SURVIVING THE STORM

Ensuring your practice survives the disruptions of COVID-19.
EYLEA Offers Dosing Flexibility in Wet AMD

3 FDA-Approved Dosing Regimens in Wet AMD

The recommended dose for EYLEA is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months).

AMD = Age-related Macular Degeneration; Q4 = every 4 weeks; Q8 = every 8 weeks; Q12 = every 12 weeks.

IMPORTANT SAFETY INFORMATION AND INDICATIONS

CONTRAINDICATIONS

• EYLEA is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in EYLEA.

WARNINGS AND PRECAUTIONS

• Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA.

• Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.


Please see Brief Summary of Prescribing Information on the following page.
Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (approximately every 25 days, monthly), additional efficacy was not demonstrated in most patients when EYLEA was dosed every 4 weeks compared to every 8 weeks. Some patients may need every-4-week (monthly) dosing after the first 12 weeks (3 months).

Although not as effective as the recommended every-8-week dosing regimen, patients may also be treated with one dose every 12 weeks after one year of effective therapy. Patients should be assessed regularly.

Visit HCP.EYLEA.US to see the data.

WARNINGS AND PRECAUTIONS (cont’d)

- There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA compared with 1.5% (9 out of 595) in patients treated with ranibizumab; through 96 weeks, the incidence was 3.3% (60 out of 1824) in the EYLEA group compared with 3.2% (19 out of 595) in the ranibizumab group. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

ADVERSE REACTIONS

- Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis and retinal detachment.
- The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.

INDICATIONS

EYLEA® (aflibercept) Injection 2 mg (0.05 mL) is indicated for the treatment of patients with Neovascular (Wet) Age-related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR).

EYLEA is a registered trademark of Regeneron Pharmaceuticals, Inc.
BRIEF SUMMARY—Please see the EYLEA full prescribing Information available on HCPEYLEAUS for additional product information.

1 INDICATIONS AND USAGE
EYLEA is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of:

- Neovascular ( Wet) Age-Related Macular Degeneration (AMD); Macular Edema Following Retinal Vein Occlusion (RVO); Diabetic Macular Edema (DME); Diabetic Retinopathy (DR).

2 CONTRAINDICATIONS
- Neovascular (Wet) AMD
- Macular Edema Following Retinal Vein Occlusion
- Diabetic Macular Edema
- Diabetic Retinopathy

3 WARNINGS AND PRECAUTIONS

5.5 Endothelial Cell and Retinal Detachments
- Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments (see Adverse Reactions (6.2)). Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately (see Patient Counseling Information (9.7)).

6.1 Clinical Trials Experience.
- There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of reported thromboembolic events in wet AMD studies during the first year was 3.8% (16 out of 425) in the control group of patients treated with EYLEA compared with 1.9% (9 out of 595) in patients treated with ranibizumab; through 96 weeks, the incidence was 3.3% (60 out of 2044) in the EYLEA group compared with 2.9% (59 out of 2010) in the ranibizumab group. The incidence in the DME studies from baseline to week 52 was 3.5% (19 out of 558) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group from baseline to week 52. The incidence was 6.6% (7 out of 578) in the control group of patients treated with EYLEA compared with 4.2% (2 out of 267) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first 6 months of the RVO studies.

6 ADVERSE REACTIONS
- The following potentially serious adverse reactions are described elsewhere in the labeling:
  - Hypersensitivity (see Contraindications (4.3))
  - Endothelial cell and retinal detachments (see Warnings and Precautions (5.5))
  - Increase in intraocular pressure (see Warnings and Precautions (5.2))
  - Thromboembolic events (see Warnings and Precautions (5.3))

9 CLINICAL STUDY DRUGS
- Safety data observed in 269 patients with neovascular diabetic retinopathy (NVD) through week 52 in the PANORAMA trial were consistent with those seen in the phase 5 VIVID and VISTA trials (see Table 3 above).

10 IMMUNOGENICITY
- As with all therapeutic proteins, there is a potential for an immune response in patients treated with EYLEA. The immunogenicity of EYLEA was evaluated in serum samples. The immunogenicity data reflect the percentage of patients whose test results were considered positive for antibodies to EYLEA in immunospec. The detection of an immune response is highly dependent on the sensitivity and specificity of the assays used, sample handling, timing of sample collection, concomitant medications, and underlying predisposition to develop antibodies. Comparison of the incidence of antibodies to EYLEA with the incidence of antibodies to other products may be misleading. In the wet AMD, RVO, and DME studies, the pre-treatment incidence of immunogenicity to EYLEA was approximately 1% to 3% across treatment groups. After dosing with EYLEA for 24-100 weeks, antibodies to EYLEA were detected in a similar percentage range of patients. There were no differences in efficacy or safety between patients with or without immunogenicity.

