AMERICAN ACADEMY OF OPHTHALMOLOGY®

EyeNet®
SUPPLEMENT

MIPS 2021: A Primer and Reference

Published May 2021
Updated July 2021

Your Ophthalmology–Specific Guide

In June 2021, CMS Published Corrections to the Quality Measure Benchmarks

WHAT COULD SHE SEE THIS YEAR?

EYLEA®
(aflibercept) Injection
For Intravitreal Injection

304 BINGO CARDS

Inspired by a real patient with Wet AMD.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

- Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA.
- Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.
- There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA compared with 1.5% (9 out of 595) in patients treated with ranibizumab; through 96 weeks, the incidence was 3.3% (60 out of 1824) in the EYLEA group compared with 3.2% (19 out of 595) in the ranibizumab group. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

REGENERON

777 Old Saw Mill River Road, Tarrytown, NY 10591

PROVEN VISUAL OUTCOMES AT YEAR 1 IN THE VIEW STUDIES

Fewer injections with EYLEA Q8 vs ranibizumab Q4

Demonstrated in the largest phase 3 anti-VEGF trials completed to date in Wet AMD (N=2412)[1-3]

Proportion of patients who maintained vision (<15 ETDRS letters lost of BCVA) at Year 1 from baseline[1-3,*]

	Primary Endpoint (Year 1)	
	VIEW 1	VIEW 2
EYLEA Q4	**95%** (12.5 injections†)	**95%** (12.6 injections†)
EYLEA Q8‡	**94%** (7.5 injections†)	**95%** (7.7 injections†)
ranibizumab Q4	**94%** (12.1 injections†)	**95%** (12.7 injections†)

*Last observation carried forward; full analysis set.
†Safety analysis set.
‡Following 3 initial monthly doses.

Vision was maintained at Year 1 with ≈5 fewer injections with EYLEA Q8 vs ranibizumab Q4

EYLEA was clinically equivalent to ranibizumab.

VIEW 1 and VIEW 2 study designs: Two multicenter, double-masked clinical studies in which patients with Wet AMD (N=2412; age range: 49-99 years, with a mean of 76 years) were randomized to receive: 1) EYLEA 2 mg Q8 following 3 initial monthly doses; 2) EYLEA 2 mg Q4; 3) EYLEA 0.5 mg Q4; or 4) ranibizumab 0.5 mg Q4. Protocol-specified visits occurred every 28 (±3) days.[1] In both studies, the primary efficacy endpoint was the proportion of patients with Wet AMD who maintained vision, defined as losing <15 letters of visual acuity at Week 52, compared with baseline.[1]

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

anti-VEGF, anti–vascular endothelial growth factor; BCVA, best-corrected visual acuity; ETDRS, Early Treatment Diabetic Retinopathy Study; Q4, every 4 weeks; Q8, every 8 weeks.

ADVERSE REACTIONS

- Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis and retinal detachment.
- The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.
- Patients may experience temporary visual disturbances after an intravitreal injection with EYLEA and the associated eye examinations. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

INDICATIONS

EYLEA® (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).

References: 1. EYLEA® (aflibercept) Injection full U.S. Prescribing Information. Regeneron Pharmaceuticals, Inc. August 2019. **2.** Data on file. Regeneron Pharmaceuticals, Inc. **3.** Heier JS, Brown DM, Chong V, et al; for the VIEW 1 and VIEW 2 Study Groups. Intravitreal aflibercept (VEGF Trap-Eye) in wet age-related macular degeneration. *Ophthalmology*. 2012;119(12):2537-2548. doi:10.1016/j.ophtha.2012.09.006

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

03/2021
EYL.21.02.0019

EYLEA®
(aflibercept) Injection
For Intravitreal Injection

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

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

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

4 CONTRAINDICATIONS

4.1 Ocular or 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

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

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

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

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

	CRVO		BRVO	
Adverse Reactions	**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

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

Less common adverse reactions reported in <1% of the patients treated with EYLEA were hypersensitivity, retinal detachment, retinal tear, corneal edema, and injection site hemorrhage.
Safety data observed in 269 patients with nonproliferative diabetic retinopathy (NPDR) through week 52 in the PANORAMA trial were consistent with those seen in the phase 3 VIVID and VISTA trials (see Table 3 above).

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy
Risk Summary
Adequate and well-controlled studies with EYLEA have not been conducted in pregnant women. Aflibercept produced adverse embryofetal effects in rabbits, including external, visceral, and skeletal malformations. A fetal No Observed Adverse Effect Level (NOAEL) was not identified. At the lowest dose shown to produce adverse embryofetal effects, systemic exposures (based on AUC for free aflibercept) were approximately 6 times higher than AUC values observed in humans after a single intravitreal treatment at the recommended clinical dose [*see Animal Data*].
Animal reproduction studies are not always predictive of human response, and it is not known whether EYLEA can cause fetal harm when administered to a pregnant woman. Based on the anti-VEGF mechanism of action for aflibercept, treatment with EYLEA may pose a risk to human embryofetal development. EYLEA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

