

Vol. 3, No. 4

The logo for "Business Matters" features the word "BUSINESS" in a large, dark blue, serif font. A teal-colored dollar sign (\$) is positioned in the center, replacing the letter 'S'. Below "BUSINESS", the word "MATTERS" is written in a smaller, dark blue, sans-serif font. Two horizontal teal lines are positioned above and below the word "BUSINESS".The logo for Retina Today, featuring the letters 'RT' in a large, bold, teal font, with the words 'Retina Today' in a smaller, dark blue font below it.

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Safety Data

**YOU CAN
TRUST¹**

**Confidence in
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Safety Data Across
4 FDA-Approved
Indications¹**



**WET AMD,
DME, DR,
and MEfRVO¹**

Visit HCP.EYLEA.US to see safety and efficacy results

anti-VEGF = anti-vascular endothelial growth factor; AMD = Age-related Macular Degeneration; DME = Diabetic Macular Edema; DR = Diabetic Retinopathy; MEfRVO = Macular Edema following Retinal Vein Occlusion.

IMPORTANT SAFETY INFORMATION AND INDICATIONS

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

- Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA.
- Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.

References: 1. EYLEA® (aflibercept) Injection full U.S. Prescribing Information. Regeneron Pharmaceuticals, Inc. August 2019.
2. Data on file. Regeneron Pharmaceuticals, Inc.

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



**Anti-VEGF
Treatment Backed
by Extensive
Clinical and
Real-World
Experience¹**

8 YEARS
of extensive
clinical experience
and the integrity
of data from large,
well-controlled
trials¹

**9 An Estimated
MILLION
DOSES**
administered to
≈790,000 eyes
since launch
(and counting)²

**8 PHASE 3
CLINICAL
TRIALS**
including more
than 3000
EYLEA-treated
patients across
all approved
indications¹

WARNINGS AND PRECAUTIONS (cont'd)

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

ADVERSE REACTIONS

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

INDICATIONS

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

EYLEA is a registered trademark of Regeneron Pharmaceuticals, Inc.

REGENERON



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:

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 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 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 CRVO in 2 clinical studies (COPERNICUS and GALILEO) and 91 patients following 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, sternbrae, 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

Manufactured by:
Regeneron Pharmaceuticals, Inc.
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Tarrytown, NY 10591

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Issue Date: 08/2019
Initial U.S. Approval: 2011

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

EYL.19.07.0306



GO WITH THE FLOW



With the COVID-19 pandemic throwing even the best laid management plans askew, we are all scrambling to find ways to better manage our patient flows, whether in the office or virtually. Technologies such as telemedicine and widefield fundus photography are becoming mainstays to minimize unnecessary interactions.

But with months of disruption ahead of us, we need to leverage other tools to help keep our practices running smoothly. This issue of *Retina Today Business Matters* takes a look at three options for reaching that goal: electronic health record (EHR) upgrades, digitized prior authorizations, and search engine optimization (SEO).

Minimizing bottlenecks in your practice is an ever-present issue due to social distancing protocols, personal protective equipment considerations, and new sanitization routines. This is where an efficient EHR system becomes invaluable. Daniel Schroder, MBA, a retina practice administrator in Florida, offers a firsthand account of his practice's transition to the Modernizing Medicine platform.

Now might be time to tackle a time-consuming aspect of medical care: obtaining prior authorizations. Paul Lucas, MSHA, a retina practice administrator in Atlanta, details the benefits of SamaCare, an online platform that consolidates prior authorization requests, approvals, and rejections onto one website.

Finally, with patient volumes in flux, now is a good time to check out the SEO tips offered by Ifland Crawford, founder and CEO of Messenger Healthcare Marketing, to make sure your site is easy to find for the majority of patients who use Google to find a physician.

Elsewhere in this issue, you will find an implementation checklist for 2021 E/M guidelines, year-end tax tips, and five action items that can help you weather the storm of COVID-19.

ALAN RUBY, MD

SECTION EDITOR

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CODING ADVISOR

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RETINA PRACTICE IMPLEMENTATION CHECKLIST FOR 2021 E/M GUIDELINES



The most significant changes to these guidelines since 1997 are coming January 1. Are you ready?

BY JOY WOODKE, COE, OCS, OCSR

In January, the most significant revisions to the guidelines for evaluation and management (E/M) codes since 1997 will be implemented. In a previous article (“E/M Coding and Documentation Guidelines for 2021,” September 2020), I previewed these changes.

Are you ready? Along with educating your coding staff on these revisions, your retina practice should prepare an internal implementation checklist to ensure a smooth transition. Here are some ideas about what should be on your checklist.

