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HOW TO COMBAT CHALLENGES

FACED IN OBTAINING ACCESS TO APPROVED ANTI-VEGF MEDICATIONS

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How to Combat Challenges Faced in Obtaining Access to Approved Anti-VEGF Medications

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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. Thus, payers have become more involved in managing the use of these agents, potentially interfering with clinical decision-making. The following activity brings together thought leaders in the field of retina to discuss the challenges they face in obtaining access to anti-VEGF medications for their patients and how they overcome those challenges.

TARGET AUDIENCE

This certified CME activity is designed for ophthalmologists and retina specialists involved in the treatment and management of patients with retinal disorders.

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 on ophthalmology and its potential impact on the prescribing of anti-VEGF agents.

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PRETEST QUESTIONS

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1. **Rate your level of confidence in your ability to engage patients in shared decision-making:**
   a. Not at all confident
   b. Not very confident
   c. Neutral
   d. Confident
   e. Very confident

2. **Rate your level of confidence in your ability to proactively avoid claim denials or late reimbursement:**
   a. Not at all confident
   b. Not very confident
   c. Neutral
   d. Confident
   e. Very confident

3. **Rate your level of confidence in discussing approved and off-label drugs with patients:**
   a. Not at all confident
   b. Not very confident
   c. Neutral
   d. Confident
   e. Very confident

For the following questions (4,5) rate how often you engage in the following activities: 5 = Always, 1 = Never

4. **I use shared decision-making tools with patients who require anti-VEGF treatment. _____**

5. **I have to abide by a fail-first policy when using US FDA-approved anti-VEGF agents. _____**

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, as step therapy has been rigorously tested with good results in randomized controlled trials in common retinal diseases, such as neovascular age-related macular degeneration (AMD).
   c. Reduce third-payer party costs, as step therapy often requires generic or off-label drug selection, usually of lower cost than other US FDA-approved alternatives.
   d. Improve patient satisfaction, as there is a less-involved informed consent process due to the lack 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 VA and moderate intraretinal fluid and central subfield thickness of 552 µm on spectral-domain OCT. The patient shows only minimal change in vision and intraretinal fluid after three 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 US 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 the cost of the new medication with the patient, and explain 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 for an injection 1 to 2 weeks later and have the office staff perform an investigation of benefits. Verify that the patient's 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 US FDA-approved medication that the patient and physician agree to try. Explain that the patient will have the payment refunded if his or her insurance reimburses the office for the US FDA-approved medication.
   d. Use a sample of the newly elected US FDA-approved medication, and 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 patient's insurance is active when the patient returns for the next visit, as 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)

8. **A patient with neovascular AMD diagnosed 18 months ago is undergoing treatment with a US 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 a 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 for neovascular AMD. The prescriber knows that this conversation means that they need to convert the patient from the successful US FDA-approved agent to bevacizumab.**
   True or False?
   a. True
   b. False

9. **An established patient with a medicare advantage plan is scheduled for amd treatment. The patient is not responding to the current medication, and the physician would like to inject 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?
   Add a check mark to the items below that are 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 the currently approved medication, and schedule for a 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 a 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 the staff to contact the insurance carrier immediately to confirm, document that the new medication is covered, and then proceed with treatment.		
Request that the patient sign 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.		

How to Combat Challenges Faced in Obtaining Access to Approved Anti-VEGF Medications

The clinical benefits of anti-VEGF agents for the treatment of age-related macular degeneration (AMD), diabetic retinopathy, and retinal vein occlusion (RVO) are well documented.[1-5] Unfortunately, ophthalmologists face a number of issues with their access and use, including cost and reimbursement, which may interfere with clinical decision-making.[6,7] The following roundtable brings together thought leaders in the field to discuss the challenges they face in obtaining access to anti-VEGF medications, how to determine the most appropriate treatment for patients given their insurance coverage, the impact of prior authorizations and stepwise policies on treatment, and how to navigate ever-changing rules and regulations, including the Drug Quality and Security Act (DQSA) and the Medicare Access and CHIP Reauthorization Act (MACRA).

— David Eichenbaum, MD, moderator

DETERMINING TREATMENT AND TIMING

Q | DAVID EICHENBAUM, MD: In order to offer your patient the best care and the best outcomes possible, you need to have a choice of therapeutics and be able to use the medication that you deem most appropriate for the patient in front of you. But it is not that simple; you also have to consider patient access to that medication, including financial issues and potential payer barriers.

Let us consider what to do when a patient doesn't respond to the initial treatment. An established patient with a Medicare Advantage plan is scheduled for AMD treatment, but the patient is not responding to the current therapeutic. You plan to change therapeutics on the next visit. What is the best approach to ensure appropriate treatment for the patient as well as reimbursement for the new medication?

DANTE PIERAMICI, MD: First, if their disease state will allow a brief delay in treatment, I would perform a benefits investigation with the insurance company's practice support program for the new medication and then have the patient return shortly for treatment. I would also ask the staff to contact the insurance carrier immediately to confirm the treatment will be covered. If so, I would ensure that I documented the authorization and then proceed to treat the patient with stock medication. I don't recommend treating the patient with the new medication from inventory, billing for it, and then performing a benefits investigation after the fact. A sample medication is another option when urgent therapy is needed.

DR. EICHENBAUM: It is not unreasonable to treat the patient with stock medication from your buy-and-bill inventory at that visit. One option is to request that the patient sign an Advance Beneficiary Notice for the new medication and collect from the patient the full allowable rate on the medication after treatment. You can then refund or credit the patient after the medication is paid for by the insurance company. This is a reasonable approach if the patient can afford the medication out of pocket, but it is often not a practical approach since US FDA-approved intravitreal medications are expensive, and patients often cannot afford the out-of-pocket expense.

Another option would be to check the carrier's published clinical policy to confirm that the medication is covered for the diagnosis and the patient plan type does not require an authorization or referral for the change in medication and then treat on the same day.