3 USE IN SPECIFIC POPULATIONS
3.1 Pregnancy
- Aflibercept produced adverse embryological effects in rabbits, including cataract, vitreous, and skeletal malformations. A Total Observed Adverse Effect Level (OAEL) was not identified. At the lowest dose shown to produce adverse embryological effects, systemic exposure (AUC for free aflibercept) was approximately 6 times higher than AUC values observed in a single intravitreal treatment at the recommended clinical dose (see Animal Data).

3.2 Lactation
- There was no data on the effects of EYLEA on milk production or milk concentrations.

3.3 Females and Males of Reproductive Potential
- Contraception

3.4 Pediatric Use
- EYLEA is not recommended for use in children because of the potential risk to the fetus.

11 PATIENT COUNSELING INFORMATION
- Patients may experience temporary visual disturbances after an intravitreal injection with EYLEA and the associated eye examinations (see Adverse Reactions (6.2)). Advice patients not to drive or use machinery until visual function has recovered sufficiently.

Table 1: Most Common Adverse Reactions (% in Wet AMD Studies)

Table 2: Most Common Adverse Reactions (% in RVO Studies)

Table 3: Most Common Adverse Reactions (% in DME Studies)
No one predicted just how severely the COVID-19 crisis would decimate the American economy. Restaurants closed. Telecommutes reigned. And, as far as our field is concerned, many patients were unable to visit the retina clinic. This isn’t good for patients—nor is it good for the financial health of a practice.

A retina doctor trying to navigate government support programs may feel a bit like a sailor without a map. Hopefully this issue of Retina Today Business Matters can be your lodestar.

Bruce Maller, founder and CEO of BSM Consulting, was at the forefront of helping ophthalmologists learn the new rules of operating in the COVID-19 era. He provides the centerpiece to this issue. If you want to learn more about what he has to say—and especially if you want to review some of the webinars he has to offer—visit BSMConsulting.com.

Elsewhere in this issue you will find pearls for implementing telemedicine in your retina practice, advice for protecting yourself from malpractice liability, and ways to prepare for targeted retina audits.

Retina Today Business Matters has shifted its focus—just like you—to adjust to COVID-19. If you have a topic you think we need to cover, reach out to Scott Krzywonos, Editor-in-Chief, at scott@bmctoday.com.

ALAN RUBY, MD
SECTION EDITOR
GO AHEAD. BE A SHOWOFF!

Have a video of an innovative technique or interesting case?

Upload it to Eyetube.net/submit. It’s easy!

Videos should be **3-7 minutes** long.

**Accepted file formats** include mov, mpg, mp4, avi, and wmv.

Videos must be accompanied by an **English** narration. Narration should describe what the surgeon is doing and why. Explain subtle maneuvers, and name any instruments and/or devices that were pivotal to the case.

Files up to 2 GB are accepted. However, files larger than 1 GB may not transfer completely. Ensure you have a **good internet connection**, or contact us for an alternate upload method.

Include any relevant **financial disclosures**, either in the video or the video description.

**Avoid** background noise, music, movie clips, or animations that may distract viewers.

Companies may submit **educational or instructional videos** for consideration. Promotional material consisting of product advertisements, webinars, and/or symposia captures will not be accepted.

Questions? Contact Laura O’Connor, Digital Technologies Director • loconnor@bmctoday.com • 484.581.1860
Approximately 70% of audit-related calls and emails to the Academy are from retina practices. Smart practices proactively prepare for audits, which are inevitable and are typically triggered by volume. Practices that react to an audit rather than prepare for it are at a disadvantage.

CMS and its Medicare Administrative Contractors (MACs) conduct several types of audits and investigations that can affect retina practices. This article reviews some of the ways your practice can prepare in advance so that these audits do not take you by surprise.

**TARGETED PROBE AND EDUCATE AUDITS**

CMS’s Targeted Probe and Educate (TPE) program is designed to help providers reduce claims denials and appeals, according to CMS. MACs conduct TPE prepayment audits, during which charts are reviewed and educational feedback is provided.

