and discounts are a set number. The benefits are a set number. The only real variable, and the only real chance that a payor has to blunt the cost of anything in terms of benefits, is going to be a robust utilization management.

The traditional management approach, from the prescription benefit stand-point, includes prior authorization, step therapy, quantity limits, distribution channel management, basically taking administrations out of the institutional setting and putting them back into the office. From the medical benefit, the traditional management approach includes medical policy, medical precertification (the medical version of the prior authorization), case management, and site-of-care management. This is the simplistic way of looking at things, but

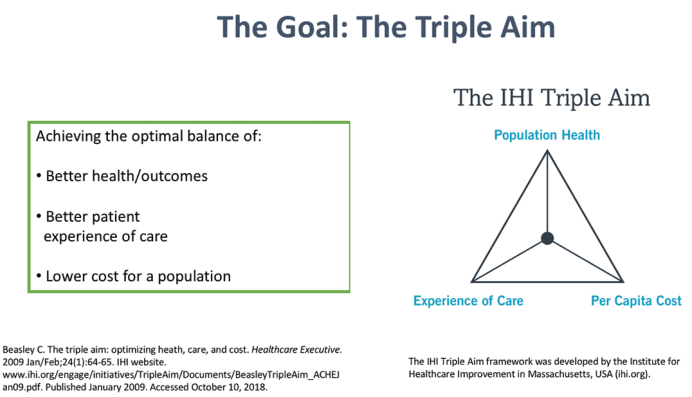


Figure 2. The Institute for Healthcare Improvement Triple Aim Framework, originally developed in 2009.

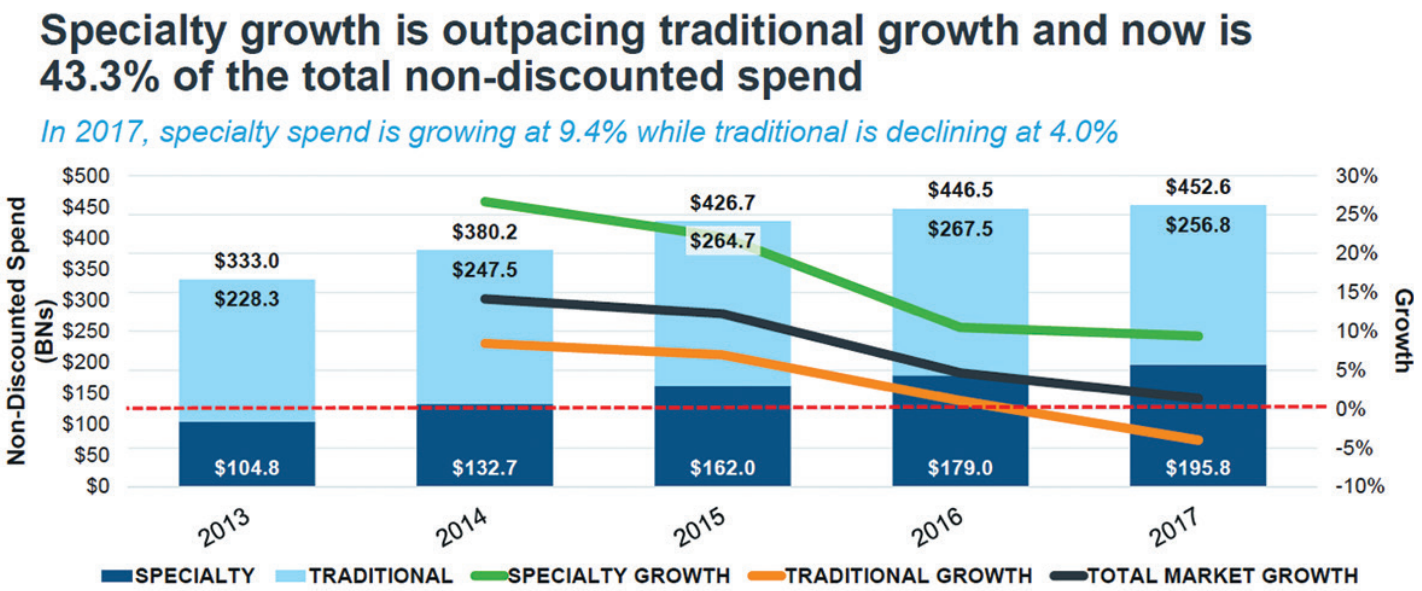
things have become confusing during the past 10 years because there are more and more plans that have a carve-out pharmacy benefit manager separate from the medical management within the plan, and they're now starting to integrate.