ASSIGN A PROJECT LEADER

Identify a physician champion or staff member to lead the change. This individual can compile and track the necessary action steps for the transition. He or she will also act as the point person for any challenges, provide practice communication, and answer questions.

COMMUNICATE WITH YOUR VENDORS

Initiate discussions with your practice’s electronic health record (EHR) and practice management system vendors regarding software functionality that will be affected by the changes to the E/M guidelines. Review the necessary updates to EHR templates that document the history and examination components. For example, the review of systems may be modified for a medically relevant systemic review for retina-related consultations.

Confirm how the EHR system will document total physician time during the face-to-face encounter and additional

activities performed the same day. Review any software functionality that may automatically track total time as an alternative to a manual process of tracking and entering the data.

For automated E/M coding software tools—programs that analyze documentation and determine the appropriate E/M codes—discuss with vendors the timeline for upgrades. Specifically review how these systems will accurately assess the medical decision-making or total time based on discrete data or narratives.

Finally, your software and hardware systems may need upgrades for coding compliance in 2021.

SUPERBILL

Remove CPT code 99201, New patient level 1, from your practice’s paper or electronic superbill, as this code will be eliminated in 2021. It may be necessary to inactivate 99201 from the procedure libraries and drop-down lists in your EHR and/or practice management systems.

TRAIN THE TEAM

Your practice should provide comprehensive training for all physicians and staff based on job roles. After you have conducted training on the revisions, you should review specific retina case studies commonly seen in the practice.

Consider conducting a session in which participants code a sample of recent encounters using both the current and the 2021 E/M guidelines. Discuss the differences in the guidelines and the impacts these will

have on code selection. Make sure to document all practice training to comply with Department of Health and Human Services Office of Inspector General protocols for compliance plan education.

FOCUS ON MEDICALLY RELEVANT HISTORY AND EXAMINATION

A significant change in the 2021 E/M coding guidelines is the elimination of required history and examination elements and the effect this elimination will have on code selection. Instead, a medically relevant history and examination will now be required for all E/M codes for office encounters and other outpatient services. This change affects the elements of the history of present illness; the review of systems; and the assessment of orientation of time, place, person, and/or mood and affect. Much of the documentation related to the history and examination is relevant to the retina specialist.

It is vital for the practice to internally review the relevant history and examination for specific retina evaluations. The essential elements may vary, for instance, for a new versus established patient visit, and due to the reason for the encounter (eg, extended history of present illness, social history, extraocular motility). Outlining these expectations for the technicians will help to create an efficient workup and clinic flow.

IDENTIFY WHAT REMAINS THE SAME

When the place of service for an encounter is other than the office or other outpatient service, the 2021 E/M documentation requirements will not change from current requirements. Table 1 outlines the place of service encounters that will not change with the 2021 E/M guidelines. The current history, examination, and medical decision-making requirements will remain for this family of E/M codes (eg, emergency department E/M codes 99281-99285).

Scenarios that affect retina practices could include inpatient retinopathy of prematurity consultations and emergency department consultations for endophthalmitis or trauma. These encounters will still be coded based on 1997 guidelines.

TABLE 1. PLACE OF SERVICE CODES NOT AFFECTED BY 2021 E/M REVISIONS	
Place of Service	Description
13	Assisted living facility
21	Inpatient hospital
23	Emergency department
31	Skilled nursing facility
32	Nursing facility

TABLE 2. MIPS 2020 QUALITY MEASURE CHART DOCUMENTATION EXAMPLES

Quality Measure	Chart Documentation
<i>Measure 1</i> Diabetes: Hemoglobin A1C Poor Control	Minimum of once per performance period, for patients 18-75 years of age with diabetes, document A1C > 9.0%
<i>Measure 110</i> Preventive Care and Screening: Influenza Immunization	For patients 6 months and older, seen for a visit in the measurement period, document influenza immunization received during the flu season
<i>Measure 130</i> Documentation of Current Medications in the Medical Record	A list of current medications, including name, dosage, frequency, and route of administration at each eligible visit during the 12-month period
Source: www.aao.org/medicare/quality-reporting-measures	

CONSIDER MIPS QUALITY MEASURES

When documenting medically relevant history and examination, any required elements for Merit-Based Incentive Payment System (MIPS) quality measures should be included. Table 2 provides examples of quality measures and the necessary documentation according to the 2020 measure specifications. Before the 2021 E/M guidelines are implemented, your practice should do the following:

- Identify which 2021 quality measures the practice is reporting;
- Review the measures' specifications and documentation requirements; and
- Communicate to physicians and staff the necessary history and examination elements for quality reporting and documentation.

