EARNING FIVE-STAR REVIEWS:
OPTIMIZING YOUR ONLINE REPUTATION

★ TIPS FOR RUNNING AN EFFECTIVE PRACTICE ★
★ STEP THERAPY: WHAT IS COMING IN 2019 ★
★ CODING FOR EXTENDED OPHTHALMOSCOPY ★
INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS
EYLEA® (aflibercept) Injection 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) in patients with DME.

CONTRAINDICATIONS
• EYLEA® (aflibercept) Injection 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.

EYLEA is a registered trademark of Regeneron Pharmaceuticals, Inc.

REGENERON
© 2018, Regeneron Pharmaceuticals, Inc. All rights reserved.
777 Old Saw Mill River Road, Tarrytown, NY 10591
• 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.

Please see Brief Summary on following pages.

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) in Patients with DME

4 CONTRAINDICATIONS
4.1 Ocular or Periocular Infections
EYLEA is contraindicated in patients with ocular or periocular 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 2,711 patients treated with EYLEA constituted the safety population in seven phase 3 studies. Among those, 2,110 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 1,824 patients with wet AMD, including 1,223 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

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>Baseline to Week 52</th>
<th>Baseline to Week 96</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EYLEA (N=1824)</td>
<td>Active Control (ranibizumab) (N=595)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EYLEA (N=1824)</td>
</tr>
<tr>
<td>Conjunctival hemorrhage</td>
<td>25%</td>
<td>28%</td>
</tr>
<tr>
<td>Eye pain</td>
<td>9%</td>
<td>9%</td>
</tr>
<tr>
<td>Cataract</td>
<td>7%</td>
<td>7%</td>
</tr>
<tr>
<td>Vitreous detachment</td>
<td>6%</td>
<td>6%</td>
</tr>
<tr>
<td>Vitreous floaters</td>
<td>6%</td>
<td>7%</td>
</tr>
<tr>
<td>Intraocular pressure increased</td>
<td>5%</td>
<td>7%</td>
</tr>
<tr>
<td>Ocular hyperemia</td>
<td>4%</td>
<td>8%</td>
</tr>
<tr>
<td>Corneal epithelium defect</td>
<td>4%</td>
<td>5%</td>
</tr>
<tr>
<td>Detachment of the retina</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Retinal pigment epithelium</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Injection site pain</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Foreign body sensation in eyes</td>
<td>3%</td>
<td>4%</td>
</tr>
<tr>
<td>Lacrimation increased</td>
<td>3%</td>
<td>1%</td>
</tr>
<tr>
<td>Vision blurred</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>Intraocular inflammation</td>
<td>2%</td>
<td>3%</td>
</tr>
<tr>
<td>Retinal pigment epithelium tear</td>
<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>Injection site hemorrhage</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Eyelid edema</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Corneal edema</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Retinal detachment</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
</tr>
</tbody>
</table>

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 CRVO in 2 clinical studies (COPERNICUS and GALILEO) and 91 patients following BRVO in one clinical study (VIBRANT).

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

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>CRVO</th>
<th>BRVO</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EYLEA (N=218)</td>
<td>Control (N=142)</td>
</tr>
<tr>
<td>Eye pain</td>
<td>13%</td>
<td>5%</td>
</tr>
<tr>
<td>Conjunctival hemorrhage</td>
<td>12%</td>
<td>11%</td>
</tr>
<tr>
<td>Intraocular pressure increased</td>
<td>8%</td>
<td>6%</td>
</tr>
<tr>
<td>Corneal epithelium defect</td>
<td>5%</td>
<td>4%</td>
</tr>
<tr>
<td>Vitreous floaters</td>
<td>5%</td>
<td>1%</td>
</tr>
<tr>
<td>Ocular hyperemia</td>
<td>5%</td>
<td>3%</td>
</tr>
<tr>
<td>Foreign body sensation in eyes</td>
<td>3%</td>
<td>5%</td>
</tr>
<tr>
<td>Vitreous detachment</td>
<td>3%</td>
<td>4%</td>
</tr>
<tr>
<td>Lacrimation increased</td>
<td>3%</td>
<td>4%</td>
</tr>
<tr>
<td>Injection site pain</td>
<td>3%</td>
<td>1%</td>
</tr>
<tr>
<td>Vision blurred</td>
<td>1%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Intraocular inflammation</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Cataract</td>
<td>&lt;1%</td>
<td>1%</td>
</tr>
<tr>
<td>Eyelid edema</td>
<td>&lt;1%</td>
<td>1%</td>
</tr>
</tbody>
</table>
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.

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, DME, 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 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

Manufactured by:
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591

EYLEA is a registered trademark of Regeneron Pharmaceuticals, Inc.
© 2018, Regeneron Pharmaceuticals, Inc.
All rights reserved.

Issue Date: November 2018
Initial U.S. Approval: 2011
Based on the August 2018 EYLEA (aflibercept) Injection full Prescribing Information.

US-LEA-13708(2)a

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

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

Adverse embryofetal effects included increased incidences of postimplantation loss and fetal malformations, including anasarca, umbilical hernia, diaphragmatic hernia, gastrochisis, cleft palate, ectrodactyly, intestinal atresia, spina bifida, encephalomeningocele, heart and major vessel defects, and skeletal malformations (fused vertebrae, sternoee, 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.

Less common adverse reactions reported in <1% of the patients treated with EYLEA were: conjunctivitis 2%, conjunctival hemorrhage 2%, conjunctivitis (5%) in DME. The adverse reactions that were ≥1% in DME studies (VIVID and VISTA) from baseline to week 52 and from baseline to week 100.

Diabetic Macular Edema (DME). 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.

8.6 Driving and Other Responsibilities

The adverse reactions that were ≥1% in DME studies (VIVID and VISTA) from baseline to week 52 and from baseline to week 100.

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.
REPUTATION IN THE INTERNET AGE

With increasing frequency, we make our decisions about where to eat, which hotel to stay in, or which destinations to visit based on reviews left by strangers online. For many patients, choosing among potential physicians is no different. Patients seeking care may Google a doctor’s name and decide whether or not to visit a practice based on web reviews from former patients. That’s why it is more important than ever to make sure that your online presence leaves potential patients with a good impression.