DR. PIERAMICI: What do you do for patients on a treat-and-extend regimen? For instance, consider a patient with neovascular AMD who has had a series of treatments with any of the three commercially available agents: bevacizumab, ranibizumab, or aflibercept. The patient returns after a second attempt at extension to 6 weeks, returning at 4 or 5 weeks instead. The patient presents with recurrent subretinal fluid, slightly decreased vision, and now two failed attempts at extension to 6 weeks on the agent. How should you proceed?

DR. EICHENBAUM: In my practice, since expecting patients to pay out-of-pocket is often impractical, these patients frequently receive an injection with a sample medication. Treating the patient with a known insurance plan with trusted reimbursement is reasonable as well because you already have a history of payment for that agent in that diagnosis. With select known insurance carriers, you have essentially already completed the "prior authorization" that is required for that agent, and you have confidence that you will be reimbursed for your stock medication.

Some patients who are transitioning to US FDA-approved medications have high out-of-pocket-cost insurance plans. Many companies offer copay assistance for these patients. How does a copay assistance discussion go in your practice if there is a situation where a patient has a high deductible or a high copay? Do you use that service?

ANKOOR R. SHAH, MD: This discussion occurs with the patient on multiple levels. When I speak to patients about their deductible or copays, I inform them what my recommended therapy can do for them medically. I inform them that, if I can get a drug approved by their insurance, then I have access to drugs that have been shown to be beneficial and superior at drying out the retina in some clinical trials. I often start

treating with bevacizumab on the very first visit just because I am unsure what I can and cannot use according to their insurance. Depending on their response, I would consider switching them to another medication if there is persistent fluid. I start the benefits investigation for any drug I believe I may want to use at the initial treatment because it often takes several days or weeks to get approval for US FDA-approved medications.

One of the challenges I have seen is that sometimes patients are authorized for bevacizumab, but they are not authorized for aflibercept, even if it is a sample. Therefore, when I choose to use a sample, the injection fee itself won't be covered in some cases. In those situations, you have to factor in the entire out-of-pocket cost to the patient. It usually results in costing the patient less to have bevacizumab covered than to have a sample medication not covered.

DR. EICHENBAUM: What do you do with that injection fee? Do you write that off, or do you charge it to the patient as a noncovered service?

DR. SHAH: It depends how badly I want them on a certain medication. For example, if I have a monocular patient with bad diabetic macular edema (DME) and 20/200 vision, I might absorb the injection fee and proceed with the aflibercept sample sooner. But, more often than not, I will typically perform a bevacizumab injection, have everything reimbursed at no extra cost to the patient, and have it covered by insurance for them next time before continuing.

DR. PIERAMICI: To summarize, if you are going to switch a patient from bevacizumab to one of the other commercial drugs, there are scenarios where you can either use a sample or you can continue using bevacizumab and then try to obtain approval prior to switching the drug for the patient. There are some insurance programs, such as Medicare, that don't require preauthorization. In those situations, you could proceed with treatment.

DR. EICHENBAUM: That is the best-case scenario. You have a patient with a Medicare primary and a trusted Medicare supplement, and then you can inject a stock medication with confidence.

DR. PIERAMICI: We worry more about the payments with patients with DME, as they tend to be younger and carry more restrictive insurance. However, Medicare Advantage plans may also require preauthorization or require that the drug be provided by a specialty pharmacy for our older patients with DME or neovascular AMD.

DR. EICHENBAUM: In my practice, we depend on the manufacturer's patient support program to help us determine what the patient's out-of-pocket responsibility is going to be with their copay or coinsurance. I find those services extremely efficient with the staffing that we have developed in our practice. But I also find that we can't efficiently use these services to investigate patient benefits on the same day that we see the patient. It is just too time consuming, and patients don't want to spend 4 hours sitting in my office waiting for that process to work. That is why we usually have patients come back another day, or for a seasonal patient who is known to need treatment, we investigate benefits before the patient returns to our clinic.

This problem occurred for me recently with a Medicare patient with an RVO whom I wanted to treat with a stock dose of a medication approved by the US FDA, whom I had treated with off-label bevacizumab and a sample previously. The patient had failed two attempts at completing the process for pharmaceutical industry-sponsored copay assistance. He would not answer the phone at home for the copay grant foundation, which is part of the copay assistance on-boarding process. In that situation, that patient is difficult to treat with US FDA-approved medications; he cannot afford the copays.

In situations like this, you must choose between using samples or bevacizumab. You can also talk to the patient about paying the copay out of pocket, if that is an option for them.

DR. EICHENBAUM: Oftentimes, when our patients return at the next prescribed visit on copay assistance, the patient receives stock medication with as-needed patient financial support services. If the patient is on a commercial plan and if a specialty pharmacy dose is required, it has been obtained by then. The patient is charged for out-of-pocket coinsurance and copay fees (reduced by copay assistance), and then that charge is settled at the time of service. That is the ideal scenario. How do you handle patients with Medicare Advantage plans requiring specialty pharmacies?

DR. PIERAMICI: Although still in the minority, it seems like Medicare Advantage plans requiring specialty pharmacies are becoming more common. My staff logs these instances when they arise, and we mark in the chart that they require the specialty drug.

DR. EICHENBAUM: Roger Goldberg, MD, MBA (Bay Area Retina Associates, California), presented HARBOR data during the American Society of Retina Specialists (ASRS) annual meeting last year.[8] The study observed the impact of delayed time to treatment on visual outcomes in the HARBOR trial, from less than 6 days to greater than 10 days (Figure 1). Although there was a trend for the patients treated earlier to perform better, by the end of 12 months, there was no statistically significant difference between patients who were treated less than 6 days from screening to greater than 10 days from screening.

