

Special Section to Retina Today

Vol. 4, No. 3

BUSINESS MATTERS

RT
Retina Today

HIRE RIGHT TO AVOID A FIGHT



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WHAT COULD SHE SEE THIS YEAR?



36 FAMILY RECIPES

Inspired by a real patient with MEfRVO.

IMPORTANT SAFETY INFORMATION 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.
- 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.

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CLINICALLY SIGNIFICANT VISION GAINS IN MEfRVO ACROSS 3 ROBUST CLINICAL TRIALS

Proportion of patients who gained ≥ 15 ETDRS letters (primary endpoint) and mean change in BCVA (ETDRS letters) (secondary endpoint) at Month 6 from baseline vs control^{1-4,*}

VIBRANT (MEfBRVO)		COPERNICUS (MEfCRVO)		GALILEO (MEfCRVO)	
Gained ≥ 15 ETDRS letters	Mean change in ETDRS letters	Gained ≥ 15 ETDRS letters	Mean change in ETDRS letters	Gained ≥ 15 ETDRS letters	Mean change in ETDRS letters
EYLEA (n=91) 53% vs 27% in the control group (n=90)	EYLEA (n=91) +17.0 vs +6.9 in the control group (n=90)	EYLEA (n=114) 56% vs 12% in the sham control group (n=73)	EYLEA (n=114) +17.3 vs -4.0 in the sham control group (n=73)	EYLEA (n=103) 60% vs 22% in the sham control group (n=68)	EYLEA (n=103) +18.0 vs +3.3 in the sham control group (n=68)

P<0.01 vs control and sham control.

VIBRANT study design: Randomized, multicenter, double-masked, controlled study in which patients with MEfBRVO (N=181; age range: 42-94 years, with a mean of 65 years) were randomized to receive: 1) EYLEA 2 mg Q4 or 2) laser photocoagulation administered at baseline and subsequently as needed (control group). The primary efficacy endpoint was the proportion of patients who gained ≥ 15 letters in BCVA at Week 24 compared with baseline.¹

COPERNICUS and GALILEO study designs: Randomized, multicenter, double-masked, sham-controlled studies in patients with MEfCRVO (N=358; age range: 22-89 years, with a mean of 64 years). Patients were assigned in a 3:2 ratio to either: 1) EYLEA 2 mg Q4 for the first 6 months or 2) sham injections (control) Q4 for a total of 6 injections. In both studies, the primary efficacy endpoint was the proportion of patients who gained ≥ 15 letters in BCVA at Week 24 compared with baseline.¹

*Last observation carried forward; full analysis set.

SEE WHAT EYLEA COULD DO FOR YOUR PATIENTS WITH MEfRVO AT HCP.EYLEA.US

BCVA, best-corrected visual acuity; ETDRS, Early Treatment Diabetic Retinopathy Study; Q4, every 4 weeks.

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 ($\geq 5\%$) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.
- Patients may experience temporary visual disturbances after an intravitreal injection with EYLEA and the associated eye examinations. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

INDICATIONS

EYLEA® (afibercept) 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).

References: 1. EYLEA® (afibercept) Injection full U.S. Prescribing Information. Regeneron Pharmaceuticals, Inc. August 2019. 2. Campochiaro PA, Clark WL, Boyer DS, et al. Intravitreal aflibercept for macular edema following branch retinal vein occlusion: the 24-week results of the VIBRANT study. *Ophthalmology*. 2015;122(3):538-544. doi:10.1016/j.ophtha.2014.08.031 3. Boyer D, Heier J, Brown DM, et al. Vascular endothelial growth factor Trap-Eye for macular edema secondary to central retinal vein occlusion: six-month results of the phase 3 COPERNICUS study. *Ophthalmology*. 2012;119(5):1024-1032. doi:10.1016/j.ophtha.2012.01.042 4. Holz FG, Roeder J, Ogura Y, et al. VEGF Trap-Eye for macular oedema secondary to central retinal vein occlusion: 6-month results of the phase III GALILEO study. *Br J Ophthalmol*. 2013;97(3):278-284. doi:10.1136/bjophthalmol-2012-301504

Please see Brief Summary of Prescribing Information on the following page.

03/2021
EYL.21.02.0050



BRIEF SUMMARY—Please see the EYLEA full Prescribing Information available on HCP.EYLEA.US for additional product information.

1 INDICATIONS AND USAGE

EYLEA is a vascular endothelial growth factor (VEGF) inhibitor 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), Diabetic Retinopathy (DR).

4 CONTRAINDICATIONS

4.1 Ocular or Periorcular Infections

EYLEA is contraindicated in patients with ocular or periorcular infections.

4.2 Active Intraocular Inflammation

EYLEA is contraindicated in patients with active intraocular inflammation.

4.3 Hypersensitivity

EYLEA is contraindicated in patients with known hypersensitivity to aflibercept or any of the excipients in EYLEA. Hypersensitivity reactions may manifest as rash, pruritus, urticaria, severe anaphylactic/anaphylactoid reactions, or severe intraocular inflammation.

5 WARNINGS AND PRECAUTIONS

5.1 Endophthalmitis and Retinal Detachments

Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments [see Adverse Reactions (6.1)]. 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 (17)].

5.2 Increase in Intraocular Pressure

Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA [see Adverse Reactions (6.1)]. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with vascular endothelial growth factor (VEGF) inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.

5.3 Thromboembolic Events

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.

6 ADVERSE REACTIONS

The following potentially serious adverse reactions are described elsewhere in the labeling:

- Hypersensitivity [see Contraindications (4.3)]
- Endophthalmitis and retinal detachments [see Warnings and Precautions (5.1)]
- Increase in intraocular pressure [see Warnings and Precautions (5.2)]
- Thromboembolic events [see Warnings and Precautions (5.3)]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in other clinical trials of the same or another drug and may not reflect the rates observed in practice.