This issue’s feature article is written by Ravi D. Goel, MD, a man who has learned a lot about the contours of using social media and having an online presence. His article outlines how to protect your online reputation. Dr. Goel provides several pearls and quick fixes to help elevate your profile.

Also in this issue: George Williams, MD, provides an overview of step therapy in 2019 (and beyond); Larry Brooks gives an in-depth guide to running an efficient practice; and Joy Woodke, COE, OCS, OCSR, explains coding for extended ophthalmoscopy.

ALAN RUBY, MD
SECTION EDITOR

TABLE OF CONTENTS

7 Coding Advisor: Coding for Extended Ophthalmoscopy
By Joy Woodke, COE, OCS, OCSR

11 Protecting Your Online Reputation
By Ravi D. Goel, MD

13 Perfecting Your Practice: Running an Efficient Practice
By Larry R. Brooks

16 Pennsylvania Avenue Updates: Step Therapy in 2019 and Beyond
By George A. Williams, MD
What do commercial payers’ audits and CMS’ Target, Probe and Educate audits currently have in common? Both are now targeting extended and subsequent ophthalmoscopy to ensure that documentation consistently meets the payer’s requirements.

DEFINING EXTENDED OPHTHALMOSCOPY

Extended ophthalmoscopy (EO) is a detailed examination and drawing of the fundus that goes beyond the standard funduscopy performed during an eye exam. It includes examination of the periphery of the eye, with dilation, and is performed for specific conditions. There are two different CPT codes for EO, one for the initial study and one for a subsequent study. The CPT code definitions can be found in Table 1.

Routine ophthalmoscopy, including routine direct and indirect ophthalmoscopy, is considered part of a standard eye examination and is included under the appropriate level of evaluation and management (also called E/M) or Eye visit code. EO, by contrast, is a more extensive examination that requires a detailed, labeled drawing of pathology that cannot be documented in any other way. It also requires that an additional diagnostic technique be performed and documented, which may include 360° scleral depression, fundus contact lens, or 90-D lens.

Initial Versus Subsequent

Determining the correct CPT code for EO starts with understanding the difference between initial and subsequent. This distinction does not refer to a new versus established patient, but rather to the diagnosis of an initial event (CPT 92225) and then, if relevant, a subsequent documentation of the progression of a chronic condition (CPT 92226).

For example, an established patient is seen and an extended
examination by scleral depression is performed. The retina specialist confirms the diagnosis of macular hole in the right eye and documents it with a retinal drawing with labels and an interpretation and report. The correct code for this EO would be 92225 Ophthalmoscopy, extended, initial.

A few months later, this same patient returns for an examination, and another EO is performed by scleral depression. The macular hole is worsening, and the retina specialist documents this with a retinal drawing and interpretation and report. This EO would be coded 92226 Ophthalmoscopy, extended, subsequent.

If the same patient is seen 6 months later for a retinal tear that is determined by EO and documented accordingly, because this is the initial diagnosis of a new problem, 92225 would be the appropriate CPT code to bill for this service.

Bilateral Indicator

CPT codes 92225 and 92226 both have a bilateral indicator of 3. This means that, when performed bilaterally with pathology, the reimbursement will be 100% allowable per eye. Most insurance carriers prefer the -RT, -LT, or -50 modifier to indicate bilateral services.

BUNDLES

Each quarter, Medicare publishes National Correct Coding Initiative (NCCI) edits to identify CPT codes that are considered bundled and not separately payable when performed on the same day. A link to these edits can be found at aao.org/coding and in the AAO’s Complete Guide to Retina Coding.

Since July 2013, EO has been bundled with retinal lasers, injections, and surgeries when performed on the same day. See Table 2 for an example of the NCCI edits for 92225 and 92226 EO and for 67028 intravitreal injection and 67108 repair of retinal detachment.

There are two types of bundled codes: mutually exclusive, which can never be unbundled and have an indicator of 0, and comprehensive, which have an indicator of 1 and may be paid separately under limited circumstances and must meet the definition of modifier -59 or per specific local coverage determinations (LCDs).

The NCCI bundles for EO have an indicator of 1. When is it appropriate to unbundle an EO performed on the same day as a surgery? When EO is performed and pathology is diagnosed in the fellow eye, not the eye undergoing surgery.

INSURANCE COVERAGE

To determine the documentation and medical necessity requirements for EO, each payer policy should be reviewed. Medicare Administrative Contractors (MACs) may have relevant LCDs or local coverage articles. Commercial payers may also publish policies related to these services.

Although coverage policies vary by payer, here are some basic requirements to keep in mind when coding for EO services:

- Documentation of medical necessity;
- A drawing that is clearly identified, labeled, and appropriately represents the retinal pathology;
- Interpretation and report;
- Extended fundus exam with documentation of diagnostic technique (eg, 90-D lens);
- Assessment of change in pathology for subsequent EO.

There are four MACs that have policies related to EO. Each of these policies is unique and should be reviewed for guidance if you practice in that jurisdiction. To review and maintain a current copy of the published LCDs per MAC, visit aao.org/lcds.

Table 3 provides a list of active LCDs for EO regarding specific MACs’ definitions of medical necessity or specific documentation requirements. For

| TABLE 1. EXTENDED OPHTHALMOSCOPY CODES |
|-----------------|----------------------------------|
| Code            | Definition                        |
| 92225 (Initial) | Ophthalmoscopy, extended, with retinal drawing (eg, for retinal detachment, melanoma), with interpretation and report; initial |
| 92226 (Subsequent) | Ophthalmoscopy, extended, with retinal drawing (eg, for retinal detachment, melanoma), with interpretation and report; subsequent |

| TABLE 2. EXAMPLES OF NCCI EDITS |
|-----------------|-----------------|-----------------|-----------------|
| Column 1 | Column 2 | Date of Bundle | Indicator |
| 67028 | 92225 | 2013/07/01 | 1 |
| 67028 | 92226 | 2013/07/01 | 1 |
| 67108 | 92225 | 2013/07/01 | 1 |
| 67108 | 92226 | 2013/07/01 | 1 |

Note: Code 67028 (intravitreal injection); 67108 (repair of retinal detachment).
example, First Coast Service Options, the MAC for Jurisdiction N, indicates in its LCD L34017 that medical records must include the following:

- Complaint or symptoms necessitating the EO;
- Notation of the dilation and drug used for the examined eye;
- Method of examination;
- “A detailed drawing of the retina showing anatomy in the patient as seen at the time of examination, including the pathology found and a legible narrative report of the findings”;
- For 92226, assessment of the change from previous encounters.