Earlier we discussed a scenario in which an insurance company asks why your practice isn't using more bevacizumab. The letter specifically was sent to a pharmacy benefit manager at Magellan, which is an independent third party that is not even interfacing with you as a specialty at all, even though they are driving your policies. That's where the issue comes down to dollars and cents. In terms of what we look at for diabetic macular edema, we are reading a study comparing aflibercept, ranibizumab, and bevacizumab. And the overall conclusion was, at least for the mild cases, is that the three drugs are basically all the same. For the more severe cases, aflibercept possibly was more effective. But they also concluded with a statement that there really was no clinical difference between the three agents.[37]

A payor is going to grasp upon that statement that there really was no clinical difference between the three agents. Again, we're book people. We read studies; we are analytical; we don't know the real-world experience.

Taking a look at AMD, we have the comparison of bevacizumab versus ranibizumab, and then we have aflibercept versus ranibizumab, basically saying they are all very similar.[13,38,39,40] We realize these are scheduled injections (which are often monthly) and not the dose-extended regimens that retina providers are doing now. However, from a payor perspective, we are going to take the worst-case scenario, taking the cost of the drugs, assuming that will be around 12 doses a year for bevacizumab, as well as for ranibizumab, seven or eight doses a year for aflibercept, and then comparing those costs. Which leads me to the comparative cost analysis (Figure 4). We compare aflibercept, ranibizumab, and bevacizumab, the regimens that are approved and indicated for certain uses by the FDA for DME and AMD, the cost, and the J-codes.[41]

For bevacizumab, I took the J-9035 and divided the cost into 10-mg increment. If you bill the J-9035 and you just bill for the entire 10 mg, you get paid for it, but most people do not know that.[41] A lot of plans will take the 10-mg increment, aliquot it down to 1.25 mg, and it comes down to a $10 cost per dose, this translates to a $121 reimbursement for the year. If you're billing the $81.18 and you're getting paid for it, that's a lot more money. I would keep that to



Share of Sales	2013	2014	2015	2016	2017
SPECIALTY	31.5%	34.9%	38.0%	40.1%	43.3%
TRADITIONAL	68.5%	65.1%	62.0%	59.9%	56.7%

Source: IQVIA, National Sales Perspectives, April 2018

Figure 3. Specialty versus nonspecialty medication trends.

yourself. If you're in an institution that bills on an out-patient clinic associated with the hospital, using the C-code billing you aliquot that up to 1.25 and it comes exactly to the $10.50 for each dose. If you're an independent office not going through a system, I would bill the J-9035. Hopefully you'll get paid that $81.18. I'm not sure you're going to find a plan that's going to be that specific, but there are aggressive plans that may do it.

I have a few key points in terms of navigating the payor landscape. First of all, these authorization programs are not going away, although there are ways to work around them. Being proactive is necessary but you've got to know exactly and specifically what the insurance carrier wants in terms of that prior authorization/precertification process. And if the insurance company gives any push-back on a clean claim, ie, all required paperwork, etc., do not be afraid to speak directly to the provider representative and explain that you're not getting paid. If they're asking for more information, you've got to go back to the medical policy and determine if it's required. And if it's not, then you need to point that out. It's important to know the payor policies and the precertification requirements, as well as whatever is required for step therapy. If you have a plan that's requiring bevacizumab to be used first, so be it. Then ask the questions about failure: How long does it? And how many doses need to be given?

Once you have all the necessary documentation, be sure the claim is being submitted completely. If you have a clean claim that goes into the insurance payor, they must pay you within 30 days. Also, when you submit for a prior authorization, the insurance company is required to respond in 72 hours as well. If you want a 24-hour turn-around time, you're probably not going to get it. They are going to be held to that 72-hour time-frame, because that's what the National Committee for Quality Assurance and Medicare both require. The take-home points are that you must submit a clean claim and you must be proactive. Then you should receive payment within 30 days. If you follow this simple process, the delays you may have had in the past will not continue.