A total of 2980 patients treated with EYLEA constituted the safety population in eight phase 3 studies. Among those, 2379 patients were treated with the recommended dose of 2 mg. 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.

Neovascular (Wet) Age-Related Macular Degeneration (AMD). The data described below reflect exposure to EYLEA in 1824 patients with wet AMD, including 1223 patients treated with the 2-mg dose, in 2 double-masked, controlled clinical studies (VIEW1 and VIEW2) for 24 months (with active control in year 1).

Safety data observed in the EYLEA group in a 52-week, double-masked, Phase 2 study were consistent with these results.

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

Adverse Reactions	Baseline to Week 52		Baseline to Week 96	
	EYLEA (N=1824)	Active Control (ranibizumab) (N=595)	EYLEA (N=1824)	Control (ranibizumab) (N=595)
Conjunctival hemorrhage	25%	28%	27%	30%
Eye pain	9%	9%	10%	10%
Cataract	7%	7%	13%	10%
Vitreous detachment	6%	6%	8%	8%
Vitreous floaters	6%	7%	8%	10%
Intraocular pressure increased	5%	7%	7%	11%
Ocular hyperemia	4%	8%	5%	10%
Corneal epithelium defect	4%	5%	5%	6%
Detachment of the retinal pigment epithelium	3%	3%	5%	5%
Injection site pain	3%	3%	3%	4%
Foreign body sensation in eyes	3%	4%	4%	4%
Lacrimation increased	3%	1%	4%	2%
Vision blurred	2%	2%	4%	3%
Intraocular inflammation	2%	3%	3%	4%
Retinal pigment epithelium tear	2%	1%	2%	2%
Injection site hemorrhage	1%	2%	2%	2%
Eyelid edema	1%	2%	2%	3%
Corneal edema	1%	1%	1%	1%
Retinal detachment	<1%	<1%	1%	1%

Less common serious adverse reactions reported in <1% of the patients treated with EYLEA were hypersensitivity, retinal tear, and endophthalmitis.

Macular Edema Following Retinal Vein Occlusion (RVO). The data described below reflect 6 months exposure to EYLEA with a monthly 2 mg dose in 218 patients following central retinal vein occlusion (CRVO) in 2 clinical studies (COPERNICUS and GALILEO) and 91 patients following branch retinal vein occlusion (BRVO) in one clinical study (VIBRANT).

Table 2: Most Common Adverse Reactions (≥1%) in RVO Studies

Adverse Reactions	CRVO		BRVO	
	EYLEA (N=218)	Control (N=142)	EYLEA (N=91)	Control (N=92)
Eye pain	13%	5%	4%	5%
Conjunctival hemorrhage	12%	11%	20%	4%
Intraocular pressure increased	8%	6%	2%	0%
Corneal epithelium defect	5%	4%	2%	0%
Vitreous floaters	5%	1%	1%	0%
Ocular hyperemia	5%	3%	2%	2%
Foreign body sensation in eyes	3%	5%	3%	0%
Vitreous detachment	3%	4%	2%	0%
Lacrimation increased	3%	4%	3%	0%
Injection site pain	3%	1%	1%	0%
Vision blurred	1%	<1%	1%	1%
Intraocular inflammation	1%	1%	0%	0%
Cataract	<1%	1%	5%	0%
Eyelid edema	<1%	1%	1%	0%

Less common adverse reactions reported in <1% of the patients treated with EYLEA in the CRVO studies were corneal edema, retinal tear, hypersensitivity, and endophthalmitis.

Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR). The data described below reflect exposure to EYLEA in 578 patients with DME treated with the 2-mg dose in 2 double-masked, controlled clinical studies (VIVID and VISTA) from baseline to week 52 and from baseline to week 100.

Table 3: Most Common Adverse Reactions (≥1%) in DME Studies

Adverse Reactions	Baseline to Week 52		Baseline to Week 100	
	EYLEA (N=578)	Control (N=287)	EYLEA (N=578)	Control (N=287)
Conjunctival hemorrhage	28%	17%	31%	21%
Eye pain	9%	6%	11%	9%
Cataract	8%	9%	19%	17%
Vitreous floaters	6%	3%	8%	6%
Corneal epithelium defect	5%	3%	7%	5%
Intraocular pressure increased	5%	3%	9%	5%
Ocular hyperemia	5%	6%	5%	6%
Vitreous detachment	3%	3%	8%	6%
Foreign body sensation in eyes	3%	3%	3%	3%
Lacrimation increased	3%	2%	4%	2%
Vision blurred	2%	2%	3%	4%
Intraocular inflammation	2%	<1%	3%	1%
Injection site pain	2%	<1%	2%	<1%
Eyelid edema	<1%	1%	2%	1%

Less common adverse reactions reported in <1% of the patients treated with EYLEA were hypersensitivity, retinal detachment, retinal tear, corneal edema, and injection site hemorrhage.

Safety data observed in 269 patients with nonproliferative diabetic retinopathy (NPDR) through week 52 in the PANORAMA trial were consistent with those seen in the phase 3 VIVID and VISTA trials (see Table 3 above).

6.2 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 immunoassays. 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 disease. For these reasons, 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 immunoreactivity 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 immunoreactivity.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Adequate and well-controlled studies with EYLEA have not been conducted in pregnant women. Aflibercept produced adverse embryofetal effects in rabbits, including external, visceral, and skeletal malformations. A fetal No Observed Adverse Effect Level (NOAEL) was not identified. At the lowest dose shown to produce adverse embryofetal effects, systemic exposures (based on AUC for free aflibercept) were approximately 6 times higher than AUC values observed in humans after a single intravitreal treatment at the recommended clinical dose [see Animal Data].