Practices with high-volume utilization of a particular CPT code may receive a TPE additional document request prompting the submission of 20 to 40 targeted chart records. Practices have 45 days to respond. The audit may consist of three rounds of prepayment review. After each round, audit results may be mailed or may require a personal review.

Passing your audit during the first two rounds is important. If a high denial rate is identified after round three, the MAC may refer your practice to CMS for further actions, including extrapolation; referral to the zone program integrity contractor, unified program integrity contractor, or recovery audit contractor; or 100% prepayment review.

**FOCUS ON RETINA**

Intravitreal injections are the top focus of TPE audits for retina specialists. These audits are performed by the MAC for the area where the practice is located, as illustrated in Table 1.

**TABLE 1. TARGETED PROBE AND EDUCATE INITIATIVES TARGETING INTRAVITREAL INJECTIONS**

<table>
<thead>
<tr>
<th>Medicare Administrative Contactor</th>
<th>States/Territories</th>
<th>Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cigna Government Services</td>
<td>KY, OH</td>
<td>Drugs and frequency of screening</td>
</tr>
<tr>
<td>First Coast Service Options</td>
<td>FL, PR, VI</td>
<td>Aflibercept</td>
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<td>Ranibizumab</td>
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<tr>
<td>Noridian</td>
<td>AK, AS, AZ, CA, GU, HI, ID, MT, MP, NO, NV, OR, SD, UT, WA, WY</td>
<td>Aflibercept</td>
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<tr>
<td></td>
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<td>Bevacizumab</td>
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<td></td>
<td>Ranibizumab</td>
</tr>
<tr>
<td>Novitas</td>
<td>AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX</td>
<td>Aflibercept</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ranibizumab</td>
</tr>
</tbody>
</table>
Targeting up to 40 claims prior to payment will affect cash flow. I suggest that you correct discrepancies in record-keeping now, so that your documentation meets the requirements regarding whether or not an exam is separately billable.

Intravitreal injections are not the only focus of audits. Codes 92014 (established patient comprehensive eye visit), 99222-99223 (initial inpatient exam), 99232-99233 (subsequent inpatient exam), and 99213-25 (E/M level 3 established patient exam), and emergency department visit codes 99284 and 99285 are also scrutinized. To see a more comprehensive list of audit targets, visit aao.org/audits. This sensitive web content will require your AAO membership login information.

**RECOVERY AUDITS**

The Medicare Recovery Audit (RA) program was created to identify and correct past improper payments to Medicare providers. RAs, which are facilitated by the MACs assigned by CMS, have targeted several retina services, including the inappropriate billing of intravitreal medication units. For example, incorrectly billing 1 unit of aflibercept (Eylea, Regeneron) instead of 2 units could be caught by RA auditors. In this case, an RA is your friend: Not only did it identify the costly error, but you will be paid for the additional unit.

RAs are performed in four regions by three contractors. The targeted retina services and regional details are outlined in Tables 2 and 3.

RA auditors conduct two types of audits. One is an automated review of claims data. This is a data-driven audit, and chart notes are not requested. When it is concluded, the physician receives a request for refund. If it is not repaid within a particular time frame, payment will be withheld from the physician’s next payable claim. If, for example, your practice submitted claims for injectable medications while a patient was in a skilled nursing facility, then the RA contractor will request a refund for the medication payment.

RA auditors may also conduct a complex review based on auditing-submitted chart documentation. In this instance, the physician will receive an additional documentation request and must submit claim documentation within 45 days. Automated and complex reviews may be appealed by the physician when appropriate.

**WHAT TO WATCH FOR: PHOTODYNAMIC THERAPY**

CMS has focused on photodynamic therapy (PDT) documentation in its most recent high-volume complex reviews. There are three CMS national coverage determinations (NCDs) related to PDT and verteporfin (Visudyne, Bausch + Lomb), each of which has been revised over the years. When referencing an NCD for an audit, review the policy in place at that specific date of service. NCDs can be downloaded at aao.org/lcds.

**PDT Documentation Checklist**

The following checklist can be used when your practice receives an RA for PDT. Confirm the date of service and reference the appropriate NCD.

All of the following must be present before therapy begins:

- Choroidal neovascular membrane (CNVM) secondary to age related macular degeneration (AMD)
- CNVM under the geometric center of the foveal avascular zone
- Evidence of classic CNVM on fluorescein angiography (FA)
- Area of classic CNVM at least 50% of the area of the total neovascular membrane
- Retreatment with PDT is reasonable and necessary if, on re-examination, the ophthalmologist finds leakage from classic CNV on FA

Note that for claims with dates of service on and after April 3, 2013, use of OCT or FA to assess treatment response is permitted.