DR. STEINLE: Those are good tips. We don't often get the opportunity to hear the payor's prospective. Thank you very much.

AUDIENCE MEMBER: Anyone having issues with insurance carriers limiting aflibercept to every 8 weeks (q8)? I have a monocular patient I just had a payor review with, and they interpreted the DME/AMD studies in the same manner that you described earlier. And once I educated them on the difference between study data and real-life practice, they approved it. But I'm concerned that could be an issue down the road for future patients.

DR. STEINLE: The original aflibercept label instructed to give the three monthly loading doses and then to go to q8 dosing for wet AMD. Well, some payors held strong to that label and only paid for aflibercept every 8 weeks. Regeneron now has had a label clarification that says that you can extend up to 8 weeks in between treatments, but that some patients require more frequent than 8-week dosing. This label clarification was pushed through to hopefully allow flexibility in treatment regimens for a given patient, because aflibercept is not

Generic Name	Aflibecept	Ranibizumab	Bevacizumab
Dose	2 mg	0.3 mg	1.25 mg
DMD Initial Regimen (1st yr # doses)	q28d x 5 months then every other month (8)	q month (12)	q month
AMD Initial Regimen (1st yr # doses)	q28d x 3 months then every other month (7)	q month (12)	q month
HCPCS J Code	J 0178	J 2778	J 9035
J Code Increment Description	Injection, aflibecept, 1 mg	Injection, ranibizumab, 0.1 mg	Injection, bevacizumab, 10 mg (12)
ASP + 4.3%/Increment	$963.54	$368.98	$81.18
ASP + 4.3%/dose	$1927.07	$1,091.94	$10.15
ASP + 4.3% Annual Cost DMD	$15,416.59	$13,103.24	$121.77
ASP + 4.3% Annual Cost AMD	$13,489.52	$13,103.24	$121.77

Figure 4. Comparative costs for anti-VEGF products.

always a q8 drug. It depends on the patient.[42] I know it was a big battle in Houston, Texas.

Has anyone had the insurance company medical directors call them and kind of nudge providers toward using an off-label agent? We have had this happen twice recently in our practice.

MR. GOODALE: We have had this happen in our practice. The insurance company representatives came to the office and asked us if we had heard about this drug. It was just an interesting conversation. It was what I like to call a softball toss. They wanted to see how we'd react, and we told them we would evaluate that. It really wasn't anything they were going to impact.

DR. STEINLE: This was a great discussion. Thank you to everyone for your participation. ■

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ADDRESSING BARRIERS TO PATIENT CARE:
Market Access Challenges With Anti-VEGF Therapies

Release Date: October 2019
Expiration Date: October 2020

INSTRUCTIONS FOR CREDIT

To receive credit, you must complete the attached Pretest/Posttest/Activity Evaluation/Satisfaction Measures Form and mail or fax to Evolve Medical Education LLC; 353 West Lancaster Avenue, Second Floor, Wayne, PA 19087; Fax: (215) 933-3950. To answer these questions online and receive real-time results, please visit http://evolvemeded.com/online-courses/1915-supplement/. If you are experiencing problems with the online test, please email us at info@evolvemeded.com. Certificates are issued electronically; please be certain to provide your email address below.

Please type or print clearly, or we will be unable to issue your certificate.

Name _____ ❑ MD/DO participant ❑ OD ❑ non-MD participant

Phone (required) _____ ❑ Email (required) _____

Address _____

City _____ State _____ Zip _____

License Number _____

OE Tracker Number _____

DEMOGRAPHIC INFORMATION

Profession
___ MD/DO
___ OD
___ NP
___ Nurse/APN
___ PA
___ Other

Years in Practice
___ > 20
___ 11-20
___ 6-10
___ 1-5
___ <1

Patients Seen Per Week (with the disease targeted in this educational activity)
___ 0
___ 1-15
___ 16-30
___ 31-50
___ 50+

Region
___ Northeast
___ Northwest
___ Midwest
___ Southeast
___ Southwest

Setting
___ Solo Practice
___ Community Hospital
___ Government or VA
___ Group Practice
___ Other
___ I do not actively practice

Models of Care
___ Fee for Service
___ ACO
___ Patient-Centered Medical Home
___ Capitation
___ Bundled Payments
___ Other