Animal reproduction studies are not always predictive of human response, and it is not known whether EYLEA can cause fetal harm when administered to a pregnant woman. Based on the anti-VEGF mechanism of action for aflibercept, treatment with EYLEA may pose a risk to human embryofetal development. EYLEA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data

Animal Data

In two embryofetal development studies, aflibercept produced adverse embryofetal effects when administered every three days during organogenesis to pregnant rabbits at intravenous doses ≥3 mg per kg, or every six days during organogenesis at subcutaneous doses ≥0.1 mg per kg.

Adverse embryofetal effects included increased incidences of postimplantation loss and fetal malformations, including anasarca, umbilical hernia, diaphragmatic hernia, gastroschisis, cleft palate, ectrodactyly, intestinal atresia, spina bifida, encephalomeningocele, heart and major vessel defects, and skeletal malformations (fused vertebrae, sternebrae, and ribs; supernumerary vertebral arches and ribs; and incomplete ossification). The maternal No Observed Adverse Effect Level (NOAEL) in these studies was 3 mg per kg. Aflibercept produced fetal malformations at all doses assessed in rabbits and the fetal NOAEL was not identified. At the lowest dose shown to produce adverse embryofetal effects in rabbits (0.1 mg per kg), systemic exposure (AUC) of free aflibercept was approximately 6 times higher than systemic exposure (AUC) observed in humans after a single intravitreal dose of 2 mg.

8.2 Lactation

Risk Summary

There is no information regarding the presence of aflibercept in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production/excretion. Because many drugs are excreted in human milk, and because the potential for absorption and harm to infant growth and development exists, EYLEA is not recommended during breastfeeding. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for EYLEA and any potential adverse effects on the breastfed child from EYLEA.

8.3 Females and Males of Reproductive Potential

Contraception

Females of reproductive potential are advised to use effective contraception prior to the initial dose, during treatment, and for at least 3 months after the last intravitreal injection of EYLEA.

Infertility

There are no data regarding the effects of EYLEA on human fertility. Aflibercept adversely affected female and male reproductive systems in cynomolgus monkeys when administered by intravenous injection at a dose approximately 1500 times higher than the systemic level observed humans with an intravitreal dose of 2 mg. A No Observed Adverse Effect Level (NOAEL) was not identified. These findings were reversible within 20 weeks after cessation of treatment.

8.4 Pediatric Use

The safety and effectiveness of EYLEA in pediatric patients have not been established.

8.5 Geriatric Use

In the clinical studies, approximately 76% (2049/2701) of patients randomized to treatment with EYLEA were ≥65 years of age and approximately 46% (1250/2701) were ≥75 years of age. No significant differences in efficacy or safety were seen with increasing age in these studies.

17 PATIENT COUNSELING INFORMATION

In the days following EYLEA administration, patients are at risk of developing endophthalmitis or retinal detachment. If the eye becomes red, sensitive to light, painful, or develops a change in vision, advise patients to seek immediate care from an ophthalmologist [see Warnings and Precautions (5.1)]. Patients may experience temporary visual disturbances after an intravitreal injection with EYLEA and the associated eye examinations [see Adverse Reactions (6)]. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

REGENERON

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Regeneron Pharmaceuticals, Inc.
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Initial U.S. Approval: 2011

Based on the August 2019
EYLEA® (aflibercept) Injection full
Prescribing Information.

EYL.20.09.0052

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SET UP FOR SUCCESS



Everyone remembers the uncertainty they felt when starting a new job; myriad questions remain unanswered, such as: Will I like the work? Will I get along with my colleagues? Is the practice culture a good fit? What about the local lifestyle?

At the same time, practice owners and hiring managers often have similar feelings of trepidation. Will the new doctor perform as expected? Will he or she work well with the rest of the team? Will this be a long-term solution to our staffing issue?

One of the best parts of hiring a new doctor for your practice is the chance to make sure the answer is “yes” to all of these questions right out of the gate. The trick is to hire with the future in mind and plan, plan, plan. A detailed employee contract and a transparent interview process can nip most problems in the bud.

Of course, everyone *wishes* they had an ironclad hiring structure; the problem is, there are almost too many facets to consider when hiring a new doctor: compensation, workload, training, partnership terms, office space, marketing, ... the list goes on. Not only that, but you must also plan for the what-ifs. Like it or not, you must address tail insurance coverage, restrictive covenants, and practice property rights in the event the new hire doesn’t work out. Ignoring these aspects of the employee agreement could make an enemy of the new employee and leave your practice vulnerable if the deal goes south.

This month’s featured article, “A New Physician: Future Friend or Foe?” can help you avoid just such a situation. Debra Phairas, an experienced health care practice consultant, discusses how to build an appropriate employee contract and hire smartly. If you take her 10 tips to heart, you will be well on your way to fostering a long-term partner-friend relationship with your new employee.

If your practice is already chock-full of talent, this issue also offers plenty of great information to help you differentiate your practice and flourish, choose smart investment options, and avoid Medicare audits. ■

ALAN RUBY, MD

SECTION EDITOR

TABLE OF CONTENTS

6 Lessons Learned from Medicare Audits of Retina Practices

By Joy Woodke, COE, OCS, OCSR

9 A New Physician: Future Friend or Foe?

By Debra Phairas

12 Growth Strategies, Part 1: Differentiate and Flourish

By Jim Flynn

14 Two Investment Options with Upside Potential and Downside Protection

By David Mandell, JD, MBA,
and Robert Peelman, CFP



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LESSONS LEARNED FROM MEDICARE AUDITS OF RETINA PRACTICES



Prepare your practice by reviewing published sources.

BY JOY WOODKE, COE, OCS, OCSR

They're back! After a (brief) reprieve during the public health emergency, CMS reinstituted audits in August 2020, including retina-specific probes and recovery audit contractor audits. Both CMS and Medicare Administrative Contractors (MACs) have published constructive feedback that can provide key lessons learned and prompt retina practices to conduct their own internal chart audits to ensure compliance and make sure they are prepared for an external audit.