Effective April 1, 2003, PDT may be covered if used for subfoveal occult with no classic CNV associated with AMD, or subfoveal minimally classic CNV (ie, the area of classic CNV occupies < 50% of the area of the entire lesion) associated with AMD. These two indications are considered reasonable and necessary only when the lesions are small (ie, ≤ 4 disc areas) at the time of initial treatment or within 3 months prior to initial treatment; and when they have shown evidence of progression with the 3 months before initial treatment.

*(Continued on page 11)*
To say that ophthalmology practices are navigating uncharted territory is an understatement. The US Bureau of Labor Statistics places the unemployment rate at 14.7% as of early May, which is the highest level since the 25.6% peak during the Great Depression. Economists are now predicting that unemployment will peak at 25% to 30% of the US population. Even though much of the first quarter of 2020 was not affected by the COVID-19 pandemic, gross domestic product still shrank by 4.8%. The second quarter will almost certainly be worse.

The good news is that capital markets—a reliable indicator of future stability—have steadied, and Washington has passed several legislative initiatives to help stimulate the economy. Although the coronavirus has upended life as we know it, the coming return to normalcy could be sooner than we realize. The question is: Will your actions now set you up for continued success or set you back for years to come?

In an interview with CNBC, Mark Cuban said, “How companies respond to [the COVID-19 pandemic] is going to define their brand for decades.” Let’s replace the word companies with practices and the word brand with reputation. How is your practice’s response affecting your reputation? Has your practice taken care of its staff or its owners? How much flexibility has been afforded to your employees? Have you done everything you need to do to ensure your practice’s survival—and, with it, the livelihoods of those you employ?

Framing these choices in absolutist terms may seem overzealous, but it is appropriate given the circumstances.

UNDERSTANDING CASH FLOW

The passionate surgeons who work in ophthalmology sometimes overlook some of the particulars on the business side of operations. With your practice’s financial health at stake due to the COVID-19 crisis, understanding daily cash flow structures...
HOW IS YOUR PRACTICE’S RESPONSE AFFECTING YOUR REPUTATION? HAS YOUR PRACTICE TAKEN CARE OF ITS STAFF OR ITS OWNERS? HOW MUCH FLEXIBILITY HAS BEEN AFFORDED TO YOUR EMPLOYEES?

is critical. I recommend operating on a 13-week cash flow forecast. This popular forecasting time horizon strikes a balance between accurately strengthening decision-making and offering enough range to support medium-term planning.

BSM Consulting has a 13-week cash flow forecast tool available on its website that can help you to build a week-by-week projection of cash flow for your practice. By breaking down expenses and revenues into clear terms, you can anticipate your future cash needs and gain a sense of how today’s adjustments can affect tomorrow’s business health. When projecting cash receipts, practices should include operating revenue (ie, collections from previously performed services) as well as cash receipts from loans, capital contributions, and government grant programs. Disbursements should include expenses paid and debt service and capital purchases.

Forecasting your 13-week cash flow can help you to have a better sense of your future cash needs. It can also help to direct your key decisions, including staffing levels that align with expected operating revenue.

UNDERSTANDING CHANGES IN LEGISLATION

The Families First Coronavirus Response Act (FFCRA) was signed on March 18, and the Coronavirus Aid, Relief, and Economic Security (CARES) Act was signed into law on March 27. There are several major components to these acts that ophthalmologists in private practice must understand.

Emergency paid sick leave. Under the FFCRA, emergency paid sick leave and family medical leave have expanded. Businesses can now receive government reimbursement for paid sick or expanded family medical leave via a tax credit. Of note, employees do not have to be sick to qualify for these additional benefits; those caring for a sick family member or who need time to assist with childcare are also eligible.

Businesses with fewer than 500 employees may provide up to 80 hours of paid sick and/or expanded childcare leave as long as schools or childcare facilities are closed. The US Department of Labor has granted an exemption so that businesses with fewer than 50 employees would not be subject to the provisions of the FFCRA.