LEARNING OBJECTIVES

DID THE PROGRAM MEET THE FOLLOWING EDUCATIONAL OBJECTIVES?	AGREE	NEUTRAL	DISAGREE
Identify and implement algorithms, decision-making tools, and patient communication approaches that can be used to determine the most appropriate treatment for the patient.	_____	_____	_____
Identify opportunities to advocate against prior authorizations and step policies and appeal them.	_____	_____	_____
Discuss the potential impact of the Drug Quality and Security Act and opportunities to advocate for continued access to compounded ophthalmologic drugs.	_____	_____	_____
Describe the impact of the Medicare Access and CHIP Reauthorization Act (MACRA) on ophthalmology and its potential impact on the prescribing of anti-VEGF agents.	_____	_____	_____

POSTTEST QUESTIONS

Please complete at the conclusion of the program.

1. Based this activity, please rate your confidence in your ability to engage patients in shared decision making (based on a scale of 1 to 5, with 1 being not at all confident and 5 being extremely confident).

a. Not at all confident
b. Not very confident
c. Neutral
d. Confident
e. Very Confident

2. Based on this activity, please rate your confidence in your ability to proactively avoid claim denials or late reimbursement (based on a scale of 1 to 5, with 1 being not at all confident and 5 being extremely confident).

a. Not at all confident
b. Not very confident
c. Neutral
d. Confident
e. Very Confident

3. Based on this activity, please rate your confidence in your ability to discuss approved and off-label drugs with patients (Based on a scale of 1 to 5, with 1 being not at all confident and 5 being extremely confident.).

a. Not at all confident
b. Not very confident
c. Neutral
d. Confident
e. Very Confident

4. Based on this activity, how often do you plan to use shared decision-making tools with patients who require anti-VEGF treatment (based on a scale of 1 to 5, with 1 = "Never" and 5 = "Always")?

a. 1
b. 2
c. 3
d. 4
e. 5

5, How often MUST you abide by a fail-first policy when using FDA-approved anti-VEGF agents (based on a scale of 1 to 5, with 1 = "Never" and 5 = "Always")?

a. 1
b. 2
c. 3
d. 4
e. 5

6. Step therapy is a policy requiring selection of a specific drug for a disease state for a treatment trial period prior to authorizing a drug of the physician's choice. The goal of step therapy is to:

a. Enhance the patient-physician relationship by removing pharmaceutical decision making from the prescriber's control.
b. Provide optimal patient results, since step therapy has been rigorously tested with good results in randomized controlled trial in common retinal diseases such as neovascular age-related macular degeneration.
c. Reduce third-payer party costs, since step therapy often requires generic or off-label drug selection, usually of lower cost than other FDA-approved alternatives.
d. Improve patient satisfaction, since there is a less-involved informed-consent process since there is not a variety of options available to newly diagnosed patients with step-therapy mandated insurance coverage.

7. A 52-year-old diabetic patient has started intravitreal anti-VEGF therapy after presenting with 20/50 vision and moderate intraretinal fluid with an SD-OCT central sub-field thickness of 552 μm. The patient shows only minimal change in vision and intraretinal fluid after 3 monthly injections of anti-VEGF agent (A). The physician treating the patient would like to switch the patient to intravitreal anti-VEGF agent (B) at this fourth visit. The patient and the physician's practice manager both have ongoing concerns about how to pay for the cost of the patient's intravitreal medication. The best option for the physician at this fourth visit is:

a. Have the technician pull a stock FDA-approved medication that the physician and the patient have elected to try from the physician's purchased inventory. Treat the patient with this medication and submit a claim to the patient's commercial insurance.
b. Discuss with the patient the cost of the new medication, explaining that the patient may be responsible for the cost if there is not coverage. Enroll the patient in copay assistance if the patient would like to participate in that program. Schedule the patient 1 to 2 weeks later for an injection and have the office staff perform an investigation of benefits. Verify that the patients' insurance is active when the patient returns for the next injection.
c. Have the patient pay in full at the time of service for the FDA-approved medication that the patient and physician agree to try. Explain that the patient will have the payment refunded if her insurance reimburses the office for the FDA-approved medication.
d. Use a sample of the newly elected FDA-approved medication, enroll the patient in copay assistance if the patient would like to participate in that program. Schedule the patient to return at the next appropriate interval for assessment of response to the new medication and consideration of another injection. Have the office staff perform an investigation of benefits in the meantime. Verify that the patients' insurance is active when the patient returns for the next visit, since stock medication should have coverage available at this point. Collect the patient's copay and coinsurance at the time of service at both visits.
e. Both (b) and (d)

POSTTEST QUESTIONS

Please complete at the conclusion of the program.