In reviewing the publications from the CMS Education and Outreach team and the regional MACs, consistent themes emerge. The four most common reasons for denials as a result of postpayment probes and audits are insufficient documentation; does not support medical necessity; incorrect coding; and claim billed in error by provider.¹⁻³

By exploring these deficiencies within retina-specific scenarios, practices can assemble a guide to ensure appropriate documentation and correct coding, and this guide can be used to mount a proactive response to the inevitable Medicare audit. Let's look at each category in turn.

INSUFFICIENT DOCUMENTATION

The bottom line is that all documentation must be complete and maintained for each unique patient and available to an insurance carrier upon request.⁴ Each page of the chart should be legible, include patient identifiers, and be signed by the physician. These basic guidelines for documentation are outlined in payer policies and contracts.

Medicare published policies, local coverage determinations

(LCDs), local coverage articles (LCAs), and national coverage determinations (NCDs) provide additional guidance and requirements for documentation of retina services. Specific requirements outlined in these documents, if missing or incomplete, would be considered insufficient documentation.

Consider these examples from Palmetto GBA's policy L33467, the MAC for several southeastern states:⁵

- For extended ophthalmoscopy, the chart documentation should include a retinal drawing that is clearly identified and labeled, along with the specific method of examination (eg, scleral depression, type of lens used), and whether the pupil was dilated.
- For fundus photography, the medical record must include a copy of the photo, an interpretation and report, and documentation of whether the pupil was dilated for the procedure.⁵

AT A GLANCE

- Constructive feedback published by Medicare and regional Medicare administrators can guide retina practices in preparing for—or, better yet, avoiding—audits.
- Based on the published information, practices can proactively perform internal chart audits and create processes to monitor compliance.

THE BOTTOM LINE IS THAT ALL DOCUMENTATION MUST BE COMPLETE AND MAINTAINED FOR EACH UNIQUE PATIENT AND AVAILABLE TO AN INSURANCE CARRIER UPON REQUEST.

When chart records are submitted for an audit, staff members should double-check that all required documentation is provided. Common errors include the following:

- Missing pages of a record for a specific date of service;
- Lack of documentation for an intravitreal injection procedure record, including indication, dosage, or wastage of 1 unit or greater;
- Documentation of testing services lacking patient identifiers and the date of service on each printed page;
- Not submitting the physician order for a delegated test or procedure (eg, intravitreal injection);
- Neglecting to send injection consents, or sending documentation for the wrong eye treated;
- Lack of a valid physician signature.

In a service-specific medical review of results for “Drug Injection Services (Eylea [Regeneron] and Lucentis [Genentech]),” Novitas Solutions, the MAC for some southern and mid-Atlantic states, noted that it will “make multiple attempts to correct these error types before completion of the review” when documentation is insufficient.⁶ But the same document also stated that, if documentation is not submitted in a timely manner or there is no response to requests, the denial will be upheld.

DOES NOT SUPPORT MEDICAL NECESSITY

The Palmetto MAC’s report “Postpayment Service-Specific Probe Results for Drugs and Biological Services: Ranibizumab (Lucentis)” provides prevention recommendations for claims deemed not to support the medical necessity of services billed:²

- Documentation submitted for review should be complete and should support medical necessity of the service billed. Complete records include the original chart notes and any other records (eg, test interpretations, consents, prior chart notes) or other documentation supporting medical necessity.
- Documentation submitted should support the level of service reported by referencing Medicare policies. The medical record documentation must support the medical necessity of the services as stated in the policy.

For services provided in a retina practice, Medicare policies provide documentation requirements, indications, frequency edits, and usage guidelines that define medical necessity. Here are a few retina scenarios establishing medical necessity:

- Fluorescein angiogram documenting the evidence of

classic choroidal neovascularization (CNV) membrane secondary to AMD or subfoveal minimally classic CNV (where the area of classic CNV occupies < 50% of the area of the entire lesion) must be present before photodynamic therapy (PDT) begins.⁷

- Documentation for scanning computerized ophthalmic diagnostic imaging (SCODI; ie, OCT) when reporting long-term drug therapy must include the medication name and the underlying systemic condition.⁸
- SCODI for retina will be considered medically necessary no more than once every 2 months for a retinal disease not undergoing treatment. SCODI will be considered medically necessary no more than one test per month (every 28 days) to manage a patient with a retinal condition undergoing active treatment.⁸
- For intravitreal injection of bevacizumab (Avastin, Genentech), records should include the appropriate informed consent with respect to off-label use.⁹
- Injecting one medication in one eye and another in the fellow eye would not be expected. If different medications are used, the rationale for the therapy must be clearly documented in the medical record.⁹

Local MAC policies may differ. Practices can confirm the requirements that pertain to their region by exploring their relevant LCDs on the AAO website: aao.org/lcds.

INCORRECT CODING

Chart documentation should support the coding reported on the CMS-1500 claim form for each encounter. Medicare LCAs list the CPT and ICD-10-CM codes that support medical necessity for specified services. During an audit, the coding is compared with the documentation, and common errors such as these may be identified:

- The number of units reported for the medication injected did not match the procedure note documentation;³
- Wasted medication of 1 unit or greater was not documented and/or reported with the -JW modifier;
- The HCPCS code reported for bevacizumab was incorrect per Medicare LCD;
- The medication billed does not match the chart documentation;
- The ICD-10-CM code linked to the testing service was not for the diagnosis documented in the medical record or an incorrect diagnosis linked to an intravitreal injection;
- Missing anatomic modifiers (-RT or -LT) appended to CPT code 67028 for procedures performed close

together—this can prompt a review of two treatments performed within 28 days of each other to confirm whether they were for the same eye;

- Inappropriate use of -59 modifier to unbundle services.