The LCD for First Coast Service Options continues with coding guidelines for ophthalmoscopy in a supplemental fact sheet discussing bilateral coding for EO codes 92225 and 92226:

- Usual payment adjustment for bilateral procedures does not apply;
- Do not append -50 modifier, report codes on separate lines appending -RT or -LT modifiers;
- Proper coding will prevent duplicate billing and allow full reimbursement per eye.

As another example, National Government Services (NGS), the MAC for Jurisdictions 6 and K, has unique requirements related to the retinal drawing in its LCD L33567:

- Size, 3 to 4 inches;
- Drawing must be identified and labeled;
- Noncolored drawings are acceptable, but color drawings with 4 to 6 standard colors are preferred;
- Separate drawing for optic nerve abnormalities.

Additional guidance regarding exclusive bundles is outlined in the NGS LCD. Although not bundled under NCCI, the NGS LCD specifies that EO performed with fundus photography (CPT 92250), fluorescein angiography (CPT 92235), ultrasound (76512), or OCT (CPT 92134) will be denied as not medically necessary. The physician must provide a “reasonable medical exception” for performing EO and “additive (nonduplicative) information.”

**TABLE 3. MEDICARE COVERAGE POLICIES FOR EO**

<table>
<thead>
<tr>
<th>MAC</th>
<th>Jurisdictions</th>
<th>Policy</th>
<th>Effective Date</th>
<th>Last Update</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cigna Government Services</td>
<td>J15 – Kentucky, Ohio</td>
<td>LCD L34399</td>
<td>10/1/2017</td>
<td>5/31/2018</td>
</tr>
<tr>
<td>Cigna Government Services</td>
<td>J15 – Kentucky, Ohio</td>
<td>LCA A52398</td>
<td>10/1/2015</td>
<td>5/31/2018</td>
</tr>
<tr>
<td>First Coast Service Options</td>
<td>JN – Florida, Puerto Rico, Virgin Islands</td>
<td>LCD L34017 and fact sheet</td>
<td>10/1/2017</td>
<td>9/22/2017</td>
</tr>
<tr>
<td>Palmetto</td>
<td>JM – Alabama, Georgia, Tennessee; J1 – North Carolina, South Carolina, Virginia, West Virginia</td>
<td>LCD L33467</td>
<td>3/15/2018</td>
<td>3/9/2018</td>
</tr>
<tr>
<td>Palmetto</td>
<td>JM – Alabama, Georgia, Tennessee; J1 – North Carolina, South Carolina, Virginia, West Virginia</td>
<td>LCA A53060</td>
<td>2/26/2018</td>
<td>1/31/2018</td>
</tr>
</tbody>
</table>

Abbreviations: EO, extended ophthalmoscopy; LCA, local coverage article; LCD, local coverage determination; MAC, Medicare administrative contractor.

**CREATING A CHECKLIST**

Insurance policies often provide requirements for medical necessity and documentation. From these policies, your office can create an internal checklist to be used as a resource. The checklist on the next page represents typical requirements and should be revised per individual payers’ policies. This resource can provide guidance for internal audits and can be used as a training resource.

JOY WOODKE, COE, OCS, OCSR
- AAO Practice Management Consultant
- joywoodke@gmail.com
- Financial disclosure: None
CHECKLIST FOR EXTENDED OPHTHALMOSCOPY DOCUMENTATION

- Documentation is not for a routine direct and/or indirect ophthalmoscopy
  - Routine ophthalmoscopy is included in the appropriate level of office visit coded.
  - The definition of EO is a more extensive examination that requires a detailed and labeled drawing that cannot be documented in any other way.

- Retinal drawing
  - Although it may be preferred, a color drawing for EO is not a documentation requirement for most payers.
  - Confirm any drawing requirements (color or size) per payer policy.
  - A drawing that is clearly identified, labeled, and appropriately represents the retinal pathology is required.
  - Documentation of the diagnostic technique used is completed (360° scleral depression, fundus contact lens, or 90-D lens).
  - Completing the retinal drawing directly from OCT findings is not appropriate.

- Interpretation and report
  - An interpretation and report is completed for each test performed and per eye.
  - There are no published documentation requirements for the interpretation and report. The required documentation could include diagnosis and findings and the impact on the treatment plan.

- Chart notes supporting medical necessity per insurance policies
  - A review of the patient’s medical records provides documentation of the medical necessity for EO including the pathology per eye if billed bilaterally.
  - MACs with local coverage determinations (LCDs) include Palmetto, NGS, CGS, and First Coast.
  - Confirmation that an EO of the fellow eye without pathology was not billed to insurance, as this would be considered not medically necessary.

- The documentation and billing of the initial and subsequent EO meets the coding definitions.
  - EO initial (92225) documents an initial EO or a new event (diagnosis).
  - EO subsequent (92226) is used when following a chronic condition, after the initial EO, with progression of the disease.

- Check NCCI bundles for services performed the same day as EO
  - Note that retina surgical procedures are bundled on the same day as EO.
  - Confirm payer policies for EO coverage the same day as other ophthalmic diagnostic testing services.

- Insurance claim
  - CMS-1500 paper claim or Electronic Data Interface (EDI) transaction 837P electronic claim completed with:
    - 92225 or 92226 with appropriate diagnosis linkage and modifiers.
    - Most payers recognize -RT and -LT modifiers when billing for bilateral EO. Some payers may require the -50 modifier.
    - EO is bundled the same day as retinal procedures.
    - 92225 and 92226 have a bilateral indicator of 3, which pays 100% allowable per eye.

- Physician signature
  - The physician signature is legible on paper chart records and a signature log created to provide during an audit. For electronic health records, the electronic physician signature is secure. The practice has an electronic signature policy and provides it in the event of an audit.

- Chart notes
  - Correct beneficiary name and date of birth on all chart records, including the retina drawing.

- Abbreviation list
  - The practice has an approved abbreviation list that is readily available for all audits.
I've been in private practice for 17 years. In the initial years of my career, I grew my practice via referrals from internal medicine colleagues and word-of-mouth referrals from patients and their family members. As the 2000s have marched forward, I noticed an increasing number of patients mentioning that they found me via the internet. Whether through health insurance, physician-rating sites, or Google searches, my referrals have migrated to online opportunities.