8. A patient with neovascular age-related macular degeneration (AMD) diagnosed 18 months prior is undergoing treatment with an FDA-approved agent and is doing well. The patient is monocular and has tolerated extension out to 8 weeks between injection visits. The patient is anxious to extend any further and is on fixed-interval 8-week treatment with this agent in his only centrally sighted eye. The patient has a Medicare replacement plan, and the injectable medication and all professional charges have been paid to date. The prescriber receives a phone call from a medical director at the Medicare replacement plan. The medical director has a discussion with the prescriber about the availability of off-label bevacizumab (Avastin) for neovascular AMD. The prescriber knows this conversation means the she needs to convert the patient from the successful FDA-approved agent to bevacizumab.

a. True
b. False

9. An established patient with a Medicare Advantage plan is scheduled for AMD treatment, but the patient is not responding to the current medication, and the physician would like to inject with a different medication on this visit. What is the best approach to ensure appropriate treatment for the patient as well as reimbursement for the new medication? Check which of the following statements are CONSISTENT or NOT CONSISTENT with your current clinical practice.

Action	Consistent	Not Consistent
Treat with a sample medication and perform a benefits investigation for the new medication for future treatments		
Treat with currently approved medication and schedule for a medication change once a benefits investigation is complete		
Treat with the newly recommended medication from inventory, bill for it, and perform a benefits investigation before next treatment		
Treat with a sample of newly recommended medication and bill the drug as stock to see if the carrier will pay for services rendered		
Reschedule and perform a benefits investigation with the pharmaceutical company's practice support program for the new medication		
Ask staff to contact the insurance carrier immediately to confirm and document that the new medication is covered, and then proceed with treatment		
Request that the patient signs an Advance Beneficiary Notice for the new medication and, collect from the patient the full allowable rate on the medication after treatment		
Check the carrier's published clinical policy to confirm the medication is covered for that diagnosis and the patient's plan type does not require an authorization or referral for the change in medication		

ACTIVITY EVALUATION

Your responses to the questions below will help us evaluate this CME activity. They will provide us with evidence that improvements were made in patient care as a result of this activity.

Rate your knowledge/skill level prior to participating in this course: 5 = High, 1 = Low _____

Rate your knowledge/skill level after participating in this course: 5 = High, 1 = Low _____

This activity improved my competence in managing patients with this disease/condition/symptom. _____ Yes _____ No

I plan to make changes to my practice based on this activity. _____ Yes _____ No

Please identify any barriers to change (check all that apply):

_____ Cost
_____ Lack of consensus or professional guidelines
_____ Lack of administrative support
_____ Lack of experience
_____ Lack of time to assess/counsel patients
_____ Lack of opportunity (patients)
_____ Reimbursement/insurance issues
_____ Lack of resources (equipment)
_____ Patient compliance issues
_____ No barriers
Other. Please specify: _____
_____
_____
_____

The design of the program was effective for the content conveyed. ___ Yes ___ No

The content supported the identified learning objectives. ___ Yes ___ No

The content was free of commercial bias. ___ Yes ___ No

The content was relative to your practice. ___ Yes ___ No

The faculty was effective. ___ Yes ___ No

You were satisfied overall with the activity. ___ Yes ___ No

Would you recommend this program to your colleagues? ___ Yes ___ No

Please check the Core Competencies (as defined by the Accreditation Council for Graduate Medical Education) that were enhanced through your participation in this activity:

_____ Patient Care

_____ Practice-Based Learning and Improvement

_____ Professionalism

_____ Medical Knowledge

_____ Interpersonal and Communication Skills

_____ System-Based Practice

Additional comments:

_____

_____ I certify that I have participated in this entire activity.

This information will help evaluate this CME activity; may we contact you by email in 3 months to see if you have made this change? If so, please provide your email address below.

_____