This implies that, on average, there is not a significant medical risk to waiting if you choose to do a benefit investigation for your neovascular AMD patient and bring them back 3 to 10 days from your initial day 0 visit, instead of treating them on day 0 with a sample drug or with bevacizumab. Does anyone feel that these are bad data? Does anyone feel that you are putting your neovascular AMD patient in significant medical risk if you make them wait 7 to 10 days from the day of diagnosis?

DR. SHAH: I have seen patients that refused an injection and then returned 2 days later with a large hemorrhage; I'm sure many of us have. If the patient is in front of me, I try my best to treat them that same day. If they are unable to or choose to defer treatment, I try to see them again within a week. I am less worried with DME, but I am more concerned about timing with AMD.

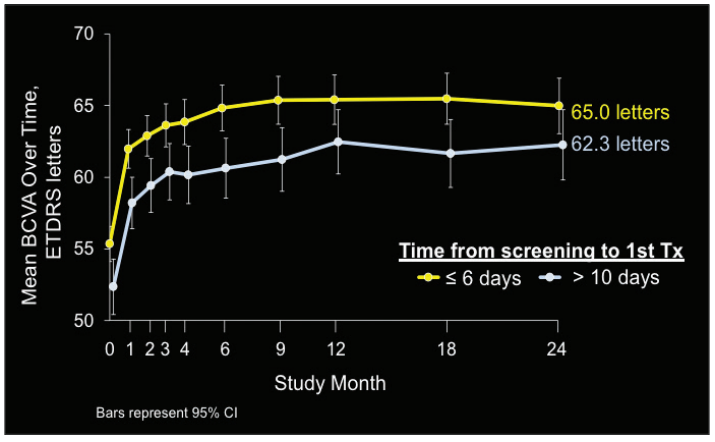


Figure 1. BCVA over time according to the HARBOR trial.[8]

DR. PIERAMICI: Ten days is a long time to go without treatment when you know treatment is necessary. The current disease state needs to factor into the decision. For example, if a patient has a small occult lesion that is barely leaking and is very subtle or asymptomatic, that patient can likely wait 3 to 10 days for treatment.

DR. EICHENBAUM: Despite the data, I prefer to treat new neovascular AMD patients on the same day, and I often do so if the patient is not going to be in a clinical trial. If they are in a clinical trial, there is this three-step process:

1. the patient is seen at the first presenting visit, then
2. the patient is screened a few days after presenting, and then
3. the patient is randomized and treated a few days later.

The rationale in the clinical trial scenario is that the patient may derive benefits from participating in a trial with regard to intense, protocol-driven follow-up or the receipt of a potentially superior investigative drug. These two factors may outweigh the delayed start to treatment. If you are going to treat the patient with routine care, it is generally in the best interest of the patient to treat them on day 0. However, we have reasonable evidence from clinical trials that you can delay treatment for a short time without a significant medical risk in most patients.

DR. SHAH: I echo Dr. Eichenbaum's comments. For AMD patients, it is important to treat them the same day unless they are being placed into a clinical trial where there is the potential for them to be treated with a better therapy. For other conditions, there may be some flexibility with the routine treatment timeframe, but for AMD specifically, it is important to treat the patient right away.

DR. PIERAMICI: Billing concerns should never be a reason to delay treatment because you can use bevacizumab or you can use a sample on day 0. If you are uncomfortable waiting, reimbursement should not be part of that decision on the first day, because there are inexpensive alternatives.

PAYER BARRIERS AND MANAGING FINANCIAL RISK

Q | **DR. EICHENBAUM:** When it comes to prescribing the right agent for the patient at the right time, we must consider the disease entity, whether it is neovascular AMD, DME, or RVO; the patient's insurance and potential for financial assistance; and discussion with the patient regarding US FDA-approved or off-label agents. We also want to limit the financial exposure of the practice. We do not want to go out of business because we cannot afford to practice with these expensive, yet highly effective and safe, medications. It is also important to involve the patient in shared decision-making. All of us try to engage the patient at different levels to help them be comfortable with the selection of the right medication for their condition.

Clinical and Utilization Management has a wide array of techniques that payers put in place to limit their risk. It is not unreasonable for a payer that is funding $2,000 for a medication to ask for justification for that expense; it is reasonable to have some level of prior authorization from payers. But the question is, when does this process become onerous? What are some of the most commonly used Utilization Management barriers that a payer puts in place to use a medication? It is important to note that some barriers can result in a treatment delay or drive utilization of less expensive and perhaps inferior off-label bevacizumab.

DR. SHAH: I agree that it is reasonable to expect verification for a $2,000 medication, but the approval rate for prior authorization is 98% in some cases. If the payer will say yes anyway, why is there an extra hurdle? You have to hire extra staff to cover this hurdle, and you lose time in your practice.

We have seen a shift toward step therapy, which is being relabeled as a "prior authorization process." Step therapy, as of July 2018, is expressly not allowed for Centers for Medicare & Medicaid Services (CMS)-related plans. However, we will call for prior authorization for patients on Medicare Advantage plans. We need to be careful and clear about what is actually intended by prior authorization because the meaning changes depending on the plan. This is something that we deal with on a routine basis, and we have a team of two to three people who get prior authorizations for all the upcoming patients to make the day go a little smoother. We put a lot of effort into trying to make that happen.

DR. PIERAMICI: My practice does the same thing with return patients, and it certainly costs us a lot more in overhead. It is an onerous process, but it makes sense. For new patients, you have to verify what insurance they have when they come in because sometimes we don't have that information prior to their visit. Sometimes you can get it from the referring doctor, but it may not be accurate.

DR. EICHENBAUM: My practice is based in Florida, and we have a lot of seasonal patients who are treated elsewhere and referred to us for the winter months. We often get our prior authorizations for new or returning seasonal patients before they come in because we want them to have access to the medications that they have previously done well on and will need. The prior authorizations are probably the most onerous and time-consuming aspect we have as a barrier. Although it is reasonable for the payers to ask for them, if they are going to approve the prior authorization 98% of the time, how much asking and telling do you really need? It is an area that can be improved upon.