CLAIM BILLED IN ERROR BY PROVIDER

One of the top reasons for denials as a result of audit is claims billed in error by the provider. Scenarios of this can include a claim submitted for the wrong patient or billing for services not provided.

Practices can proactively avoid this type of error by performing internal chart audits and creating processes to monitor compliance. A proactive approach is also a key component of a compliance program offered by the Department of Health and Human Services Office of Inspector General, designed to assist practices in preventing the submission of erroneous claims.¹⁰

AUDIT PREPAREDNESS

The reports published by Medicare provide retina practices with a clear focus for internal reviews. Guided by published payer policies, practices can formulate detailed plans to ensure compliance prior to an audit.

To learn more about preparing for audits, review my article “Preparing for Targeted Retina Audits” in the May/

June 2020 issue. Visit the AAO website (aao.org/retinapm) to find other resources. ■

1. CMS.gov. Cognitive Assessment: What's in the Written Care Plan? June 10, 2021. Accessed June 22, 2021. www.cms.gov/outreach-and-education/outreach/ffsprovpartprogprovider-partnership-email-archive/2021-06-10-minc
2. Palmetto GBA. Postpayment service-specific probe results for drugs and biological services: Ranibizumab (Lucentis) for January through March 2021. May 7, 2021. Accessed June 22, 2021. <https://palmettogba.com/palmetto/jmb.nsf/DID/22680E1WNX>
3. Novitas Solutions. Service Specific Review Results. Service Specific Review Results Drug Injection Services. March 9, 2021. Accessed June 22, 2021. www.novitas-solutions.com/webcenter/portal/Medicare/H/pagebyid?contentId=00246302
4. Local Coverage Determination (LCD): Scanning Computerized Ophthalmic Diagnostic Imaging (L35038). Medicare Coverage Database. October 25, 2019. Accessed June 22, 2021. www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=35038
5. Medicare Coverage Database. Local Coverage Determination (LCD): Ophthalmology: Extended Ophthalmoscopy and Fundus Photography (L33467). March 9, 2021. Accessed July 6, 2021. www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=33467
6. Novitas Solutions. Service Specific Review Results. March 9, 2021. Accessed June 22, 2021. <https://www.novitas-solutions.com/webcenter/portal/Medicare/H/pagebyid?contentId=00246302>
7. Medicare Coverage Database. National Coverage Determination (NCD) for Photodynamic Therapy (80.2). July 13, 2013. Accessed June 22, 2021. www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=128
8. Medicare Coverage Database. Local Coverage Determination for Scanning Computerized Ophthalmic Diagnostic Imaging (L35038). October 31, 2019. Accessed June 25, 2021. www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=35038
9. Medicare Coverage Database. Local Coverage Determination (LCD): Vascular Endothelial Growth Factor Inhibitors for the Treatment of Ophthalmological Diseases (L36962). October 1, 2019. Accessed June 25, 2021. www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=36962
10. Department of Health and Human Services. OIG Compliance Program for Individual and Small Group Physician Practices. October 5, 2000. Accessed June 25, 2021. Federal Register vol 65. <https://oig.hhs.gov/authorities/docs/physician.pdf>

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A NEW PHYSICIAN: FUTURE FRIEND OR FOE?



When hiring a new doctor, plan ahead to avoid headaches down the road.

BY DEBRA PHAIRAS

The decision to add a new physician to your practice is a big one, and not something you want to get wrong. After all, you are looking to create an open, trusting, fully transparent, long-term, *partner-friend* relationship with the new person. With the right mindset going into the hiring process, you can make the right choice and ensure that everyone is happy with the terms of employment from the outset.

The biggest mistake to avoid is to say, “Let’s see how it goes with you as an employee, and we will figure out the shareholder or partnership terms in a few years.” This is a recipe for disaster.

You do not want to create a *foe*, or possible competitor, if the new employee physician decides to leave and set up a practice around the corner because the terms were not clearly spelled out, or if feelings of distrust arise due to lack of clarity regarding the road to becoming a partner.

AT A GLANCE

- ▶ In interviews, discuss the practice’s philosophies (eg, cash or credit for purchases; conservative or progressive) and try to discern whether the candidate has the same values and mindset.
- ▶ Before you offer a candidate the job, decide on the methodology and approximate cost of a buy-in to the practice.
- ▶ Mentor the new employee physician, and demonstrate how to build referral sources and patient confidence to book procedures and surgeries.

HELP EMPLOYEE PHYSICIAN CANDIDATES MAKE A GOOD DECISION ABOUT THE OPPORTUNITY BY ALSO DISCUSSING LIFESTYLE ISSUES SUCH AS REAL ESTATE, SCHOOLS, RECREATION, CULTURE, ENTERTAINMENT, SPORTS, AND YOUR BUSINESS AND MEDICAL PHILOSOPHIES.

The recommendations that follow are based on my years of experience helping practice owners both to bring in employee physicians and to repair damage to existing relationships. (This includes doctors who sued each other over verbal promises made during the employment period.)

10 TIPS FOR FINDING THE RIGHT EMPLOYMENT STRUCTURE

1 Make a list and discuss the following: compensation and how and when salary is paid; benefits; hours and days of the week; surgery or procedure times; work locations; the new person's ability to dictate schedules, exam room space, and physician office space; memberships in national, state, and local organizations; cellphone plans and expectations; transportation and entertainment perks; working conditions; and practice-building expectations.

2 Write an employment offer or contract that spells out the terms discussed in Tip No. 1.

3 When you interview, look for a candidate with a confident attitude, willingness to work hard, and marketing and management capabilities. Discuss the practice's philosophies (eg, cash or credit for purchases; conservative or progressive) and try to discern if the candidate has the same values and mindset.