Incentives for employee retention. By now, most practices have applied for and received loan proceeds under the Paycheck Protection Program (PPP). These loans were authorized under the CARES Act and are intended to encourage practices to maintain staffing levels and associated compensation. Under the PPP, a business may receive a loan up to 2.5 times its average monthly payroll. The terms of these loans incentivize businesses to continue employee payments on normal terms, and the portion of any loan equal to the amount that was used to keep employees on payroll may be forgiven. Additionally, loan proceeds can be used for rent, utilities, and interest on debts. These expenses are also eligible for loan forgiveness. The Small Business Administration and Department of Treasury are expected to release guidance on the loan forgiveness provisions of the PPP.

Initial funding for the PPP ($349 billion) was exhausted in April and another $320 billion in funding was approved. Due to overwhelming demand for PPP loans, it is expected these additional funds will soon be exhausted.

Practices have also benefited from relief funds available through the US Department of Health and Human Services (HHS) and authorized under the CARES Act. These dollars were also authorized under the CARES Act. Each program has specific terms and conditions which that to be followed to avoid any unintended consequences.

OPHTHALMOLOGY OFF THE GRID

Listen Now!
bit.ly/Maller0620

Ophthalmology Off the Grid hosts Gary Wörtz, MD, and Blake K. Williamson, MD, MPH, MS, speak with Bruce Maller (BSM Consulting) and Matt Jensen (Matt Jensen Marketing) about government programs designed to help small businesses in response to the COVID-19 pandemic.
UNDERSTANDING YOUR PATIENTS’ NEEDS

Patients are the heart of any practice. Despite the changing conditions of patient care, there is no reason to abandon what has worked for you for many years. You must continue to focus on their needs and remind yourself that small acts can have lasting effects.

Some patients will expect a continued connection with your practice. For patients who require consistent evaluation and treatment with anti-VEGF agents, modified appointments may require that imaging is skipped and that injection-only visits are implemented. For those whose conditions are conducive to telemedicine management, setting up and properly billing for telemedicine appointments could be an effective way to stay connected with the patients who rely on you for care.

FINDING POSITIVES AND MOVING FORWARD

Find positives in the current COVID-19 climate. Many have used their newfound time to acquire continuing medical education credits, collaborate with colleagues, or communicate with strategic partners such as industry members. Taking 15 to 20 minutes per day to think about the future of your practice is also beneficial to your practice’s well-being on the other side of the pandemic. You might find yourself in the position to expand the practice, or you may decide that you have spread yourself too thin and that now it is time to re-assess your priorities. Regardless of the outcome, thinking about the health of your practice is an exercise that you might otherwise not have had time to complete.

Remember what Mark Cuban said when you think about the relationship between your actions during this crisis and the reputation of your practice. Your colleagues, staff, and patients expect leadership in the time of crisis. Shoring up your business financials, ensuring the security of staff members, finding innovative ways to connect with patients, and thinking strategically about your practice’s future may not normally be on your mind in the middle of the year. But then again, nothing about the COVID-19 pandemic is normal.

PREPARE YOUR PRACTICE

Monitoring the types of audits being conducted on retina practices is the first step to strengthening your audit armor. Visit aao.org/audits to learn about auditing trends and targeted services for your region.

A comprehensive internal review can prepare your practice for the next audit. Identify the services performed in your practice and review the relevant current local coverage determinations (LCDs) detailed at aao.org/lcds.

When you review your practice’s protocols, review the frequency limitations, documentation requirements, and diagnoses that establish medical necessity. Create an internal checklist outlining the documentation requirements, and conduct your own targeted internal chart review. Confirm that your insurance claims accurately reflect your chart documentation. Take corrective action if deficiencies are found in your documentation, and educate all physicians and staff on the results of your review.

There are many types of audits to monitor, and targeted services that may directly affect retina practices. Being prepared with accurate documentation and appropriate coding is the best way to prevent a failed audit. Periodic reviews of audit targets and internal reviews will help protect your practice and minimize the impact of the inevitable request for records.

(Continued from page 8)

PDT is not covered for the treatment of juxtafoveal CNV lesions, extrafoveal CNV lesions, or dry AMD. It is also not covered if FA was unobtainable.

Procedure notes should include the following:

• Diagnosis supporting medical necessity and appropriate indication for use
• Relevant diagnostic testing services within the policy guidelines (ie, FA, OCT)
• Physician order including medication name, dosage, and signature
• Route of administration and site of injection
• Dosage (mg) and volume (mL)
• Medication wastage recorded (billing of wastage with -JW modifier required)
• Completed consent
• Legible physician signature, either on paper chart or electronic health record

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Financial disclosure: BSM Consulting provides fee-based consulting services
Most ophthalmologists at one time or another have worried about malpractice liability, as it is a reality of practicing medicine. In this article, I lay out a three-part solution to the challenge of shielding wealth from potential malpractice claims.