There are several other barriers that are put in place to reduce or restrict our patients' access to these medications. There are policies that change and that are instituted without adequate notice from various commercial payers. Bevacizumab reimbursement can sometimes be too low. For example, one ASRS member reported receiving $10 reimbursements for bevacizumab (unpublished data, ASRS). However, other markets, such as Magellan Health, which handles the Medicare pharmaceutical accounts for certain large payers, are paying more for bevacizumab and making sales calls to doctors to discuss how much more they are paying for bevacizumab in order to influence MD prescribing patterns.

ASRS recently reported payer problems and tactics that the payers have been using to change our practice patterns, change our patient's access patterns, or reduce our ability to recommend certain medications.[9] I recently received an email from Magellan asking to speak to me about my utilization and how my Medicare Advantage patients can save on injectables. The email reminded me intravitreal antiangiogenic bevacizumab J9035 has been reimbursed to me at $250 per dose for some plans since April 1, 2016. It is an interesting tactic. What do you think the point is of these differential payments?

DR. SHAH: This is about steering the physician to choose certain pharmaceuticals based on financial incentive. It works on some level, but some of these incentives do change practice patterns. ASRS advocates on our behalf regarding these reimbursement issues, even though you may not be aware of it. For example, consider vitrectomy codes. There was a National Correct Coding Initiative edit change that made treating a patient for a macular hole with a macular hole repair inappropriate as a diagnosis. Another example was when there was an incident with a 25 modifier where your exam was being reimbursed at a reduced rate by 50% to 80% or not being reimbursed at all. The ASRS advocacy effort was able to rescind those decisions with the payers.

In terms of market access, there have been many issues. In one market, the bevacizumab J code, for example, was being written down to nearly $10. The insurer, Blue Cross Blue Shield of Tennessee, took the cost of 10 mg bevacizumab, which is used for intravenous dosing, and converted it to intravitreal dosing. Even though ASRS has posted a policy strongly advocating against this,[9] it was not in the insurer's financial interest to make bevacizumab so affordable that it was not possible for practitioners to cover their own costs of using that medication. That has since extended into step therapy with an incentive to push patients onto bevacizumab-first treatment policies. The goal is to drive and shift practitioner behavior, to make it so onerous that you stick with that initial therapy.[10,11]

DR. EICHENBAUM: There is no discussion about science regarding the variability in potency of commercially available bevacizumab repackaged for intravitreal injection, the small but real risk of contamination with repackaging, or the silicone oil problem with bevacizumab injections. There is no discussion about level 1 evidence for ranibizumab or aflibercept. It is strictly a discussion about how the prescriber can save Magellan money and how they can pay the prescriber more money per dose for use of off-label bevacizumab. The program is to recommend a therapeutic based on financial motivation.

DR. PIERAMICI: This is a perfect example of how our government is dysfunctional. On the one hand, CMS is trying to incentivize us to use bevacizumab. On the other hand, the US FDA makes it more difficult to use bevacizumab. Physicians are caught in the middle of compounding pharmacy issues and the government trying to incentivize us to use the less expensive drug. It is disjointed for the pharmaceutical companies as well. On the one hand, you have to go through this long, expensive US FDA approval process to get a drug marketed. On the other hand, the same government is going to incentivize physicians or mandate that physicians use an off-label drug. You have two heads of the government sending us very complicated mixed messages.

MANAGING STEP THERAPY CHALLENGES

Q | DR. EICHENBAUM: 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.

Step therapy, from a practical standpoint, is supposedly designed to use a medication that a payer defines as both clinically effective and cost-effective to result in long-term savings and drive utilization of a preferred agent. There is patient and physician dissatisfaction with this approach.

Step therapy is not going away anytime soon. The Department of Health and Human Services Secretary Alex Azar has authorized Medicare Advantage plans to utilize step therapy.[12] This has received some pushback from patient advocacy groups already, but it is on track to be available to Medicare Advantage insurers in 2019.[13] The current administration is considering targeting anti-VEGF drugs as part of this step therapy initiative. Bevacizumab is being proposed as an off-label, first-line therapy that will be mandated for certain disease states.

The goal of this tactic is to reduce drug prices, but the ASRS believes that mandating compounded drug use off-label as a first-line therapy sets a bad precedent by undercutting the authority of the US FDA and discouraging future innovation.[9]

DR. PIERAMICI: This is another example of conflicting government priorities. The government wants to cut drug costs, but they are doing it in an indirect way by disincentivizing physicians to use expensive drugs instead of mandating pharmaceutical companies to lower their drug prices to begin with.

Requiring that physicians follow a fail-first approach interferes with their diagnostic evaluation and clinical decision-making and places a barrier between the physician and patient. It may also affect patient outcomes. For instance, the additional visits and injections required to "fail" bevacizumab may lead to patient nonadherence, while delaying effective treatment may permanently affect vision. The practice is so controversial that a national organization, Fail First Hurts, has been created to advocate against these policies.

—David Eichenbaum, MD

DR. EICHENBAUM: Requiring that physicians follow a fail-first approach interferes with their diagnostic evaluation and clinical decision-making and places a barrier between the physician and patient. It may also affect patient outcomes.[14] For instance, the additional visits and injections required to "fail" bevacizumab may lead to patient nonadherence, while delaying effective treatment may permanently affect vision. The practice is so controversial that a national organization, Fail First Hurts, has been created to advocate against these policies.[15]

There are numerous clinical and ethical issues associated with step therapy policies. For instance, what does "failure" mean? How often do payers review the most recent clinical data and make changes to the policy based on randomized controlled data? Will payers consider changing these policies after bevacizumab is considered outmoded due to new drugs coming down the pipeline, such as brolucizumab or abicipar?