I was often afraid to look up my profile online. Once a year, around Thanksgiving, I would Google myself and casually glance at my patient reviews. As physicians and ophthalmologists, we are engaged in a shared mission of protecting our patients’ sight and empowering their lives. As a profession, we stereotypically do not do well with criticism. Before the advent of online patient reviews, I thought the only “seal of approval” I needed was board certification (with or without maintenance of certification!).

**THE IMPORTANCE OF ONLINE REPUTATION**

More than 40 online sites feature physician reviews or ratings. An article in the *Wall Street Journal* noted that physicians are “wary of bad reviews from disgruntled patients” and that many regularly check their reviews and make changes as a result.¹ (See Correspondence With a Former Colleague.)

Hanauer and colleagues conducted a survey to assess the factors patients use when selecting a physician.² I group their findings into three broad categories, from high importance to lower importance. High importance includes whether a physician accepted a patient’s insurance (95% very important or somewhat important), was conveniently located (95%), or had many years of experience (92%). Slightly lower in importance, a second category included whether a physician is part of a trusted group practice (81%), word of mouth from family and friends (85%), and referral from another physician (80%). Lower still, a physician’s rating on websites was reported to be very important or somewhat important by 59% of respondents.

Of note, the study showed that 35% of individuals selected physicians with good reviews or ratings and 37% avoided physicians with bad reviews or ratings.

Last year, a survey by the marketing firm BrightLocal asked

### AT A GLANCE

- More than 50% of respondents to a consumer survey indicated that reputation was the most important factor in selecting a physician.
- Physicians should not respond directly to patient reviews, as this may violate patients’ HIPAA rights.
- Keys to protecting your online reputation and building a brand: using one professional photo, updating online profiles, engaging patients, addressing critics, and establishing a social media presence.

---

Five pearls to build your brand and optimize your social media presence.

**BY RAVI D. GOEL, MD**
consumers, “For which of these local businesses does ‘Reputation’ matter the most when choosing a business?” More than 50% of respondents said that, for physician practices and restaurants, reputation was the most important factor in selecting a business. As a foodie myself, I typically look up a restaurant’s online reputation through numerous sites before making a reservation. (I sometimes even look at my own Yelp profile when I look up a restaurant, but that’s another issue.)

Anna Fels, a blogger for the New York Times Opinionator, pointed to the many challenges that physicians face when considering a response to online patient reviews. Physicians are indeed held to a higher standard than other service providers, she noted, and HIPAA prevents physicians from revealing patient information.

SEARCH ENGINE SELF-EXAMINATION

In 2012, I Googled myself through numerous searches: “Ravi Goel… Ravi Goel, MD… Ravi Goel MD, rating.” I found that Healthgrades, a physician review site, was among the top websites returned on a Google search. Other sites included my practice page, LinkedIn profile, and YouTube channels.

My goal was to optimize my first two pages of Google search results. Studies have shown that consumers have a 35% probability of clicking on the first organic search result they find, 12% on the second, and less than 10% on the third. Subsequent results have a less than 5% chance of being selected, but the impression can still be important.

In my quest for search engine optimization (SEO), I asked happy and satisfied patients to submit patient reviews. As a result, I slowly increased my ratings online. I also posted links on my practice website and the social media platforms Facebook and Twitter. (My practice has recently initiated patient surveys for every patient through our portal and I have initiated a plan to better engage patients who respond to internal surveys).

By 2014, I found that 60% (12 of 20) of the first two pages of Google search results for “Ravi Goel, MD,” were physician rating sites; my practice website, LinkedIn page, Twitter account, and YouTube channels were the remaining results.

FIVE PEARLS FOR YOUR PRACTICE

For busy retina practices, I offer the following pearls to protect your online reputation and build your brand:

• Get one great professional photo. Your image is your brand. Every website that you engage with online—practice website, health system, eye hospital and ophthalmology department sites, social media pages, and physician rating sites—should include one recent professional photo.

• Curate content. As noted above, there are more than 40 physician

(Continued on page 15)
RUNNING AN EFFICIENT PRACTICE

To establish efficient practice flow, make sure the doctor is busy doing doctor tasks, then work backward from there.

BY LARRY R. BROOKS

Do you find yourself frustrated with running behind? With not having staff available when you need them? With not having a patient ready to be seen? Does your practice seem more chaotic and hectic than you would like? You’re not alone. Over the past 28 years I have spent countless hours observing and performing time and motion studies on medical practices. These concerns are a common thread I have seen across many practices.

The issue causing these inefficiencies is simple: There is a disconnect between the input, the throughput, and the output of patients flowing through the office. In other words, the rate that doctors are seeing patients (output) is out of sync with the systems and staff processing those patients (throughput) and the rate that the appointment template brings in patients (input).

Solving this issue is not so simple. The key is understanding the controlling factor. In a retina practice, the controlling factor should be the doctor’s style and potential rate of seeing patients. The doctors’ potential—not current—rate of seeing patients should dictate the organization of all aspects of the practice’s throughput and input.

This article explains how to identify a doctor’s potential patient rate and how to set up throughput and input systems to match that rate. But first I want to explain the concept of maximizing output.

The weakest link in a process dictates the output. In a medical practice, there are typically four links in the process of seeing patients (see Links in the Process).

If your practice’s doctor is capable of seeing six patients per hour, but one or more of the other links are not set up to process at least six patients per hour, the doctor will never reach his or her potential. On the flip side, if the appointment template is bringing in patients at nine per hour but the staffing, systems, or doctor can handle only six per hour, after 2 hours you are 1 hour behind.

How do you find the perfect balance? A good visual is to think of your practice as a funnel: wide at the top and narrow at the bottom. To maximize the output of the funnel, the input is wider than the output opening. There is excess capacity upstream from the output (Figure). With that image in mind, let’s consider how to identify the needs for each section—the top of the funnel (input), middle (throughput), and bottom (output). We’ll start at the bottom.

OUTPUT

Looking at computer data to see how many patients your doctor sees in a day does not tell you your output capacity; it only provides you with the current output. To determine what the doctor’s capacity or potential is, you must determine how much of this or her present time is spent practicing medicine—doing the tasks that only the doctor can do—versus time consumed performing tasks that could be delegated to staff or technology, or time lost due to not having a patient ready.