UPDATE INTERNAL PROTOCOLS AND RESOURCES

Any practice procedures and protocols related to E/M coding and documentation should be reviewed and updated as appropriate. Your practice should develop new internal training resources and quick reference guides to support end users. Examples of this can be found in Table 3.

MONITOR AND AUDIT

As the 2021 guidelines are implemented, it is essential for retina practices to monitor E/M coding, promptly resolve any payer denials, and perform internal chart audits. Continue to communicate with all practice stakeholders regarding any internal errors and corrective measures.

(Continued on page 11)



LATEST TRENDS IN SEARCH ENGINE OPTIMIZATION



SEO is a field that changes rapidly. Here are a few relevant updates for retina practices.

BY CRAWFORD IFLAND

When it comes to search engine optimization (SEO) and health care, only two statistics matter: (1) More than eight out of 10 patients use Google as their first step in researching a medical condition or selecting a physician¹; and (2) Fewer than one in 100 patients will ever click through to page 2 (or beyond) of Google search results.²

SEO, in a nutshell is the process of getting your practice on that first page of Google search results.

The aim of SEO is to boost the visibility of a website or a web page in a search engine's unpaid results—often referred

to as *natural*, *organic*, or *earned* results. Most SEO strategies use a combination of keywords, images, links, and social media activity to drive traffic to a given website; these items are all designed to get the specified web page higher in the list of search engine results.³

Your practice's ability to appear high in organic search engine results is crucial for patient acquisition and growth. If your practice website does not appear on page 1, you're missing out on patients and revenue.

To help physicians and their marketing managers stay on top of the latest developments in SEO, here are several

actionable tips and insights that practices can use to respond to market changes, stay on top of their online presence, and keep acquiring patients from organic search.

FIXING GOOGLE INDEXING BUGS

What Happened

In September, Google experienced an issue with websites dropping from its index entirely, causing major declines in traffic for websites that usually ranked on page 1. Google took more than a week to admit that it was experiencing an issue. The company then noted that the problem was twofold: one issue had to do with *canonicalization*, or how Google decides which content is most authoritative, and the other was related to mobile indexing.

Why It Matters

Organic search is the largest source of website traffic for most practices, so even a temporary removal from Google's rankings could have an outsize effect on patient acquisition. Although issues like these are rare, it is important for practices and their marketing teams to ensure that their website was not affected.

What You Should Do

In response to the indexing issues, Google tweeted, "There's no action to take with these issues on the part of site owners. We apologize for the issues here and are working rapidly to resolve them." Still, any time an indexing error occurs, it is wise for marketing managers to check their website analytics platform (eg, Google Analytics) and Google Search Console—first, to verify whether they were affected, and second, to continue to closely monitor any pages that were affected to ensure that they fully recover.

If you find that your practice website was affected by the September incident, there is no need for action, but you will want to monitor the affected pages closely to ensure that they get put back into the index, as Google claims they will.

CONSEQUENTIAL CHANGES MADE TO SEARCH TERMS REPORT

What Happened

In September, Google notified advertisers on its Google Ads platform of an impending change. The company stated that, going forward, the Search Terms Report will "only include terms that were searched by a significant number of users." The Search Terms Report shows advertisers the real-world Google searches that triggered their ads. It is an incredibly valuable source of keyword ideas for advertisers and marketers, as well as for SEO efforts.

Importantly, this policy change by Google lacks transparency. What exactly is the threshold that constitutes a *significant number* of users? The fewer data the Search

Terms Report contains, the less valuable it is to advertisers. Google's policy change here ostensibly enhances user privacy, but it also has the potential to make billions of dollars in advertising spending invisible to advertisers. This is of enormous significance to practices engaging in paid advertising or SEO.

Why It Matters

Although this change primarily affects practices that pay for advertising on Google Ads, it also has outsize effects on practices that engage in SEO efforts. The Search Terms Report is one of the best ways for practices to identify new keywords, as it uses real-life data to show which searches triggered their ads. The Search Terms Report can be a great tool to help practices identify and target new organic keywords as they try to increase their share of voice and build brand awareness in their local markets. Google's changes enhance user privacy somewhat, but practices may now need to go elsewhere to find new keyword ideas.