4 In both the interview and the employment contract, state that the employee physician will report to the senior physician or physician owners any marketing activities the employee has conducted each quarter to help build the practice. Examples may include visiting referring ophthalmologists' offices; taking referring doctors to lunch; publishing articles; and speaking at grand rounds and community locations such as retirement or senior living facilities or on radio, TV, or newspaper programs.

5 Decide who will be responsible for any tail insurance should the associate leave the practice before

becoming a partner. This generally follows the rules of supply and demand. If you have many candidates eager to join your practice, you may require that the employee be responsible for tail insurance. If your applicant pool is small, you may have to pay the tail. You can also decide to split the tail 50/50. Unfortunately, the decision on how to handle the tail is often left out of contracts, leading to misunderstandings.

6 Clearly state that all accounts receivable, charts, lists, and practice trade secrets are the employer's property. The new employee physician should not have rights to any of these. If the associate does not stay with the practice, the information in patients' charts can be obtained through proper release-of-information requests, but the actual hard copy chart is the work product of the physician owner of the practice.

7 Find out if restrictive covenants are legal in your state by calling your state medical association. If so, you can specify in the contract that the employee physician cannot leave your practice and set up a competing practice within a certain distance of your practice. Depending on the state, restrictive covenants may be allowable only after a physician becomes a shareholder or partner. If such covenants are allowed, they must be reasonable: for example, limited geographically to the draw area of the practice and temporally to 2 to 3 years.

8 Help employee physician candidates make a good decision about the opportunity by also discussing lifestyle issues such as real estate, schools, recreation, culture, entertainment, sports, and your business and medical philosophies.

9 Create an incentive program that will help the employee physician know what is expected in terms of productivity. Share practice expense information with the physician to illustrate what it takes to run a practice and what revenue is necessary to achieve a desired net income. If you have a

serious candidate, share financial data to the degree you are comfortable, but ensure that the employee physician signs a confidentiality agreement. After the physician reaches the incentive threshold, the additional money generated should either be given in bonus or placed in escrow to satisfy the buy-in should partnership be offered. If the doctor decides not to join the practice and become a partner, the bonus amount belongs to the associate and should be given in the final paycheck.

10 The practice's current overhead ratio should be calculated to determine break-even. A 50% operating overhead would double the direct costs in additional overhead. It is only fair to the new employee physician to exclude the senior partner or partners' discretionary expenses such as travel, entertainment, etc. This will determine a break-even point the employee physician must achieve to pay for his or her salary, benefits, and contribution to overhead.

The employer deserves a return on investment for outlaying money for salary and benefits. The employee could be given 25% of the excess revenue generated beyond the break-even point, with the employer retaining 25% for return on investment. The entire bonus can be given to the employee, placed in escrow for credit against the buy-in, or split in some proportion. Here is an example.

Employee Cost

\$300,000 Salary
 + \$75,000 Benefits (payroll tax, worker's compensation, health and life insurance, 401K)
 = **\$375,000** Total direct MD costs
 + **\$375,000** Overhead costs (at 50% overhead ratio; this includes share of fixed costs such as rent, and new and incremental variable costs such as medical, office supplies, telephone, dues, and subscriptions)
 = **\$750,000** Break-even needed in revenue/collections

Employee Revenue

\$800,000 Associate revenue/collections
 - \$750,000 Break-even
 = **\$50,000** Excess

Excess Distribution

- **\$25,000** (50%) applied to operating overhead
 - **\$12,500** (25%) to owners for return on investment
 - **\$12,500** (25%) to employee for bonus or escrow toward buy-in

ROAD TO PARTNERSHIP

Before you offer a candidate the job, make sure to decide on the methodology and approximate cost of a buy-in to the practice. Having this prepared in advance allows the

prospective employee physician to make a long-term decision about future opportunities within the practice.

Here are a few questions you should be answering as a part of that process.

- **Will goodwill or intangible asset value be included, and, if so, by what methodology?** Give an estimate of this amount in today's dollars. You should assess goodwill or intangible asset value back to the point in time the employee physician came into the practice. Thereafter, the employee is also building goodwill.
- **Will accounts receivable be included in the buy-in?** These should be discounted by insurance adjustments and age.
- **How will tangible assets be valued?** Will they be based on book value or fair market value? Fair market value is usually more in line with true value. Items may have been purchased and expensed but are not on the depreciation schedule; if older than 12 years and still in use, book value would place this value at zero.
- **Will a buy-out be valued the same way?** Will the new physician have a buy-in and buy-out of a senior partner at the same time?
- **How will the physician pay for the buy-in?** Will a lump sum borrowed from the bank be required, or will the senior partner or group allow the associate to make payments over time taken out of his or her monthly draw over, say, 3 to 6 years? You should keep the practice buy-in and any surgery center buy-in as two transactions and value them separately, just as real estate transactions would be.

FINAL TO-DOS

In addition to these considerations, be sure to tell the potential associate that marketing activities are a requirement to become a partner.

Once hired, you should mentor the new employee physician and demonstrate how to build referral sources and patient confidence to book procedures and surgeries.

Assign an area of management responsibility before offering partnership, and assess whether the associate is shareholder or partnership material by his or her degree of involvement and ability.

The road to future successful partnerships with any associate can be summed up with the four C's: Have the *courage* to *communicate*, *confront*, and *compromise*.

After all, it's better to have a friend in the practice than a foe around the corner. ■

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GROWTH STRATEGIES, PART 1: DIFFERENTIATE AND FLOURISH



A successful practice embraces what makes it special.

BY JIM FLYNN

The COVID-19 pandemic had a profound impact on patient volume and revenues for most retina practices. To help regrow your practice, now is the time to focus on building a differentiated practice brand. Couple this with the adoption of measurable online growth strategies, and you have a long-term recipe for continued success.