To calculate the amount of lost and misused time, you need to do a time study. I know, many of you are saying, “Been there, done that.” But this type of time study is not simply placing a tracking slip on a chart or a patient, as many time studies do. Those studies tell you only how long the patient or chart is at each stop. To actually determine output potential, you must watch the output resource—the doctor. This requires observing and timing every task the doctor completes for a few hours. Then, after gathering this data, place each event and the time that the event consumed into one of three categories:

- Category 1, Doctor: Tasks that
- Category 2, Staff: Tasks that
- Category 3, Systems: Tasks that

At a Glance

- The key to efficient patient flow is understanding the controlling factor.
- The controlling factor should be the doctor’s style and potential rate of seeing patients.
- Think of your practice as a funnel, wide at the top (input) and narrow at the bottom (output).
- There are four links in the process of practice flow: the doctor’s style, staff, systems, and space.
only the doctor can do;
• Category 2, Delegate: Tasks that
the doctor is doing now but does
not necessarily have to do;
• Category 3, Lost: Time lost
because no patient is ready or
the task being done provided no
patient care benefit.

Remember, the criterion is “Does
the doctor have to do this certain
task or event?” If not, it does not go
in Category 1. You must be critical of
statements like “That’s how we have
always done it” or “There is no one else
available to do it.”

Once you’ve gathered this data, take
the amount of time the doctor spent
doing only “doctor” things and divide
that by the number of patients the
doctor saw while being observed. This
gives you that doctor’s potential aver-
age patient-per-hour (PPH) rate.

THROUGHPUT
The same type of time study can
be performed on the technicians
and check-in and checkout staff to
determine their capacity and properly
project the need in this area. By focus-
ing on tasks that are not specific to
these staff members’ primary jobs, you
can identify the things that are pulling
them off track and creating delays in
processing patients.

As you perform the time study on
the staff, keep an eye out for job duties
that conflict with or are not aligned
with the ultimate goal of always having
a patient ready for the doctor to see.

Here are a few things to look out for:
• Are staff members walking to
deliver information or instructions
that could be sent electronically?
• Is the same staff member handling
phones (patient calls, reminder
calls, pharmacy orders, etc.) and
patients in the office?
• Are the technicians assigned to
prep or work up patients for the
doctor also performing other
duties that pull them off track?
• Are the doctor’s lanes grouped
to reduce walking or exposure to
waiting patients?
• Are technicians or patients
waiting for available rooms or
equipment?

Once you know the potential of
your doctors and staff, you can begin
to design a staffing model for the prac-
tice to properly handle that patient
volume or throughput.

In addition to determining the
proper number of staff, you must
also put in place efficient systems to
best use the staff’s time. One adage to
remember when assessing a staffing
model is, “A staff member cannot per-
form two stat functions and succeed
at both.” For example, receptionists
cannot answer the phone and check in
patients at the same time. They will fail
at one of their two tasks—through no
fault of their own.

The amount and configuration of
space is based on the doctor’s style
and the PPH rate from the time study.
The number of lanes the doctor needs
is based on his or her average time in
the lane per patient and how long the
staff needs to ready another patient in
that same lane once the doctor leaves
(called lane turn time). The idea is that
the doctor needs enough lanes to keep
himself or herself effectively seeing
patients and to give the staff time to
ready a patient in the last lane used.

For example, if the doctor’s PPH
average is six, he or she spends an aver-
age of 10 minutes in each lane. If the
staff needs 12 minutes to turn a lane
(finish up follow-up instructions, move
the patient out, clean the room, ready
the next patient in the lane), then the
doctor needs two other lanes to keep
effectively busy. The lanes the techni-
cian needs to work up the patient
(history, complaint, vision, etc.) are in
addition to these doctor lanes.

INPUT
Input is the information gathered
before the patient’s arrival and the
subsequent appointment template.

Figure. Thinking of your practice as a funnel can help you visualize practice flow.
“THE KEY TO MAKING YOUR PRACTICE FLOW EFFICIENT AND PRODUCTIVE IS NOT THINKING OF YOUR BUSINESS AS A MEDICAL PRACTICE AND CONCERNING YOURSELF ONLY WITH PATIENT FLOW.”

As much as possible, data-gathering should be completed beforehand (via mail-in forms, web portals, phone, etc.) to lessen the time and effort it takes to check patients in.

Set up the appointment template to bring in patients a bit faster than the doctor’s PPH rate, so that there is a small pool of patients ready to be seen. One to three patients more than the doctor’s rate is a good range. Then, cut back for the last hour of the day.

Scheduling a lot faster than the doctor’s PPH rate will overflow the waiting room and cause frustration. It does no good to have four, five, or six patients sitting around, ready for the doctor. The practice needs to stay only one or two patients ahead of the doctor. Scheduling at a rate slower than the doctor’s potential PPH rate will create gaps in the doctor’s time.

THE KEY TO EFFICIENT FLOW

The key to making your practice flow efficient and productive is not thinking of your business as a medical practice and concerning yourself only with patient flow. You are orchestrating the movement of many parts that all need to be in sync. Think of it as a manufacturing plant that assembles patient visits. Concentrate on identifying output capacity, and then build your systems and resources upstream based on that capacity.

LARRY R. BROOKS
President and Co-owner, Practice Flow Solutions
brooks@PracticeFlowSolutions.com
Financial disclosure: None acknowledged

(Continued from page 12)

rating sites. Each site should correctly list your current physician demographics, credentials, and practice information. I have found significant errors on these sites, and I correct them when I find them. Start with Google Business, Healthgrades, Vitals, and Yelp.

• Engage patients. Patients of all ages engage with the internet and look to their physicians for reliable information. Give your patients the resources they need to make informed health care decisions. I rely heavily on the AAO’s EyeSmart pages for patient education. We achieve patient education marks in the Merit-based Incentive Payment System (otherwise known as MIPS) by sending patients links to EyeSmart the day after their patient visits. I also post educational videos on YouTube, which I can share with patients many years before they need surgery.