**RISK MANAGEMENT**

The first strategy to protect against malpractice liability is to reduce risk and practice the best medicine possible. This begins with a dedication to being the best physician you can be and maintaining your ongoing knowledge through education and continuing medical education (CME).

Beyond this medicine-centered approach, ophthalmologists would be well-served to incorporate nonspecialty-specific risk management techniques. Learning how best to communicate with patients, especially when dealing with difficult patients or bad outcomes, is essential. Other techniques include how to handle protected health information and how to manage the risks of communication technologies, from blogs and websites to texting and email. This has become even more important in 2020 with the increased need for telemedicine.

Many of these techniques are covered in the eighth edition of my CME monograph, *Risk Management for the Practicing Physician*.

**MEDICAL MALPRACTICE INSURANCE**

Perhaps the most obvious way to protect against malpractice claims is to purchase medical malpractice insurance. This will typically cover both defense costs and any judgments that might be rendered against the defendant physician—within policy limits, of course. Although a comprehensive treatment of malpractice insurance goes beyond the scope of this article, I will highlight two salient issues.

**Claims-Made Versus Occurrence-Based**

A claims-made insurance policy provides coverage only for incidents that occur and are reported while you are insured with that carrier. Both the incident and the filing of the claim must happen while the policy is in effect. By contrast, occurrence-based coverage provides lifetime coverage for incidents that occurred while the policy was in effect, regardless of when the claim is filed. Thus, if you had an occurrence-based policy in effect for the calendar year 2017 and a patient files a claim in 2020 for an incident that happened during 2017, the policy covers you for that claim, even if you no longer have insurance with that carrier.

Claims-made policies are typically cheaper than occurrence-based policies for the first several years because the potential for claims builds slowly as policy years accumulate. In comparing costs of malpractice insurance policies, be sure to ask how much the premium will increase after the first year.

**Coverage Limits**

All policies have coverage limits, with “$1 million/$3 million” being quite common. The first number is the maximum amount the insurance company will pay per claim during the policy period, which is usually 1 year. The second amount is the maximum the company will pay for all claims during the same policy period. If there are claims or judgments against you, you will be personally responsible for any damages that exceed your insurance policy limits.

Reasonable coverage limits for your practice may depend on several factors, including the litigation award history in your area, whether or not your state has caps on noneconomic damages in malpractice actions, and what acts it covers. Be sure to work with an experienced agent to determine the right coverage limits and type of policy for your practice.

**ASSET PROTECTION**

Mistakes will happen, and bad outcomes will occur even when all best practices are followed. Bad outcomes can lead to liability, even if the physician believes he or she did nothing wrong, and malpractice awards can exceed even significant malpractice insurance limits.
For these reasons, many ophthalmologists have chosen to buttress their practice risk management and malpractice insurance with asset protection planning.

The goal of asset protection planning is to position a client’s assets in a way that makes it difficult, and in certain cases nearly impossible, for a potential future lawsuit plaintiff to gain access to them.

If the goal for an ophthalmologist is to feel more secure and sleep better at night knowing that what he or she worked hard to build will be safe, then asset protection planning is an important part of the solution.

**Practice Asset Protection**

The first priority of most physicians will be to protect their personal assets, but practice protection should not be overlooked. The most important practice assets are cash flow and income.

The good news is that the tools that protect your cash flow also typically help you save on income taxes and build retirement wealth. These include qualified retirement plans such as defined benefit plans, 401(k)s and combination plans, nonqualified plans, and captive insurance arrangements.

Other important practice assets include the real estate, if any, and valuable equipment. If your practice has valuable real estate or equipment, you can separate these assets from the main practice and use a limited liability company or companies (LLCs) to lease them back to the main practice entity.

**Personal Asset Protection**

Personal asset protection encompasses shielding the physician’s home, retirement accounts, other investment accounts, second home or rental real estate, and valuable personal property.

We typically recommend leveraging your state’s exempt assets as a priority because (1) they enjoy the highest level of protection and (2) they involve no legal fees, state fees, accounting fees, or gifting programs. In other words, you can own the exempt assets outright in your name, have access to any values, and still have the assets 100% protected from lawsuits against you.