What You Should Do

Regardless of whether your practice's patient acquisition efforts hinge on organic or paid traffic, if you use Google's tools you may need to get more inventive going forward. Be sure to analyze past data in your Search Terms Report, as those data are likely as good as they're going to get. Download the data as a spreadsheet to retain the insights and minimize the risk of data loss. Consider using Google's Keyword Planner Tool (also in Google Ads) or third-party tools such as Ahrefs or SEMRush as sources of ideas for paid and organic keywords.

MOVING FORWARD

Change is the only constant in the SEO world, and these changes can be difficult to navigate. As Google seeks to improve the experience and results it surfaces for its 1.7 billion daily active users, health care professionals must stay on top of these changes and adapt to continue serving their patients and growing their practices. Hopefully this SEO roundup will help. ■

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MAXIMIZE YOUR PRACTICE WITH DIGITAL TOOLS



Leverage these helpers to bring efficiencies to your retina practice.

BY PAUL LUCAS, MSHA, AND DANIEL SCHRODER, MBA

Digital practice management tools can help to streamline the frequently time-consuming tasks required in retina practice management. Here, two authors offer two quick tips on how to use digital tools to optimize your practice.

DIGITIZING PRIOR AUTHORIZATIONS

By Paul Lucas, MSHA

Obtaining prior authorizations is one of the time-consuming but necessary tasks that can be a burden for busy retina practice administrators. At Georgia Retina, we have implemented SamaCare (SamaCare), a digital platform that provides one uniform tool to obtain prior authorizations from almost any payer. This platform has been around for several years, during which time it has increased the number of eligible payers. SamaCare works with each provider to add payers as needed.

Using one single source for requesting and receiving prior authorizations received from multiple payers can add tremendous efficiency to a labor-intensive and inherently inefficient process. For our practice, having all prior authorization requests, approvals, and rejections housed on one convenient website has significantly reduced the burden of obtaining, documenting, and communicating this critical information to multiple locations on a timely basis. Not only has it streamlined getting the prior authorizations, but also our clinics now have instant access to this information through the host website.

Given the ease and efficiency of this process, we have centralized it in our practice. Now prior authorizations for our multi-doctor, multi-location practice can be handled by one person.

Before we implemented SamaCare, we had to use a number of different methods for obtaining prior authorizations, from faxed requests to phone calls. This was very inefficient—being kept on hold and dealing with busy fax lines and follow-up calls to payers, only to later hear that they never received the original request. All this resulted in a significant amount of duplicative work. Further, we had little consistency in how information from



payers was returned. Before SamaCare, we had to manually communicate and document this information across the practice, which caused many delays.

Digitizing and streamlining prior authorizations has allowed us to manage every aspect of our practice more efficiently.

FINDING THE RIGHT EHR

By Daniel Schroder, MBA

As the practice administrator for Bay Area Retina, I have overseen the implementation of two electronic health record (EHR) platforms. Believe it or not, I was a technician the first time I was charged with researching, selecting, and overseeing our transition to an EHR. Our practice leaders chose a technician for this task because we wanted to select a platform with the perspective of the medical professional's workflow and user experience in mind. Due to the business failure of our first EHR vendor, I was recently tasked once again with selecting the right EHR for our practice and overseeing our transition to it. This time we chose a specialty-specific solution provided by Modernizing



Medicine, modmed Ophthalmology.

In this article, I describe the process we used to choose the right EHR and the key features we were looking for in our EHR system.

Efficiency. User experience and efficiency during patient examinations was the main feature we focused on in choosing this system. Implementing any EHR system will help to improve practice efficiency, but the system's user interface and ease of use within your particular practice's workflow are two important factors influencing practice efficiency. The optimal choice can vary greatly between practices.

One reason behind our decision to opt for Modernizing Medicine's EHR was the platform's ability to learn and adjust to the user. In addition to including retina-specific procedure workflows and treatment plans right out of the box, as a user continues to make selections in the system, it starts remembering his or her choices and customizing itself to that user. Subsequently, the most popular selections for a given user are presented as a list of choices, and the most relevant treatment plans appear as a list based on diagnosis, etc. Essentially, the platform learns and optimizes the workflow interface automatically.

Integration. A major draw of the Modernizing Medicine EMR platform was its ability to integrate functionality with our existing imaging equipment. Finding an EHR capable of this was a common sticking point during our search.

The Modernizing Medicine platform presents images in the patient chart so that the doctor can see the latest image alongside those from previous visits. Being able to see all the patient's tests in the chart without having to do the digital equivalent of paging through the chart to find them is quite convenient, and that feature has only gotten better over time. Also, as patients have started to use their portals to access information from home, the system has become more interactive.