• Address critics. Practices need a rapid response plan to address critics who “flame” your name, your practice, or your brand. I recommend that all responses be off-line (a phone call, a note of apology, an offer of VIP scheduling), with the goal of enhancing the flaming patient’s experience. Physicians should not respond directly to patient reviews as this may violate the patient’s HIPAA rights. Internal patient surveys that are sent to patients the next day (similar to those one receives after getting an oil change) can often help to identify patients who need extra attention.

• Engage in social media. The question of whether an ophthalmologist should engage in social media was asked and answered about 5 to 7 years ago. Today, patients and colleagues expect thought leaders to have an engaging social media presence. By effectively using platforms such as LinkedIn, Twitter, Facebook, Instagram, and blogs, you can build your brand online.

RAVI D. GOEL, MD
ophthalmologist, cataract and refractive surgeon, regional eye associates, Cherry Hill, New Jersey
comprehensive ophthalmologist, cataract and primary eye care, Wills Eye Hospital, Philadelphia
ravigoelmd@reanj.com; Twitter @RaviDGoel
Financial disclosure: None

The cost of drugs has skyrocketed over the past decade and is projected to grow faster than any other health care service over the next decade. President Trump has promised to cut drug costs, and there is bipartisan support to do something to lower expenditures.

In 2017, according to a CMS analysis, US prescription drug costs were $333.4 billion, accounting for nearly 10% of the country’s total health care expenditures. Under Medicare, from 2012 to 2016, Part B drug costs increased 42% and Part D costs increased 71%. Total Medicare expenditures increased only 18% during the same period, highlighting the disproportionate effect of drugs on overall spending.

In Part B, seven drugs accounted for 38% of the expenditures, and ophthalmology drugs were at the top of list. From 2013 to 2016, Medicare spent $98 billion on Part B drugs. Aflibercept (Eylea, Regeneron), at $6.4 billion, and ranibizumab (Lucentis, Genentech), at $4.9 billion, were Nos. 1 and 4, respectively, accounting for 12.2% of total expenditures.

Recently, CMS announced a policy to allow Medicare Advantage (MA) organizations to institute step therapy for enrolled Medicare beneficiaries beginning in January 2019 with the express purpose of lowering drug costs for patients and payers. Whether or not CMS has the authority to institute such a policy is controversial, and this decision may yet be challenged. Regardless, step therapy is already the most common type of coverage restriction used by commercial payers for specialty drugs.

An analysis of a specialty drug evidence and coverage database at Tufts Medical Center demonstrated that, as of August 2017, nearly one in four coverage decisions involved a step therapy protocol, with wide and seemingly random variations in how and when protocols are applied. For example, only 16% of drug indication pairs were covered by all plans, and fewer than half were covered the same by at least 75% of plans. When step therapy coverage was analyzed by FDA-approved indications, the protocols were consistent with FDA labeling 52% of the time, more restrictive 33% of the time, and not covered at all 4.5% of the time. This wide variation suggests a lack of evidence-based medicine underlying these protocols.

Step therapy for retina specialists is primarily focused on the use of off-label, compounded bevacizumab (Avastin, Genentech). We are all familiar with the many studies that have demonstrated bevacizumab to be a safe and effective treatment for a variety of retinal pathologies. Indeed, ophthalmologists have embraced bevacizumab. Across more than 6.2 million intravitreal injections in the AAO’s Intelligent Research in Sight (IRIS) Registry from 2013 through 2016, 46% of patients received bevacizumab.

The simple truth is that, without the many dedicated ophthalmologists who fought for access to and payment for bevacizumab and participated in clinical trials, there would be no alternative to aflibercept and ranibizumab. The use of bevacizumab by ophthalmologists has saved Medicare tens of billions of dollars to date and will continue to do so as long as it remains available.

What are the potential issues likely to be associated with the advent of step therapy by MA organizations? If past performance is any indica-
“THE ADVENT OF STEP THERAPY IN [MEDICARE ADVANTAGE PLANS] WILL REQUIRE INCREASED PHYSICIAN AND STAFF TIME THAT FURTHER IMPEDES PATIENT CARE. IT MAY BE PRUDENT FOR PRACTICES TO DEVELOP INTERNAL PROTOCOLS TO DEAL WITH STEP THERAPY.”

The implementation of step therapy requiring initial treatment with bevacizumab raises many questions, including these:

- What are the criteria for determining treatment failure with bevacizumab? Will it be a loss of vision? If so, how much? Does lack of visual improvement constitute failure? Are imaging changes such as OCT or angiography appropriate criteria?
- How many injections are necessary to establish failure?
- What about patients who, after appropriate informed consent regarding off-label and compounded drugs, are unwilling to receive bevacizumab?
- Will step therapy be required even when there are compelling data that bevacizumab is not the treatment of choice, such as in patients with diabetic macular edema and poor vision?
- Will a repeat trial of step therapy be required for the second eye?
- Will there be standardization of step therapy protocols? There are more than 500 Medicare Advantage (MA) contracts or plans. The same MA organization may have multiple different plans. How can providers be expected to know the requirements and nuances of many disparate plans?
- What is the appeals process when the ophthalmologist and the plan disagree on treatment failure? In the preauthorization denials reviewed the Office of the Inspector General, the most urgent timeline for resolution was 72 hours.
- Anti-VEGF therapy is commonly a multiyear treatment program. What are the implications of patients changing MA plans?

The title of the report is an accurate summary: “Medicare Advantage appeal outcomes and audit findings raise concerns about service and payment denials.”

This report examined denial of service or payment data from 422 MA contracts covering over 15 million beneficiaries. From 2014 to 2016, when beneficiaries and providers appealed preauthorization and payment denials, MA organizations overturned 75% of their own denials. During the same period, independent reviewers at higher levels of the appeals process overturned additional denials in favor of beneficiaries and providers.

The OIG concluded that the high number of overturned denials raises concerns that some MA beneficiaries and providers were initially denied services and payments that should have been provided. Furthermore, the report noted that beneficiaries and providers rarely used the appeals process designed to ensure access to care and payment. From 2014 to 2016, beneficiaries and providers appealed only 1% of denials.

An OIG review of CMS audits found that CMS cited 56% of audited MA organization contracts for inappropriately denying services or payment. CMS also cited 45% of audited MA organization contracts for sending denial letters with incomplete or incorrect information, which may inhibit the ability of beneficiaries and providers to file successful appeals.