DR. SHAH: Medicare and Horizon Healthcare of New Jersey has a detailed list of what is considered a failure. First, the patient must have three bevacizumab treatments. If, after those treatments, the central retinal thickness is less than 350 µm or VA is better than 20/50, the treatment was considered successful. However, none of us would consider that VA a success if fluid was still present. The policy further states that, 6 months out, if retinal thickness is greater than 250 µm and if VA is worse than 20/20, the patient may be switched to a US FDA-approved medication such as aflibercept.

There are many issues with this. We know from many clinical trials, such as VISTA/VIVID, RISE/RIDE, that a 6-month treatment delay can lead to permanent vision loss.[16-18] We sent a letter to Medicare and Horizon Healthcare of New Jersey highlighting all the arguments against step therapy.

Alabama	No legislation signed or considered last session
Alaska	No legislation signed or considered last session
Arizona	No legislation signed or considered last session
Arkansas	Pending
California	Stalled last session
Colorado	Passed
Connecticut	Passed
Delaware	No legislation signed or considered last session
Florida	Stalled last session
Georgia	Stalled last session
Hawaii	Stalled last session
Idaho	No legislation signed or considered last session
Illinois	Pending
Indiana	Passed
Iowa	Passed
Kansas	Stalled last session
Kentucky	Passed
Louisiana	Passed
Maine	Pending
Maryland	Passed
Massachusetts	Stalled last session
Michigan	No legislation signed or considered last session
Minnesota	Stalled last session
Mississippi	Passed
Missouri	Passed
Montana	No legislation signed or considered last session
Nebraska	No legislation signed or considered last session
Nevada	Stalled last session
New Hampshire	No legislation signed or considered last session
New Jersey	Pending
New Mexico	Passed
New York	Passed
North Carolina	No legislation signed or considered last session
North Dakota	No legislation signed or considered last session
Ohio	Pending
Oklahoma	No legislation signed or considered last session
Oregon	Passed
Pennsylvania	Stalled last session
Rhode Island	Stalled last session
South Carolina	No legislation signed or considered last session
South Dakota	No legislation signed or considered last session
Tennessee	No legislation signed or considered last session
Texas	Passed
Utah	Stalled last session
Vermont	Passed
Virginia	Stalled last session
Washington	Pending
West Virginia	Passed
Wisconsin	No legislation signed or considered last session
Wyoming	No legislation signed or considered last session

Figure 2. The status of fail-first state legislation in the United States. Adapted from Fail First Hurts 2016.[15]

We must be able to select the best treatment for our patients in order to personalize their medical care. We have electronic medical records and a wealth of imaging data. In the future, we will utilize big data so as to determine how best to treat an individual. Personalized medicine should improve outcomes.

—Dante Pieramici, MD

DR. PIERAMICI: We must be able to select the best treatment for our patients in order to personalize their medical care. We have electronic medical records and a wealth of imaging data. In the future, we will utilize big data so as to determine how best to treat an individual. Personalized medicine should improve outcomes.

DR. SHAH: I agree, but the physician choice argument doesn't work well with insurance carriers. They don't care if you get to choose or not. We can, however, turn to hard data to argue our case. In the example I gave before, Medicare and Horizon Healthcare of New Jersey declared every patient needs to start on bevacizumab. We have data clearly showing why this mandate is inappropriate in terms of efficacy, as Protocol T demonstrated patients with certain initial VAs do better with US FDA-approved medications. Additionally, floaters and silicone oil bubbles, which have led to lawsuits, are a real concern with bevacizumab.

DR. PIERAMICI: When bevacizumab comes compounded to me, I question how much volume of the drug is in the syringe, as it seems variable at times.

DR. EICHENBAUM: There are good data for what you are alluding to. The potency of the bevacizumab that we receive commercially has been tested, and it is variable.[1] The bevacizumab that was used in the Comparison of AMD Treatments Trials (CATT), for example, was very consistent.[19] Bevacizumab is a wonderful drug to have in our armamentarium, especially for patients who cannot receive US FDA-approved agents despite our best efforts, but it may not be the right first choice for all patients when you have two US FDA-approved alternatives, especially when there is a suggestion of superiority of the US FDA-approved agents in both CATT and Protocol T.

Several states, such as Colorado, Iowa, Maryland, and Texas, 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.[14,20] Other states, such as Alabama, Idaho, Montana, and North Carolina, have no legislation signed or considered (Figure 2).

When you are electing your state legislators, you may want to consider supporting candidates who favor medicine over step therapy. At the very least, donate to your state ophthalmic society. Our state societies fund lobbying efforts favoring medicine and often have political action committees that support pro-ophthalmology candidates.

NAVIGATING THE INSURANCE MAZE

Q | **DR. EICHENBAUM:** At my practice, we have an office manager for five retinal specialists. She has three full-time staff members who do nothing but deal with payers, including obtaining authorizations, filing claims, and checking on claims. There is also a full-time person who works with patients to verify coverage, obtain copayments, and, when necessary, help patients find financial assistance to pay for the drugs. Each of the five doctors might do 10 to 20 injections a day. What challenges does this office manager face? What can the staff do to reduce the risk of denial for the patient?

DR. PIERAMICI: My practice has centralized billing. We have a staff of nearly 10 who are working on billing and who help with preauthorizations if necessary. When I first joined this practice, we had a staff of four: one front desk manager, one technician, one person obtaining angiograms, and one physician. Now, we have four people at the front desk alone, two of whom are obtaining preauthorizations for the next day's patients. Our overhead has increased significantly over the last few years, in part due to the hassles of insurance authorization.

DR. EICHENBAUM: My process is similar. Our front desk staff verifies the insurance for every patient, every visit. Commercial insurance can become inactive between visits. We have the investigation of benefits completed annually, and we have to check the funds that the patient may be receiving from copay assistance. Copay assistance checks are done every visit to ensure that there are funds available and attached to that patient. Those activities are all done by the front desk.