CONCLUSION

Transitioning to an EHR is a daunting, complicated, and time-consuming endeavor that will ultimately prove more than worthwhile. Using an EHR in your practice can help to optimize workflows, create efficiencies, and facilitate future growth. Although it can be a challenge to find the right system for your particular practice, exercising your due diligence can lead to a successful pairing. ■

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(Continued from page 7)

TABLE 3. RESOURCE EXAMPLE: QUICK REFERENCE GUIDE FOR 2021 E/M AND EYE VISIT CODES

	E/M Office and Other Outpatient Encounters	Eye Visit Code Comprehensive Exam Components
	CPT codes 99202-99215	CPT codes 92004, 92014
History	Medically relevant	• History (not defined) • General medical observation (not defined) • Chief complaint
Examination	Medically relevant, dilate as medically necessary	Exam: 12 elements, often includes dilation
Medical Decision-Making	Number and complexity of problems addressed at the encounter; amount and/or complexity of data to be reviewed and analyzed; risk of complications and/or morbidity or mortality of patient management (2 of 3)	Initiation or continuation of diagnostic and treatment programs

BE READY FOR 2021

For more information, consult these AAO resources:

- Visit Conquering New E/M Documentation Guidelines for Ophthalmology (bit.ly/1220RTBMCoding1).
- Consult the AAO's dedicated webpage: aao.org/em.
- Use the AAO's Ophthalmic Advisors Group to help identify private consulting services to assist with your transition to 2021 E/M guidelines and internal chart audits (bit.ly/1220RTBMCoding2). ■

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NAVIGATING COVID-19 AND THE SEAS OF CHANGE



Learn lessons from COVID-19 to position your practice for enduring success.

BY JOHN B. PINTO AND CORINNE Z. WOHL, MHSA, COE

The COVID-19 pandemic has left many practices adrift, bobbing up and down at the mercy of the pandemic's many waves of change. Some have been hit by harder and bigger waves, leaving them on the verge of drowning, whereas others have been mostly unaffected. As of this writing, our average client is operating at about 80% to 85% of their historical 2019 baselines, but there is wide variation among our client base, with some just now reopening and others operating at well over 100% of their 2019 baselines.

The luxury of time has allowed us to reflect on and analyze ophthalmology's response to the pandemic. In doing so, we identified six variables that strongly influenced a practice's ability to survive the pandemic (see *Variables Influencing Practice Success During the COVID-19 Pandemic*). An understanding of practice financials combined with greater capital access, boldness, and leadership have carried the most fortunate practices—typically those located farther away from hard-hit urban areas—through this pandemic quite briskly. These variables will continue to influence a practice's success throughout the COVID-19 pandemic as we enter a second wave, not to mention any future crisis.

This article discusses five actions that you can take to help your practice emerge from this pandemic successfully and to position your practice for success in the future.

VARIABLES INFLUENCING PRACTICE SUCCESS DURING THE COVID-19 PANDEMIC



LOCATION

In our experience, rural practices in places *off the grid*, so to speak, such as Montana or Idaho, have been less affected by the coronavirus pandemic than urban practices. Certainly, this varies among clients, some of whom have both urban centers and rural satellite offices. There's a difference in patient perspectives on COVID-19. When patients, staff, and doctors alike are less frightened, business gets back to normal faster.



PATIENT POPULATION

The practices that we have found to be the most resilient are those that treat catastrophic ocular diseases. Retina practices, for example, have largely done just fine. A typical retina practice among our clients bottomed out in April and May but still reported patient volumes at about 80% of historical levels in that same timeframe. Most of these practices (as this article goes to press) are now back or nearly back to 2019 patient volume baselines.



BOLDNESS AND DRIVE

If they've been bold, the doctors who are in control of their practices have been faster to dig out and restore prepandemic practice volume. These doctors set the tone and expectation in their practices that the pandemic would not unduly delay a return to old plans and patient volume.



CAPITAL ACCESS

This allows a practice time to emerge slowly from the COVID-19 pandemic, if a slow emergence is indicated. Practices with greater capital access and doctors with strong personal

balance sheets can afford to move more slowly out of lockdown. This factor has been especially important in urban practices that shut down earlier and have had to take an incremental approach to reopening because of their location.

Capital access also buys seasoned practitioners time. Doctors in their 30s or 40s may be able to be a little bolder in returning to a full volume of patients and resuming full personal exposure to patients and staff. Doctors in their 60s and 70s may get back to business more slowly. Many of our clients in that age group are returning to practice with limited schedules.