This article discusses how to discover your practice brand distinction, grow your referral base, and improve your visibility to patients. In addition, a how-to diagnostic included here will help you assess the effectiveness and optimization of your medical practice website. Part 2 of this two-part series will be a deeper dive into how search engines work; the role of content; and the importance of paid online media, patient nurturing, and strategies for assessing return on investment (ROI).

At the core of any successful practice growth initiative are three key components:

- Differentiate
- Get found
- Convert

This article focuses on the first two; Part 2 of the series will focus on conversion.

DIFFERENTIATED PRACTICE VALUE

To grow your patient base and revenue, your practice must offer patients something that other practices do not. After all, differentiation is how Starbucks can sell specialty coffee for \$6.00 while the coffee at your local gas station is only a fraction of that.

I often hear ophthalmologists and practice administrators say, “We are not really different, we do the same things as the practice across town.” However, your practice *is* different. It has its own vibe, its own culture, its own look. It has a different reason for existing, and you and your fellow retina specialists are at the core of that difference. Everything is centered on how what you say you’ll do (your promise) matches up with what you actually do (your performance). The greater the overlap between what you say you’ll do and what you actually do, the greater the trust you build with patients (Figure 1).

To find the truth behind your practice differentiation, take a close look at the inner workings of your practice. The differentiated practice value—what sets your practice apart from

others—will be your practice brand.

To help with this discovery process, you can plan a summit of your team, led by an outside moderator. The discovery session will look different depending on your practice type—whether a solo practice or a multispecialty group—but the objectives should always include these four questions.

- Who are you today?
- What makes you different?
- Why do you do what you do?
- What are you capable of becoming?

Your differentiated practice value, once clarified, provides direction for every other aspect of your business development process.

BECOME A VALUED RESOURCE

Unless you are part of a multispecialty practice, a large percentage of your new patients likely comes from referrals, including primary care providers, other ophthalmologists, and optometrists. They value your expertise on the retina; use this to your advantage by being available for phone and, more important, e-consults. Patients no longer need to be in your chair to have an initial consultation. With fundus cameras, OCT, and ultra-widefield imaging, you can assist your fellow practitioners in making critical diagnoses. Some practices take this outreach and relationship-building a step further by conducting continuing education classes or other

AT A GLANCE

- The greater the overlap between what you say you’ll do and what you actually do, the greater the trust you build with patients.
- Your differentiated practice value, once clarified, provides direction for every other aspect of your business development process.
- Between 50% and 65% of a practice’s web traffic comes from mobile devices, yet many practices have outdated websites that are not mobile-friendly.

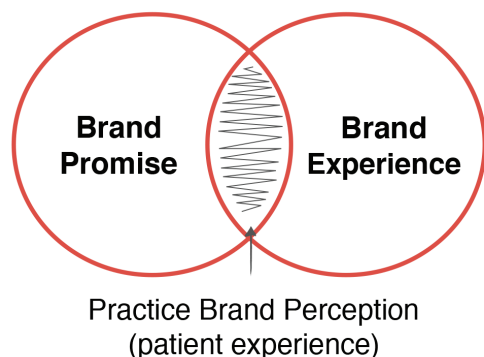


Figure 1. The greater the overlap between your differentiated practice brand promise and the performance of your brand, the greater the trust will be with patients and referral partners.



Figure 2. The journey patients take to find your practice is often a serpentine path that includes many online touchpoints; being visible at those touchpoints drives success.

seminars for optometrists and general ophthalmologists on evenings or weekends.

These steps can help to differentiate your practice and build your referral pipeline. They also position you well to become a valuable expert in the area. Some practices provide a resource section on their website for referring physicians, where they post unusual and interesting pathology, commonly asked questions, and other pearls of wisdom.

SERVE PATIENTS ALONG THEIR JOURNEY

Today's patients are much more educated on medical conditions and available treatment options than were previous generations. According to one survey, 80% of adult internet users have researched at least one major health topic online.¹ Half of this research is done on behalf of family members. This is particularly important for retina practices, considering that the adult children of your patients are likely the ones doing that online research.

This trend has a clear impact on the way patients and family members seek information and choose a provider. For example, we have found that most health care practices that we work with have between 50% and 65% of their web traffic coming from mobile devices, yet many practices have outdated websites that are not mobile-friendly.

It's a brave new (mostly digital) journey that patients take today, and understanding what that journey looks like for prospective patients can affect the growth and success of your practice in important ways (Figure 2).

Many practice owners and administrators know that their websites are outdated but neglect to update them. But if you

RATE YOUR WEBSITE PERFORMANCE

Rate each metric on a scale from 1 to 5; 1 = not at all, 5 = very well.

1. Demonstrates clear differentiated practice value compared with competitors.
2. Provides content and visuals that help the visitor understand your narrow and unique expertise.
3. Includes fresh and relevant content for patients. The Google algorithm gives content that is fresh a higher quality score, which helps with your ranking on the search engine results page; Relevant content is judged based on the keywords in the content that are being searched for and when people stay on a page to read the content.
4. Presents enduring (evergreen) content on key procedures.
5. Uses a responsive design and is mobile- and tablet-friendly.
6. Performs well in organic search (ie, it appears on page 1 using keywords that patients would use, not including your practice name).
7. Effectively integrates with social media channels to drive engagement and traffic.
8. Is easy to navigate, with no outdated or confusing navigation elements.
9. Uses persona targeting (content, offers, and visuals targeting a specific type of patient) to help users identify themselves as prospective patients.
10. Has a clear strategy to convert visitors to patients.
11. Effectively uses calls to action (ie, "Schedule an Appointment" button).
12. Drives content and other offers to landing pages, rather than pages on your website.
13. Includes HIPAA-compliant customer relationship management database integration to capture prospective patients as leads.
14. Incorporates automated marketing tools to foster ongoing engagement with users.
15. Has a clear return-on-investment strategy (ie, the marketing dollars spent to get a visitor to the website and converted to a patient are outweighed by the lifetime value of the patient).

compare your website to those of other practices in your region, you might be surprised by how much a dated look and poor usability are damaging to your web presence.