Each state law specifies assets that are absolutely exempt from creditor claims. These may include qualified retirement plans and IRAs, cash within life insurance policies, annuities, and primary homes. Make sure you seek an expert on this to determine your state’s exemptions.

Beyond exempt assets, basic asset protection tools such as family limited partnerships (FLPs) and LLCs, along with certain types of trusts, can be used. FLPs and LLCs can provide good asset protection against future lawsuits, allow you (the client) to maintain control, and provide estate and income tax benefits in certain situations. For these reasons, we often call FLPs and LLCs the building blocks of a basic asset protection plan. Irrevocable trusts can also play an important role in asset protection planning.

Obviously, for all these legal tools, their asset protection benefits are dependent upon proper drafting of the documentation, proper maintenance and respect for formalities, and proper ownership arrangements. If all of these are in place, the physician will have solid asset protection for a relatively low cost.

**CONCLUSION**

The practice of ophthalmology has inherent lawsuit risks, including those from medical malpractice. Risk management, malpractice insurance, and asset protection planning can be combined to help physicians reduce the risk of and offer protection against liability.

**SPECIAL OFFERS:** The author has recently completed Wealth Planning for the Modern Physician, his first book for physicians in 5 years. To receive free print copies or eBook downloads of this book or Wealth Management Made Simple, text RETINA to 555-888, or visit www.ojmbookstore.com and enter promotional code RETINA at checkout.

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David Mandell, JD, MBA, is an attorney and author of more than a dozen books for doctors, including Wealth Planning for the Modern Physician. He is a partner in the wealth management firm OJM Group (www.ojmgroup.com).

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- Financial disclosure: Employee (OJM Group)

**BOOKS**

Wealth and Asset Protection for Physicians, Third Edition

Wealth Planning for the Modern Physician

Wealth Management Made Simple

Financial Planning for the Modern Physician

Wealth and Asset Protection for Optometrists, Third Edition

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TELEMEDICINE IN THE AGE OF COVID-19

Remote encounters minimize exposure to pathogens for all parties.

BY NIKOLA RAGUSA, MD

Telemedicine is often touted as the way of the future, but it was not until recently that ophthalmologists felt a pressing need to implement the practice into routine care. Now, in the age of COVID-19, telemedicine is the safest and most secure way for us to connect with high-risk patients and to minimize exposure to the pathogen for all parties involved. With the recent relaxation of HIPAA requirements, multiple real-time audio and video programs are available for ophthalmologists’ use. This article discusses practical pointers to keep in mind when using telemedicine.

DOCUMENTATION

When conducting a virtual patient visit, the provider should document:

- The patient’s verbal consent to discuss his or her health information;
- The length of the virtual visit;
- The date and time of the virtual visit, down to the minute;
- The content of the virtual visit, as if the patient were sitting in the office chair; and
- Whether the visit was conducted via telemedicine (with real-time audio and video) or by phone call (audio only).

BILLING REAL-TIME AUDIO-VIDEO

In ophthalmology, we are fortunate to have two choices when it comes to the code selection of an in-office examination: (1) evaluation and management (E/M) codes (99XXX) and (2) eye visit codes (92XXX). Unlike the E/M coding guidelines, eye visit codes do not specify required history elements. The guidelines simply indicate that a medical history is required, and leave it up to the provider to document what is appropriate for each patient based on his or her presenting conditions. It is expected that the medical history will be commensurate with the patient’s overall health and presenting conditions. E/M coding requires more documentation than most ophthalmologists are used to, as the note must include history, examination, and medical decision-making. For guidance on E/M coding, visit cms.gov.

When billing real-time audio and video, a provider should not use eye visit codes because they are not approved for telemedicine consultations. E/M codes should be used instead (Table). For place of service, CMS is instructing physicians and practitioners who bill for Medicare telehealth services to report the POS code that would have been reported had the service been furnished in person (ie, Office: 11).

SHORT-TERM SOLUTIONS

Non–HIPAA-compliant platforms may serve as sufficient short-term telemedicine solutions. However, I suspect that many patients will grow accustomed to these virtual interactions, so physicians may want to opt for a program with greater security that can be used over a longer term.

Skype. Although Skype has been in use for years, the platform offers more capabilities than most users realize. Skype enables not only video-based visits but also messaging and file sharing. Further, patients who use Skype to connect with their physicians need an email account to sign up, making the platform more secure than some others. Additionally, the program works from a desktop or a smartphone, which is a big advantage. The one downside is that using Skype may give a patient unfettered access to his or her physician, which can present challenges.