LEADERSHIP

Practices with strong lay and physician-owner leadership were able to respond, secure staff compliance, and make better decisions faster at the outset of the pandemic. The practices that were less organized or had fewer leadership capabilities have had a more challenging time responding in real time to the pandemic and an equally hard time coming out of lockdown. It's the practices with poor administrative and physician leadership that are struggling the most today. Practices that lack leadership and capital access are in particular trouble.



FINANCIAL VOLUME AND METRIC AWARENESS

Without a stopwatch, track stars can't evaluate how fast they are running and set goals for improvement. Practice-owners who went into the pandemic with a clear, real-time understanding of their practices' financial and volumetric performance were able to assess how they were doing, gauge their trajectories through the pandemic, and plan for the future.



WRITE A STRATEGIC BUSINESS PLAN

Let's consider two extreme examples. The first is a solo practitioner well into his 70s who plans to work for only 3 more years. His strategic plan might appropriately be to close the practice because it will be too difficult to spend the next year getting back up to full volume only to close the practice down in 1 to 2 years.

The other extreme is a large, multigenerational, multispecialty practice that has a couple of hundred families depending on its future success. It's important to think about the long-term future of this type of practice. The owners must ask themselves, "Is there something that we should be doing differently to be better prepared next time?" The longer that a practice is in business, the higher the odds are that it will experience something similar to this global pandemic again. (Our clients in Asia, where coronavirus illnesses have been more common, are more accustomed to responding to novel coronavirus outbreaks.)

Whatever your practice situation, it is important to write a strategic plan. Once it has been drafted, it should be revised annually. A strategic plan should have been in place before COVID-19 hit. If you have not drafted one yet, it's important to write one whether your practice is large or small. A strategic plan will help you respond faster and cope better with similar challenges as they arise.



REFRESH AND INCREASE CAPITAL ACCESS

Funding may be available from various sources, including active bank accounts, pledges from your practice's owners to provide capital for the business if it's in trouble, the recoverable portion of the accounts receivable, and bank lines of credit. Before COVID-19, we advised clients that all of those capital sources taken together should be no less than three times the practice's monthly operating costs. So we'd have said that, to keep

the doors open and the staff paid, a practice with a \$100,000 burn rate every month should have \$300,000 in ready capital access.

Somewhat chastened by the COVID-19 pandemic, we currently advise owners to have at least five or six times their practice's monthly burn rate readily accessible. For most practices, this necessitates keeping higher working reserves, potentially by distributing less capital to the owners each year for a while to build up those reserves. Practices must also negotiate a higher line of credit with a bank to ensure that five or six times their monthly operating costs is readily at hand.



RECALIBRATE EXPENSES

If you are going to reduce your practice's volume permanently—to account for social distancing or simply to lessen the workload—it's important to decrease your practice's expenses so that they stay in line. Operating expenses should not exceed \$0.70 for every \$1.00 of income. In the best-run practices, \$0.50 to \$0.60 of every dollar earned goes toward covering expenses each month.



INCREASE PATIENT VOLUME

If your practice is achieving 85% to 90% of its 2019 baselines and you're feeling stuck on that plateau, dig deep and—within the bounds of safety and comfort—try to increase patient volume incrementally. The goal, regardless of the pandemic, is to improve profitability by increasing revenue. Seeing just three more patients per clinic day can increase a practice's profit by \$100,000 a year, so take a close look at your patient volume. If yours is still a shadow of its 2019 figures, work with your team to safely add a few patients per day.



ADJUST PERSONAL FINANCIAL PLANS

Take a fresh look at your personal financial goals as a doctor. We all took a lot for granted

up until 2019; we were emerging quite well from the recession, and it looked as if the next few years of investments would treat us well. COVID-19 reset expectations for market volatility for many of our clients deciding how much longer they want or need to work, what they'll need in retirement, and what their earning potential will be between now and then.

Make sure that you, like your practice, have capital reserves and financial resilience. Ensure that you have the savings rate and the flexible thrift to respond and thrive when future economic changes come sweeping through.

CONCLUSION

During the past several months, our average client practice has done much better than we might have expected based on the forecast in March when everyone was running for the hills. At that time, there were fears that the pandemic could deliver a mortal blow to many practices. Overall, we've seen instead that practices, staff, and providers are more resilient.

Even so, there's good reason to learn from the lessons of the past year. For example, some practices saw that they could run with leaner staffing ratios. Take the time to analyze the year and how it affected you. Ask yourself, "What did we learn about our practice's functioning during this time? What did we do well? What didn't we do well? How can we be better prepared the next time?"

Your answers to questions such as these can help you to prepare for the next unforeseeable and significant economic downturn. ■

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2020 YEAR-END TAX TIPS



Plan for the current year and preview possible changes ahead.