The billing office has to verify what balance is due and what the paid claims are for the patient with the front desk. That is communicated electronically between the front desk and the billing office so the front desk knows what the balance due is at the time of service. We also do our own in-house billing. Our goal is to have a 0 balance on each patient account when they complete each visit. As long as those steps have been taken, there is active insurance, a completed investigation of benefits, and there are active and present copay assistance funds available as needed, then the patient's out-of-pocket fee should be minimal and reproducible between visits. But all of this takes an enormous amount of in-house staff time. Prenner et al published a paper in *Ophthalmology* that discussed the number of hours staff devotes to AMD injections (Figure 3).[21] They determined that a practice spends, on average, 225 staff hours per week dedicated to managing AMD injections.

TABLE. Number of Staff Members and Amount of Time Dedicated to Management of Neovascular Age-Related Macular Degeneration

Staff Type	Average Number of Staff Type Involved in Neovascular AMD (Range)	Average Total % Time in a 40-Hour Work Week Spent in Neovascular AMD Care (Range)	Average Time per Staff Member per Week Spent on Neovascular AMD	Average Hours per Week Spent on Neovascular AMD, All Staff Members
Receptionist	5 (1–18 people)	20% (1%–75%)	8 hours	28 hours
Office manager	2 (0–10 people)	13% (0%–75%)	4 hours	10 hours
Billing manager	2 (0–6 people)	22% (0%–80%)	8 hours	18 hours
Technician[a]	8 (1–50 people)	34% (3%–90%)	14 hours	112 hours
Physicians other than retina specialists[b]	2 (0–18 people)	15% (0%–65%)	6 hours	12 hours
Other staff members[c]	4 (1–12 people)	25% (5%–70%)	10 hours	40 hours
Total	23 people	Average 20% of individual's work week	Average 10 hours of individual's work week	Total office time of 225 hours

AMD = age-related macular degeneration.
[a]Technician includes photographer, scribe, and lead technician.
[b]Physicians other than retina specialists include residents, fellows, other ophthalmologists in the practice, or physician assistants.
[c]Other staff include medical assistants, optometrists, and nurse technicians.

Figure 3. Staff time required to manage AMD. Reprinted from *Am J Ophthalmol*, Vol. 160, edition 4, Prenner JL, Halperin LS, Rycroft C, et al., Disease burden in the treatment of age-related macular degeneration: findings from a time-and-motion study, 725-731.e1., Copyright (2015), with permission from Elsevier.[21]

DR. SHAH: How do you handle the process at the beginning of the year? Do you have every medication preapproved? Do you go through a month when you're going to use samples?

DR. PIERAMICI: We make sure patients fill out forms again at the beginning of the year with their copay assistance information.

DR. SHAH: We shifted to trying to do that in November and December of each year. We used to have patients fill out the forms only in December and found that does not work. Since we made that switch, we found that about 90% of our patients on US FDA-approved medications can stay on their medication without any issue. That is a huge improvement from what we used to have.

DR. EICHENBAUM: We try to do it sooner in November and December. We ask for extra samples in the beginning of the year to cover our seasonal patients who come to Florida for the winter; a few always come to the clinic without completed benefits investigations. The beginning of the year is a time to have a lot of samples on hand if you want to maintain patients on branded therapy. Have you noticed or been told by your billing staff about rejections for injections with a sample?

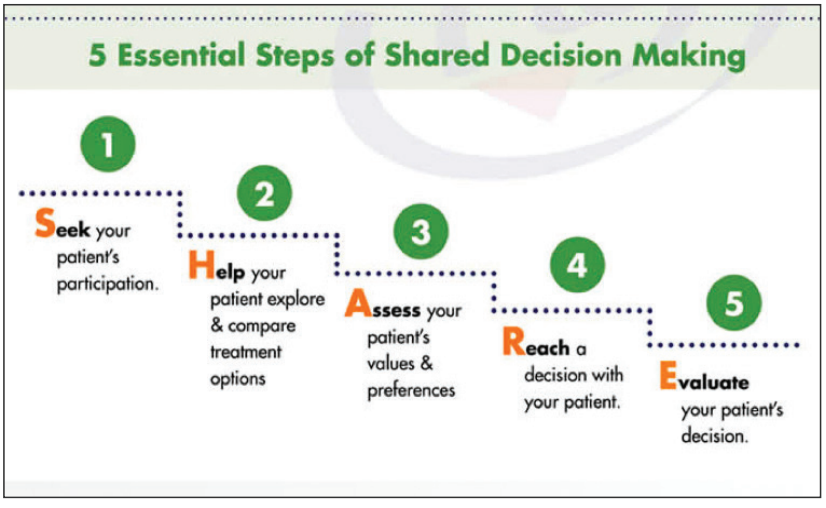
DR. SHAH: We have seen it only when we are switching drugs. If the patient is approved for bevacizumab and then you sample a different drug, you still have to list your branded drug with it, even if it is a sample. In that case, the insurance company may say it is not authorized and not cover the administration fee. It does not always happen, but we have seen cases like that.

DR. EICHENBAUM: Consider another scenario. Mrs. D. is a 67-year-old retired teacher who comes to see you for vision problems. She has been noticing a change in her vision over the past 6 months and is having a difficult time reading, even with her reading glasses. She sees wavy lines and says what she sees looks dirty. She also has diabetes controlled with metformin and a sodium-glucose cotransporter-2 inhibitor, hypertension controlled with an angiotensin-converting enzyme inhibitor, and osteoporosis. She has a Medicare Advantage plan.

After a thorough exam, including a fluorescein angiogram of the eyes, you confirm that Mrs. D. has neovascular AMD in her right eye. You recommend treatment with a VEGF inhibitor. What do you do first? Would you offer this patient a sample, plan to treat another day, or treat that same day with bevacizumab?