Google Hangouts. Google Hangouts has the same pros and cons as Skype. The program works seamlessly when used with individuals who have Google accounts. Plus, I find the Google Hangouts user interface easier to interact with than Skype’s. Platforms such as Zoom and BlueJeans present similar challenges as Skype and Google Hangouts.

It is also important to note that, if a patient wishes to talk to his or her physician using one of these platforms, a substantial amount of back and forth is required to schedule the virtual visit and ensure proper configuration.

HIPAA-COMPLIANT PLATFORMS

Doxy.me. Doxy.me is a popular HIPAA-compliant telemedicine platform, primarily because it is free. The user interface is bare-bones—it entails the doctor talking with the patient with no frills—which I think is a benefit. One caveat: Upon logging in, a patient can enter any name he or she wants, so there is no way to verify if the virtual visit is indeed coming from the intended patient. Doxy.me provides a timestamp at the end, which the physician has to manually enter into his or her note. It
is important to note that the data are not stored and therefore cannot be accessed in the event of an audit.

**Paid services.** Several paid services allow seamless connection with patients, document call length and duration, control who initiates the call, and give providers the ability to make themselves unavailable. Paid services also provide dedicated support, depending on the service.

**TELEMEDICINE ETIQUETTE**

When conducting a virtual patient visit, the following telemedicine etiquette tips are advisable.

- Work in a quiet space.
- Be aware of your surroundings. Patients will see whatever is behind you, unless you are using Skype, which can blur out the background. I suggest sitting in front of a blank wall.
- Facial expressions matter and will be the patient’s primary focus. Smile: You’re on camera.
- Wear a presentable shirt and consider your physical appearance.
- Speak louder than usual. The audio may be worse than in a real-world setting.
- Use a headset. Simple earbuds with a microphone are adequate.

**CONCLUSION**

Having experimented with telemedicine for years and testing every available platform, I recommend utilizing a HIPAA-compliant paid program. The prices for most services are not excessive, and the capabilities and security afforded far outweigh the cost. Keep in mind that whichever service you choose should offer a streamlined process for you, your staff, and your patients. The easier a platform is to use, the better the experience will be for all involved.

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**TABLE. 2020 UPDATES FOR E/M CODES**

<table>
<thead>
<tr>
<th>Code</th>
<th>Level of MDM</th>
<th>Number and Nature of Diagnoses/Problems or Management Options</th>
<th>Amount and/or Complexity of Data to be Reviewed</th>
<th>Risk of Complications and/or Morbidity or Mortality of Diagnostic or Treatment Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>99211</td>
<td>N/A</td>
<td>Minimal</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>99212</td>
<td>Straightforward</td>
<td>1 Problem: • Self-limited; or • Low risk of morbidity without treatment</td>
<td>Not more than 1 of the following: • Encounter/referral letter by another physician/qualified health care professional; or • 1 diagnostic test result</td>
<td>Minimal</td>
</tr>
<tr>
<td>99213</td>
<td>Low</td>
<td>2-3 Problems: • At least 1 with moderate risk of morbidity without treatment</td>
<td>2 of the following: • 1 prior encounter or referral letter; or • 1 diagnostic test result or • Multiple systems history and examination required by condition</td>
<td>Low risk</td>
</tr>
<tr>
<td>99214</td>
<td>Moderate</td>
<td>3 Problems: • Moderate risk of morbidity without treatment 1 Problem: • High risk of mortality without treatment</td>
<td>1 of the following: • A combination of 4 past encounters or test results; or • Independent interpretation of a test performed by another physician/qualified health care professional; or discussion with another physician/qualified health care professional</td>
<td>Moderate</td>
</tr>
<tr>
<td>99215</td>
<td>High</td>
<td>4+ Problems: • Moderate risk of morbidity without treatment 2 Problems: • Moderate risk with therapy changes 1 Problem: • High risk of mortality despite treatment</td>
<td>1 of the following: • A combination of 5+ past encounters or test results; or • Independent interpretation of a test performed by another physician/qualified health care professional; or discussion with another physician/qualified health care professional</td>
<td>High</td>
</tr>
</tbody>
</table>

Source: AOA Coding and Reimbursement Committee; Abbreviations: medical decision-making (MDM)

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