FISH WHERE THE FISH ARE

During my childhood, my family would take summer vacations to Lake Van Auken near Hartford, Michigan. Every day we would get up early and go fishing, and usually we came home with hardly a fingerling. Joe, the old fisherman next door, always came home with a full basket. After days of returning without fish to cook, Joe finally shared his secret, "You need to fish where the fish are." Joe taught us where the fish were, why they were there, and how to use bait the fish actually liked.

The same concepts that shaped our fishing experience apply to building a pipeline of new patients. Part 2 of this series will focus on unpacking those lessons. ■

1. Internet Health Resources. Pew Research Center. July 16, 2003. Accessed August 5, 2021. www.pewresearch.org/internet/2003/07/16/internet-health-resources

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TWO INVESTMENT OPTIONS WITH UPSIDE POTENTIAL AND DOWNSIDE PROTECTION



Equity indexed life policies and structured notes can be valuable additions to your portfolio.

BY DAVID MANDELL, JD, MBA, AND ROBERT PEELMAN, CFP

With stock market volatility likely to remain high until the COVID-19 crisis ends, many investors, including retina specialists, have become more risk averse. At the same time, bank account, CD, and treasury yields are near all-time lows. In this environment, many physicians may be looking for investment options that provide some upside potential with downside protection. In this article we discuss two options that, if implemented properly, can achieve this goal: equity indexed universal life (EIUL) insurance policies and structured notes.

EQUITY INDEXED UNIVERSAL LIFE POLICY BASICS

An EIUL policy is a type of cash-value life insurance policy, as it has a cash value and investment portion as well as a death benefit. Cash-value policies are also called permanent policies because they do not have a term after which they will expire (as term policies do) and are intended to be kept in place until the insured dies.

There are several types of cash-value insurance, including variable and whole life, for which the cash values grow based on a variety of methods. With an EIUL policy, the cash values are used to implement what's known as a *collar strategy*.

In this type of strategy, the insurance carrier sells call options and buys protective put options on positions it owns. In return, the policy's performance is tied to an index, such as the S&P 500.

Through the collar strategy, the carrier can guarantee policyholders a floor, or minimum return (eg, 0%) that protects them from losses. With an EIUL, if the index the policy is tied to goes down 20%, the cash value does not go down. EIUL policy cash values also have a ceiling, or cap, on the upside (eg, 10%), which means that if the index goes up beyond the

cap, the policyholder will get a portion of the total upswing, capped at 10%.

Because of their upside potential and downside protection, EIUL products have been extremely popular since the Great Recession, with more than \$2 billion invested into new EIUL policies in 2018 alone.¹

Benefits

In addition to the downside protection and upside potential, EIUL policies have the benefit of the cash value growing tax-free and, if managed properly, accessible tax-free. Also, in many states, the cash value is protected from lawsuits by statute.

Risks

As with any investment product, EIUL insurance has risks. One is that EIUL policies are not 100% liquid; in fact, policies generally have a surrender period of 8 to 12 years, during which, if one surrenders the policy completely, a surrender charge is assessed against the cash value. This charge can be avoided by withdrawing some, but not all, of the cash value.

Another risk is the possibility that the insured will not be able to adhere to the designed premium schedule. A policy's size and costs are based on the premium schedule charted out when the policy is implemented (eg, \$10,000 premiums each year for 10 years). A deviation from this premium schedule by the policyholder can result in a significant negative impact on the policy performance.

Finally, because an EIUL policy's cash values are managed by the insurance carrier, there is carrier solvency risk. Thus, using top-rated companies with track records of at least 100 years is crucial.

STRUCTURED NOTES BASICS

Structured notes are hybrid securities, as they combine the features of multiple different financial products into one. Issued by some of the largest banks in the world, structured notes combine bonds and additional investments to offer the features of both debt assets and investment assets. It is estimated that \$2 trillion is invested in structured notes worldwide.

Structured notes are not direct investments; they are derivatives, as their value is derived from another linked asset. The return on the note depends on the issuer repaying the underlying bond plus a premium based on the linked asset, less the bank's fee.

Most structured notes have four common elements:

- Maturity can range from 6 months to many years; most are 3 to 5 years.
- The linked asset is typically a stock, bond, exchange-traded fund, index, currency, or commodity.
- There is a payoff—the amount the investor gets at maturity.
- The investor has a level of protection if the linked asset loses value.

Risks

There are several risks inherent in a structured note investment.

Complexity: Structured notes are complex financial instruments. Investors should understand the reference assets or indexes involved and determine how the note's payoff structure incorporates these in calculating the note's performance.

Market risk: Although some notes have buffers and other protection factors built in to reduce the impact of a bad market, the investor may still suffer a financial loss as with any other investment that is not FDIC insured or principal-protected.

Lack of liquidity: Should investors need access to their funds prior to maturity, they will be forced to sell the note on the open market. Although there may be a buyer willing to purchase it at some price, typically it is at a deep discount to what the note is worth.

Issuer risk: Ultimately, the structured note is only as strong as the issuer. If the issuer defaults, the entire principal could be lost.

WORK WITH THE RIGHT ADVISOR

Both EIUL policies and structured notes can be valuable components of a physician's overall portfolio, especially for investors looking for downside protection with upside potential.

Because these products are complex and contain inherent risks, working with a knowledgeable professional advisor to evaluate the options is always recommended. ■

1. Iacurci G. Indexed universal life insurance sales continue hot streak. InvestmentNews. March 15, 2019. www.investmentnews.com/indexed-universal-life-insurance-sales-continue-hot-streak-78621

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