DR. SHAH: I typically would start with bevacizumab to get some anti-VEGF medication to control the problem. I would also have a benefits investigation done on the same day to try to get the optimal medication approved for the patient for future visits.

DR. EICHENBAUM: One of the first decisions I would need to make about Mrs. D. is which VEGF inhibitor to use—off-label bevacizumab or the US FDA-approved ranibizumab and aflibercept. In a situation like this, when there is more than one reasonable option and no one option has a clear advantage, and when the possible benefits and harms of each option may affect patients differently, I turn to shared decision-making (Figure 4).



(Courtesy of the Agency for Healthcare Research and Quality).

Figure 4. A shared decision-making chart.

Put simply, shared decision-making is a process in which clinicians and patients work together to make decisions and select tests, treatments, and care plans based on clinical evidence that balances risks and expected outcomes with patient preferences and values.

DR. PIERAMICI: When a patient selects an insurance plan, they do not know what they are choosing half the time. We should try to educate them on the limits and restrictions of their specific insurance. It is okay to have that conversation.

DR. EICHENBAUM: The Medicare Advantage plans are fairly aggressive in trying to get patients in my market. Patients do not know what they are signing up for. All they know is they are signing up for a lower or an absent monthly payment. I inform them that they are exchanging their Medicare for a managed plan with a network. I explain that the benefit of that is that they do not have to pay more out of pocket every month. However, the downside is the insurance is going to cost them more and restrict their health care access if they get sick. As physicians, we need to encourage patients to make better decisions.

Let us discuss what to do if an insurance company does not pay you in a timely manner. You have a 67-year-old female with DME. You want to start her on a US FDA-approved anti-VEGF agent. Her insurance benefits are investigated, an authorization is obtained, and the drug is pulled from the stock and injected. The patient has had two aflibercept injections and is coming in for the third. It has been 90 days, and you have not been paid for the first two commercial claims. What do you do?

DR. SHAH: In my practice, I start sampling because they are falling deeper in a hole, and there are some slow payers that will pay eventually. Maybe you have to give them a bit more leeway. At this point, I would discuss using a sample drug to bridge them through and make sure these claims keep coming in. I also have my staff look into the claims to make sure the error is not on our end due to inadvertent coding or documentation errors.

DR. PIERAMICI: I call my billing office and ask for details. Most of the time, the billing office will explain that this payer takes a while to pay. But if there was any hesitation on their part, then I would sample or choose bevacizumab.

DR. EICHENBAUM: I also typically go with samples in this situation. If I am out of samples, then I will sometimes switch to bevacizumab. If the payer is a known "slow-payer" but claims do eventually get processed, I will sometimes continue with stock medication since the patient is doing well, and the claims are likely to eventually be paid. I do not prefer to do that, though, and I almost always have enough samples to get me through.

NAVIGATING REGULATIONS AND QUALITY MEASURES

Q | **DR. EICHENBAUM:** The DQSA is a law that amended the Federal Food, Drug, and Cosmetic Act and gave the US FDA more authority to regulate and monitor the manufacturing of compounded drugs and pharmacies, drug repackagers, and a new class of outsourcing manufacturers. The Act was initiated by Congress in 2013. Some physicians report that the DQSA is slowing access to bevacizumab, which almost all retinal specialists prescribe and need access to.[22,23] The government may be instituting step therapy, but it may also simultaneously be restricting our access to bevacizumab by increasing the cost and complexity of it being fractionated for our offices. Both policies can limit access and hinder physician and patient choice in separate ways.

Have you seen any change in your access to bevacizumab or your cost for bevacizumab? Is this more of a theoretical problem than a practical access problem?

DR. PIERAMICI: Initially, there was a fair bit of uncertainty when the DQSA came out because many of the small compounding pharmacies disappeared. There were concerns regarding access to bevacizumab, reports of counterfeit versions, and the potential for infections from repackaged vials.[24,25] However, the situation has calmed down, and things have been pretty stable. We have had some issues with silicone bubbles, receiving syringes that get clogged occasionally, and inconsistency or uncertainty about the potency of the drug. That said, I think the DQSA adds value from a safety standpoint.

DR. EICHENBAUM: The MACRA of 2015 and the Merit-Based Incentive Payments System (MIPS) repealed the Sustainable Growth Rate formula. MACRA will introduce new reporting mechanisms and new value modifiers for physicians based on a set of quantitative indicators, including, by 2021, resource use. They will change how Medicare rewards clinicians for value of care over volume of care.

MIPS offers bonuses for participation in eligible alternative payment models and streamlines multiple quality programs. The field of ophthalmology has the fourth highest Medicare Part B payments of any medical specialty, and it is Medicare that is leading the drive away from fee-for-service and toward value-based reimbursement. The implementation of MACRA introducing new reporting mechanisms and value modifiers for physicians based on a set of quantitative indicators has a big impact on practice and puts some reimbursement at risk.

Recently, my practice received our assessment from the MACRA/MIPS program regarding our performance in 2017. My practice fortunately did well and is going to receive a very small Medicare bonus going into 2019. But the rules are changing. The utilization of high-cost medication is going to factor into how your practice is rewarded or penalized. To some extent, it is going to be a fraction of your

assessment. Does this policy alter your practice patterns or cause you to think twice when considering medications for your patients?

DR. SHAH: One of the challenges of navigating this is the overall question of where it is going. Right now, value-based reimbursement is just ramping up. The cost factor is about 10% for 2018, and the goal is to ramp it up to 30%. As it stands right now, your use of drug, that cost of Part B drugs, is included in considering your cost factor. It is not, however, included in the penalty or the bonus.

DR. EICHENBAUM: It is still going to indirectly affect your penalty or bonus because it goes into your overall grade at a weighting of 10%.

DR. PIERAMICI: But they are not going to penalize you based on that amount of money.

DR. SHAH: Correct. When it goes up to 30%, it will become a greater issue. The other issue that arises is that the bonus and penalty portion is also ramping up from 4% to 9%, which is a substantial amount of money. That percentage is coming right off the top line. My practice has yet to make any changes based off it, but we cannot hit a penalty.