The pattern of behavior was one of denial, obstruction, and confusion. Should we expect implementation of step therapy to be any different?

The OIG report noted a central concern about the capitated payment model used in MA plans: the potential incentive for insurers to inappropriately deny access to services and payment in an attempt to increase their profit. MA organizations that
inappropriately deny services to Medicare beneficiaries, or payments to providers, not only contribute to physical or financial harm, but also misuse Medicare program dollars that CMS pays for beneficiary health care. The OIG noted that the growth in the MA program from 8 million beneficiaries in 2011 to 21 million in 2018 increased the potential adverse impact of its findings.

A BUMPY RIDE

Many retina practices are already struggling with the implementation of step therapy. The advent of step therapy in MA plans will require increased physician and staff time that further impedes patient care. It may be prudent for practices to develop internal protocols to deal with step therapy. Such protocols should be designed to minimize administrative hassles but be flexible enough to optimize patient care.

The obvious default solution is to simply start all patients on bevacizumab and see what happens. For many, perhaps most, patients, this approach will work well. The devil will be in the details for patients who do not respond as well as they or their ophthalmologist had hoped. We need step therapy protocols to be evidence-based, transparent, and standardized so that patients and ophthalmologists can know what to expect. Buckle up, it is going to be a bumpy ride.

INDEX OF ADVERTISERS

EyePoint Pharmaceuticals ............................................................... 19, Cover 4
www.eyepointpharma.com

Regeneron .......................................................... Cover 2, 3, 4, 5
www.regeneron.com

This advertiser index is published as a convenience and not as part of the advertising contract. Although great care will be taken to index correctly, no allowance will be made for errors due to spelling, incorrect page number, or failure to insert.
YUTIQ™ (fluocinolone acetonide intravitreal implant) 0.18 mg, for intravitreal injection Initial U.S. Approval: 1983

BRIEF SUMMARY: Please see package insert for full prescribing information.

1. INDICATIONS AND USAGE. YUTIQ™ (fluocinolone acetonide intravitreal implant) 0.18 mg is indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.

4. CONTRAINDICATIONS. 4.1 Ocular or Periocular Infections. YUTIQ is contraindicated in patients with a history of ocular herpes simplex because of the potential for reactivation of the viral infection. 4.3. Risk of Implant Migration. Patients in whom the posterior capsule of the lens is absent or has a tear are at risk of implant migration into the anterior chamber.

5. WARNINGS AND PRECAUTIONS. 5.1 Intravitreal Injection-related Effects. Intravitreal injections, including those with YUTIQ, have been associated with endophthalmitis, eye inflammation, increased or decreased intraocular pressure, and choroidal or retinal detachments. Hypotony has been observed within 24 hours of injection and has resolved within 2 weeks. Patients should be monitored following the intravitreal injection (see Patient Counseling Information (17) in the full prescribing information). 5.2 Steroid-related Effects. Use of corticosteroids including YUTIQ may produce posterior subcapsular cataracts, increased intraocular pressure and glaucoma. Use of corticosteroids may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses. Corticosteroids are not recommended to be used in patients with a history of ocular herpes simplex because of the potential for reactivation of the viral infection. 5.3. Risk of Implant Migration. Patients in whom the posterior capsule of the lens is absent or has a tear are at risk of implant migration into the anterior chamber.

6. ADVERSE REACTIONS. 6.1 Clinical Studies Experience. Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. Adverse reactions associated with ophthalmic steroids including YUTIQ include cataract formation and subsequent cataract surgery, elevated intraocular pressure, which may be associated with optic nerve damage, visual acuity and field defects, secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera. Studies 1 and 2 were multicenter, randomized, sham injection-controlled, masked trials in which patients with non-infectious uveitis affecting the posterior segment of the eye were all treated once with YUTIQ or sham injection, and then received standard care for the duration of the study. Study 3 was a multicenter, randomized, masked trial in which patients with non-infectious uveitis affecting the posterior segment of the eye were all treated once with YUTIQ, administered by one of two different applicators, and then received standard care for the duration of the study. Table 1 summarizes data available from studies 1, 2 and 3 through 12 months for study eyes treated with YUTIQ (n=226) or sham injection (n=94). The most common ocular (study eye) and non-ocular adverse reactions are shown in Table 1 and Table 2.

Table 1: Ocular Adverse Reactions Reported in ≥ 1% of Subject Eyes and Non-Ocular Adverse Reactions Reported in ≥ 2% of Patients

<table>
<thead>
<tr>
<th>Ocular ADVERSE REACTIONS (N=226 Eyes)</th>
<th>Sham Injection (N=94 Eyes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cataract 1</td>
<td>63/113 (56%)</td>
</tr>
<tr>
<td>Visual Acuity Reduced</td>
<td>33 (15%)</td>
</tr>
<tr>
<td>Macular Edema</td>
<td>25 (11%)</td>
</tr>
<tr>
<td>Uveitis</td>
<td>22 (10%)</td>
</tr>
<tr>
<td>Conjunctival Hemorrhage</td>
<td>17 (8%)</td>
</tr>
<tr>
<td>Eye Pain</td>
<td>17 (8%)</td>
</tr>
<tr>
<td>Hypotony Of Eye</td>
<td>16 (7%)</td>
</tr>
<tr>
<td>Anterior Chamber Inflammation</td>
<td>12 (5%)</td>
</tr>
<tr>
<td>Dry Eye</td>
<td>10 (4%)</td>
</tr>
<tr>
<td>Vitreous Opacities</td>
<td>9 (4%)</td>
</tr>
<tr>
<td>Conjonctivitis</td>
<td>9 (4%)</td>
</tr>
<tr>
<td>Posterior Capsule Opacification</td>
<td>8 (4%)</td>
</tr>
<tr>
<td>Ocular Hyperemia</td>
<td>8 (4%)</td>
</tr>
<tr>
<td>Vitreous Haze</td>
<td>7 (3%)</td>
</tr>
<tr>
<td>Foreign Body Sensation In Eyes</td>
<td>7 (3%)</td>
</tr>
<tr>
<td>Vitril</td>
<td>6 (3%)</td>
</tr>
<tr>
<td>Vitreous Floaters</td>
<td>6 (3%)</td>
</tr>
<tr>
<td>Eye Pruritus</td>
<td>6 (3%)</td>
</tr>
<tr>
<td>Conjonctival Hyperemia</td>
<td>5 (2%)</td>
</tr>
<tr>
<td>Ocular Discomfort</td>
<td>5 (2%)</td>
</tr>
<tr>
<td>Macular Fibrosis</td>
<td>5 (2%)</td>
</tr>
<tr>
<td>Glaucoma</td>
<td>4 (2%)</td>
</tr>
<tr>
<td>Photopsia</td>
<td>4 (2%)</td>
</tr>
</tbody>
</table>