BY CAROLE C. FOOS, CPA

In addition to several tax changes related to the COVID-19 pandemic, the results of the US Presidential, congressional, and senatorial elections will affect tax planning beyond 2020. This article shares some tax planning tips for this year and describes some of the proposed changes under a Biden administration.

PAYROLL AND WITHHOLDING

Many taxpayers, and certainly many physicians, saw payroll changes during the COVID-19 shutdown. For this reason, it may be more important this year than in years past to review your projected 2020 income, your withholding, and your estimated tax payments. If you were taking a reduced paycheck or no paycheck during the shutdown but were counting on a certain amount of tax withholding to keep you safe from underpayment penalties, you still have time to make any necessary adjustments. Withheld taxes are considered to be paid evenly throughout the year, whereas estimated payments are considered paid on the actual payment date. If you find that you have underpaid, it may be better to increase withholding rather than increase your fourth quarter estimated payment.

The Biden tax plan proposes to return the top tax rate to 39.6% from the current 37%. President-elect Biden has also proposed imposing the 12.4% Social Security payroll tax on wages and self-employment income that is higher than \$400,000. The 12.4% tax would be split between employers and employees. Because this tax is not currently imposed

on wages and self-employment earnings above \$137,700, the Biden plan would create a gap in the Social Security payroll tax, so wages between \$137,700 and \$400,000 would not be taxed.

PLAN CONTRIBUTIONS

A lack of paychecks, distributions, and revenue caused many physicians to stop or reduce funding of their retirement plans during the shutdown. You may maximize your retirement account contributions before year's end. The 2020 limits for 401(k) salary deferrals are \$19,500 for taxpayers who are 49 years of age or younger and \$26,000 for those who are 50 years of age or older. If you are over age 70½ or have a parent over that age, the CARES Act waived required minimum distributions for 2020 both for account owners and for beneficiaries who inherited a retirement account.

Taxpayers who are eligible for health savings account contributions have

time to maximize those as well. A health savings account allows you to use pretax dollars to pay for health care expenses. If your family is covered under your plan, you may contribute up to \$7,100 in 2020 plus an extra \$1,000 if you are 55 years of age or older.

ITEMIZED DEDUCTIONS

With the current limitations on deductions for state and local income and property taxes (\$10,000 maximum deduction) and the increased standard deduction for taxpayers, many taxpayers are taking the standard deduction instead of itemizing. You may want to consider bunching 2 years' worth of charitable contributions into 1 tax year to itemize 1 year and take the standard deduction the next year. You may also do this if you have medical expenses that approach but don't quite meet the adjusted gross income threshold for deductibility each year. In this situation, try to bunch the medical expenses into 1 year to gain some tax benefit.

AT A GLANCE

- ▶ In addition to several tax changes related to the COVID-19 pandemic, the results of the US presidential, congressional, and senatorial elections will affect tax planning beyond 2020.
- ▶ Review your 2020 taxable income, deductions, withholding, and estimated payments so you know where you stand.
- ▶ If the COVID-19 shutdown or other factors reduced your income in 2020 but you expect it to increase next year, you may want to push some of your deductions into 2021.

President-elect Biden is reportedly in favor of removing the cap on the federal deductions for state and local taxes, as are Speaker of the US House of Representatives Nancy Pelosi and US Senate Minority Leader Charles Schumer. The Biden plan proposes capping the value of all itemized deductions at 28% for taxpayers in the top tax bracket. He has also proposed restoring the Pease limitation on itemized deductions for those with more than \$400,000 in taxable income. This limitation required taxpayers to subtract 3% of some deductions (including mortgage interest, state and local taxes, and charitable contributions) if adjusted gross income was above certain thresholds.

HARVESTING CAPITAL LOSSES AGAINST GAINS

Harvesting capital losses is a strategy in which you sell investment assets at a loss in order to offset capital gains income in the same tax year. Doing so allows you to reduce the capital gains tax you owe. In 2020, you might have sold investment assets when the market was at a low point during the COVID-19 pandemic. If so, keep in mind the following if capital losses exceed capital gains for this year: You may only deduct \$3,000 in losses against non-capital gains income, and any remaining capital losses will be carried forward to future tax years.

The proposal includes taxing capital gains at ordinary income tax rates for those earning more than \$1 million. The current top capital gains tax rate for those in the highest tax bracket is 23.8%. The proposal restores the 39.6% top individual income tax rate that was in effect prior to the 2017 Tax Cuts and Jobs Act. Therefore, capital gains for those with income above \$1 million would be taxed at 39.6%.