DR. EICHENBAUM: One concern is that the use of cost measures could incentivize providers to provide lower-cost treatments that may be less cost-effective over time, while penalizing early adopters of new technologies.[26] In the 2018 transition year, CMS predicts that about half of ophthalmologists will see additional payments, while about 45% will see fewer.[26] Nonetheless, it is not completely clear what the impact of penalties and bonuses will be on the field. We cannot predict the future, but it is certainly something that we are going to all have to deal with in the next 2 to 5 years.

DR. PIERAMICI: The program is set up to change our behavior and reduce costs. It may not be painful or particularly costly now, but it is just ramping up.

DR. EICHENBAUM: MIPS includes retina-specific quality measures that we need to think about as well. These include

- adult primary rhegmatogenous retinal detachment (RRD) surgery: no return to the OR within 90 days of surgery.
- Adult primary RRD surgery: VA improvement within 90 days of surgery.
- AMD: counseling on antioxidant supplement.

Not returning to the OR within 90 days after RRD may affect our utilization of pneumatic retinopexy, which is a very good procedure with a low risk profile and a reasonable success rate. However, because it has a higher failure rate than operative repairs in the OR, it may become underutilized because of this type of quality measure.

A recent study assessing the impact of Medicare access and MACRA on ophthalmology by Kinker et al included the following statement:

"Because the cost subcategory is imperfectly aligned with quality, incentives may also exist for physicians to offer cheaper but lower-quality care, or to forego preventive care on the margins. Ophthalmology—with its heavy reliance on technology, rapidly evolving ocular treatments, and focus on preventive services—may be disproportionately impacted by these provisions."[26]

In 2014, CMS released physician-level reimbursement data, and *The New York Times* reported that ophthalmologists received 7% of all Medicare reimbursements in 2012, primarily due to prescriptions for anti-VEGF agents.[27] Ophthalmology under MACRA/MIPS is a target because ophthalmology has a heavy reliance on technology, evolving treatments, and a focus on preventative services, which can be expensive.

Thank you for the discussion. ■

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HOW TO COMBAT CHALLENGES FACED
in Obtaining Access to Approved Anti-VEGF Medications

Release Date: November 2018
Expiration Date: November 2019

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

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

Phone (required) _____ ❑ Email (required) _____

Address _____

City _____ State _____ Zip _____

License Number _____

DEMOGRAPHIC INFORMATION

Profession
___ MD/DO
___ 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 activity)
___ 0
___ 1-20
___ 21-40
___ 41-55
___ 56-75
___ 75+

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 on ophthalmology and its potential impact on the prescribing of anti-VEGF agents.	_____	_____	_____

POSTTEST QUESTIONS

1. Rate your level of confidence in your ability to engage patients in shared decision-making after reviewing this activity:
   a. Not at all confident
   b. Not very confident
   c. Neutral
   d. Confident
   e. Very confident

2. Rate your level of confidence in your ability to proactively avoid claim denials or late reimbursement after reviewing this activity:
   a. Not at all confident
   b. Not very confident
   c. Neutral
   d. Confident
   e. Very confident

3. Rate your level of confidence in discussing approved and off-label drugs with patients after reading this activity:
   a. Not at all confident
   b. Not very confident
   c. Neutral
   d. Confident
   e. Very confident

For the following questions (4,5) rate how often you engage in the following activities: 5 = Always, 1 = Never

4. I use shared decision-making tools with patients who require anti-VEGF treatment. _____

5. I have to abide by a fail-first policy when using US FDA-approved anti-VEGF agents. _____

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, as step therapy has been rigorously tested with good results in randomized controlled trials in common retinal diseases, such as neovascular age-related macular degeneration (AMD).
   c. Reduce third-payer party costs, as step therapy often requires generic or off-label drug selection, usually of lower cost than other US FDA-approved alternatives.
   d. Improve patient satisfaction, as there is a less-involved informed consent process due to the lack 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 VA and moderate intraretinal fluid and central subfield thickness of 552 µm on spectral-domain OCT. The patient shows only minimal change in vision and intraretinal fluid after three 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 US 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 the cost of the new medication with the patient, and explain 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 for an injection 1 to 2 weeks later and have the office staff perform an investigation of benefits. Verify that the patient's 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 US FDA-approved medication that the patient and physician agree to try. Explain that the patient will have the payment refunded if his or her insurance reimburses the office for the US FDA-approved medication.
   d. Use a sample of the newly elected US FDA-approved medication, and 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 patient's insurance is active when the patient returns for the next visit, as 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)

8. A patient with neovascular AMD diagnosed 18 months ago is undergoing treatment with a US 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 a 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 for neovascular AMD. The prescriber knows that this conversation means that they need to convert the patient from the successful US FDA-approved agent to bevacizumab.
True or False?
   a. True
   b. False

9. An established patient with a medicare advantage plan is scheduled for AMD treatment. The patient is not responding to the current medication, and the physician would like to inject 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?
Add a check mark to the items below that are 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 the currently approved medication, and schedule for a 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 a 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 the staff to contact the insurance carrier immediately to confirm, document that the new medication is covered, and then proceed with treatment.		
Request that the patient sign 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/SATISFACTION MEASURES

Your responses to the questions below will help us evaluate this continuing medical education (CME) activity. They will provide us with evidence that improvements were made in patient care as a result of this activity as required by the Accreditation Council for Continuing Medical Education (ACCME).

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 administrative support

_____ Lack of time to assess/counsel patients

_____ Reimbursement/insurance issues

_____ Patient compliance issues

_____ Other. Please specify: _____

_____ Lack of consensus or professional guidelines

_____ Lack of experience

_____ Lack of opportunity (patients)

_____ Lack of resources (equipment)

_____ No barriers

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.

_____