6.2. Precautions for Specific Ocular Conditions. 6.2.1. Open-angle glaucoma. Corticosteroids may decrease outflow facility and cause IOP elevation ≥ 2 mmHg from baseline. 6.2.2. Secondary open-angle glaucoma. Additional treatment of glaucoma may be required. 6.2.3. Patients with a history of ocular herpes simplex are at risk of reactivation of the viral infection if treated with YUTIQ. 6.2.4. Patients with known hypersensitivity to any component of this product.

6.3. Laboratory Tests. Pharmacodynamic tests associated with YUTIQ treatment include elevated intraocular pressure, glaucoma, and IOP elevation ≥ 2 mmHg from baseline. Clinical or nonclinical lactation studies have not been conducted with YUTIQ. It is not known whether YUTIQ can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. YUTIQ should be given to a pregnant woman only if the potential benefit justifies the potential risk to the fetus. All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the United States general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. 6.4. Infertility. A pregnancy history should be taken, and appropriate counseling given. 6.5. Pediatric Use. Safety and effectiveness of YUTIQ in pediatric patients have not been established.

Table 1: Ocular Adverse Reactions Reported in ≥ 1% of Subject Eyes and Non-Ocular Adverse Reactions Reported in ≥ 2% of Patients

<table>
<thead>
<tr>
<th>ADVERSE REACTIONS (N=226 Eyes)</th>
<th>Sham Injection (N=94 Eyes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitreous Hemorrhage</td>
<td>4 (2%)</td>
</tr>
<tr>
<td>Iridocyclitis</td>
<td>3 (1%)</td>
</tr>
<tr>
<td>Eye Inflammation</td>
<td>3 (1%)</td>
</tr>
<tr>
<td>Choroiditis</td>
<td>3 (1%)</td>
</tr>
<tr>
<td>Eye Irritation</td>
<td>3 (1%)</td>
</tr>
<tr>
<td>Visual Field Defect</td>
<td>3 (1%)</td>
</tr>
<tr>
<td>Lacration Increased</td>
<td>3 (1%)</td>
</tr>
</tbody>
</table>

8. USE IN SPECIFIC POPULATIONS. 8.1 Pregnancy. Risk Summary. Adequate and well-controlled studies with YUTIQ have not been conducted in pregnant women to inform drug associated risk. Animal reproduction studies have not been conducted with YUTIQ. It is not known whether YUTIQ can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. YUTIQ should be given to a pregnant woman only if the potential benefit justifies the potential risk to the fetus. All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the United States general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. 8.2 Lactation. Risk Summary. Systemically administered corticosteroids are present in human milk and can suppress growth, interfere with endogenous corticosteroid production. Clinical or nonclinical lactation studies have not been conducted with YUTIQ. It is not known whether intravitreal treatment with YUTIQ could result in sufficient systemic absorption to produce detectable quantities of fluocinolone acetonide in human milk, or affect breastfed infants or milk production. The developmental and health benefits of breastfeeding should be considered, along with the mother’s clinical need for YUTIQ and any potential adverse effects on the breastfed child from YUTIQ. 8.4 Pediatric Use. Safety and effectiveness of YUTIQ in pediatric patients have not been established.

Table 2: Summary of Elevated IOP Related Adverse Reactions

<table>
<thead>
<tr>
<th>ADVERSE REACTIONS (N=226 Eyes)</th>
<th>Sham Injection (N=94 Eyes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IOP elevation ≥ 10 mmHg from Baseline</td>
<td>50 (22%)</td>
</tr>
<tr>
<td>IOP elevation &gt; 30 mmHg</td>
<td>28 (12%)</td>
</tr>
<tr>
<td>Any IOP-lowering medication</td>
<td>98 (43%)</td>
</tr>
<tr>
<td>Any surgical intervention for elevated IOP</td>
<td>5 (2%)</td>
</tr>
</tbody>
</table>
**INDICATIONS AND USAGE**

YUTIQ™ (fluocinolone acetonide intravitreal implant) 0.18 mg is indicated for the treatment of chronic noninfectious uveitis affecting the posterior segment of the eye.

**IMPORTANT SAFETY INFORMATION**

**Contraindications**
- Ocular or Periocular Infections: YUTIQ is contraindicated in patients with active or suspected ocular or periocular infections including most viral disease of the cornea and conjunctiva including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections and fungal diseases.
- Hypersensitivity: YUTIQ is contraindicated in patients with known hypersensitivity to any components of this product.

**Warnings and Precautions**
- Intravitreal Injection-related Effects: Intravitreal injections, including those with YUTIQ, have been associated with endophthalmitis, eye inflammation, increased or decreased intraocular pressure, and choroidal or retinal detachments. Hypotony has been observed within 24 hours of injection and has resolved within 2 weeks. Patients should be monitored following the intravitreal injection.
- Steroid-related Effects: Use of corticosteroids including YUTIQ may produce posterior subcapsular cataracts, increased intraocular pressure and glaucoma. Use of corticosteroids may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses. Corticosteroids are not recommended to be used in patients with a history of ocular herpes simplex because of the potential for reactivation of the viral infection.
- Risk of Implant Migration: Patients in whom the posterior capsule of the lens is absent or has a tear are at risk of implant migration into the anterior chamber.

**Adverse Reactions**

In controlled studies, the most common adverse reactions reported were cataract development and increases in intraocular pressure.

**References:**
1. YUTIQ™ (fluocinolone acetonide intravitreal implant) 0.18 mg full U.S. Prescribing Information.

**For more information, visit YUTIQ.com**

©2019, EyePoint Pharmaceuticals, Inc. All rights reserved.
480 Pleasant Street, Suite B300, Watertown, MA 02472
YUTIQ and the EyePoint logo are trademarks of EyePoint Pharmaceuticals, Inc.

US-YUT-1900018