QUALIFIED BUSINESS INCOME DEDUCTION

A physician's practice is considered a specified service trade or business

(SSTB) and thus is generally excluded from taking the Section 199A pass-through income deduction. Because this deduction is taken at the individual level, however, some physicians are able to take the deduction against practice income. Individual taxpayers with less than \$326,600 (married) or \$163,300 (single) of taxable income may claim a 20% Section 199A deduction even if the income is from an SSTB. The deduction is phased out until it goes away completely for specified service business income once taxable income reaches \$426,600 (married) or \$213,300 (single).

You may have other non-SSTB pass-through income that qualifies for the deduction. In addition, if you are above the threshold amount, qualified plan contributions and increased charitable contributions may enable you to reduce your taxable income to below the threshold amount.

President-elect Biden's proposal would phase out the Section 199A deduction for those taxpayers who earn more than \$400,000 per year. This deduction is currently scheduled to expire after 2025.

C CORPORATIONS

If your practice is taxed as a C corporation, the owners are likely reducing corporate taxable income by paying themselves compensation in the form of W-2 wages and bonuses. The current tax rate for C corporations is 21%. The Biden proposal increases that rate to 28%, which remains below the previous 35% top rate.

CONCLUSION

Review your 2020 taxable income, deductions, withholding, and estimated payments so you know where you stand. If the COVID-19 shutdown or other factors reduced your income in 2020 but you expect it to increase next year, you may want to push some of your deductions into 2021.

Educated planning is often the best defense against future unknowns. ■

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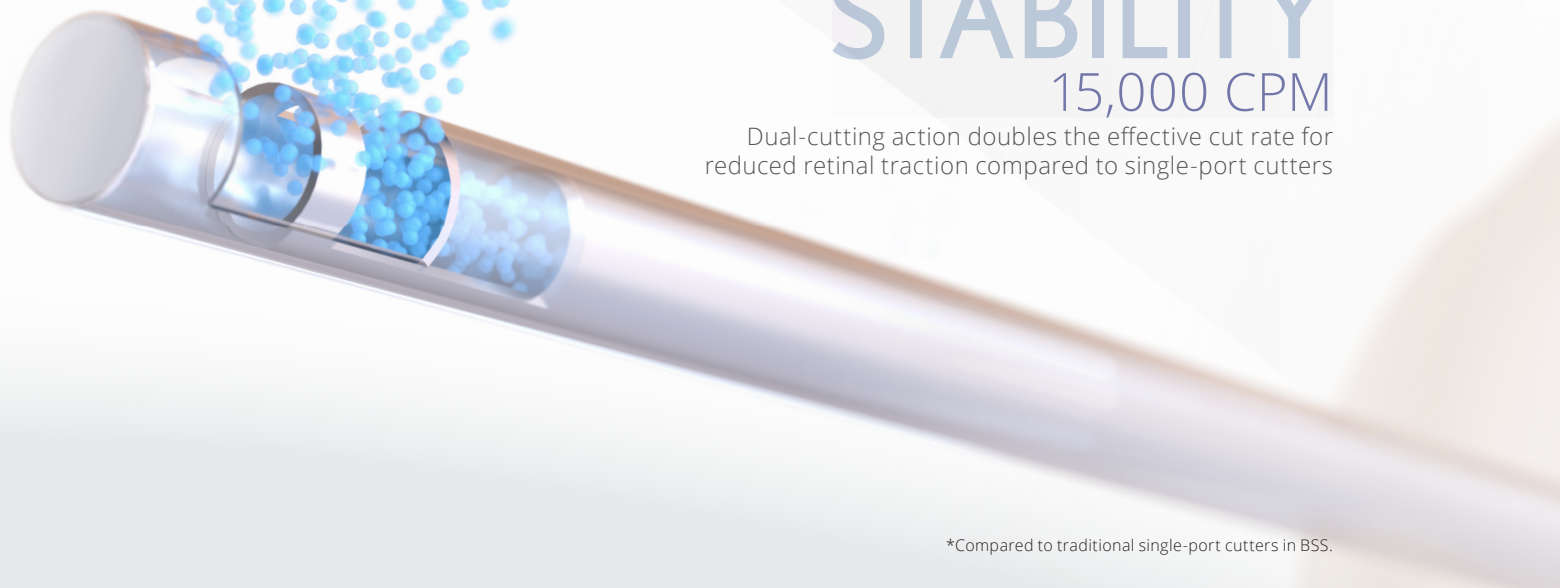


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