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

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

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

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

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

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

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

REGENERON

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

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

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

EYL.20.09.0052

EyeNet® MAGAZINE

David W. Parke II, MD
Editor-in-Chief

Ruth D. Williams, MD
Chief Medical Editor

Dale E. Fajardo, EdD, MBA
Publisher

Patty Ames
Executive Editor

Carey S. Ballard
Art Director / Program Manager

Chris McDonagh, Jean Shaw
Senior Editors

Miranda Smith
Associate Editor / Advertising Manager

Mark Mrvica, Kelly Miller
M.J. Mrvica Associates, Inc.
2 West Taunton Ave.,
Berlin, NJ 08009
856-768-9360
mjmrvica@mrvica.com
Advertising Sales

AMERICAN ACADEMY OF OPHTHALMOLOGY®
655 Beach St.
San Francisco, CA 94109
866-561-8558, 415-561-8500
aao.org

Governmental Affairs Division
20 F Street NW, Suite 400
Washington, DC 20001
202-737-6662

***MIPS 2021* Editor and Author**
Chris McDonagh
EyeNet *Senior Editor*

***MIPS 2021* Authors**
Kayla L. Amodeo, PhD
Director, Health Policy

Sarah Kong
Representative, Customer Service

Flora Lum, MD
Vice President, Quality and Data Science Division

Cherie McNett
Director, Health Policy

Molly Peltzman
Manager, Reimbursement Policy & Regulatory Affairs

Sue Vicchrilli, COT, OCS, OCSR
Director, Coding and Reimbursement

John Ward
Manager, Customer Service

Joy Woodke, COE, OCS, OCSR
Coding & Practice Management Executive

MIPS 2021: A Primer and Reference

MIPS 2021:
A Primer and Reference

COVER PHOTOGRAPH
Iakov Filimonov/Shutterstock.com

Please note: IRIS Registry is a registered trademark of the American Academy of Ophthalmology (AAO). All of the AAO-developed quality measures ("Measures") outlined in this supplement are copyrighted by the H. Dunbar Hoskins Jr., MD, Center for Quality Eye Care of the AAO. These Measures are not clinical guidelines and do not establish a medical standard. They have not been tested in all possible applications. The Measures, while copyrighted, can be reproduced and distributed with appropriate credit, without modification, for noncommercial purposes, e.g., use by health care providers in connection with their practices. The Academy encourages use of the Measures by other health care professionals, where applicable. Commercial use is defined as the sale, license, or distribution of the Measures for commercial gain, or incorporation of some or all of a Measure(s) into a product or service that is sold, licensed, or distributed for commercial gain. Commercial uses of the Measures require a license agreement between the user and the AAO. The AAO, its employees, and its members, are not responsible for any use of the Measures. The measures and specifications are provided "as is," without warranty of any kind.

MIPS 2021 is a supplement to *EyeNet Magazine.*

EyeNet® MAGAZINE

AMERICAN ACADEMY OF OPHTHALMOLOGY®

655 Beach St.
San Francisco, CA 94109
866-561-8558, 415-561-8500
aao.org

Governmental Affairs Division
20 F Street NW, Suite 400
Washington, DC 20001
202-737-6662

MAKE SURE YOUR TEAM HAS WHAT IT NEEDS

Succeed at MIPS in 2021

The Merit-Based Incentive Payment System (MIPS) has made it much more challenging to avoid the MIPS payment penalty. Consequently, you can't assume that repeating what you did in 2020 will be enough for 2021, especially if you are in in a small practice that doesn't have an electronic health record (EHR) system (see page 38).

Are You and Your Practice on Track?

Who is on your MIPS team? Your practice should have a MIPS point person and, in case of illness or staff turnover, at least one backup. With the maximum penalty at –9%, a physician should serve as the practice's MIPS champion, and he or she should make sure your MIPS staff have what they need.

Don't make assumptions about MIPS status. The MIPS point person should check whether each of the practice's clinicians is a MIPS eligible clinician and can do so using the QPP Participation Status tool (see page 15). Also use this tool to check other MIPS designations, such as practice size.

Is your 2021 MIPS performance on track? You should have already picked a quality reporting option (see pages 18-19) and know what quality measures you are reporting. You should also have reviewed the improvement activities (see pages 51-64) and, if applicable, the promoting interoperability (PI) measures. Has your practice decided whether its clinicians are reporting as individuals or as a group? If the latter, make sure all clinicians know which quality measures and improvement activities your group plans to report.

Have clinicians joined or left your practice? CMS determines practice size based on the information that it has in its Provider Enrollment, Chain and Ownership System (PECOS). To check that the information is current, visit the PECOS portal at https://pecos.cms.hhs.gov.

Boost your promoting interoperability (PI) score. Many ophthalmology practices that participate in the PI performance category have been scoring lower than they should for the Provide Patients Electronic Access to Their Health Information measure. For tips on improving your score for this measure, visit aao.org/practice-management/article/mips-tips-provide-patients-electronic-access.

Make the Most of the IRIS Registry

The IRIS Registry is ophthalmology's tool of choice for MIPS reporting (aao.org/iris-registry/medicare-reporting). Last year, ophthalmology practices received $78 million in MIPS bonuses, thanks in no small part to widespread use of the IRIS Registry.

Make sure your practice and provider information is up to date. Whenever there is clinician turnover, make sure you update your provider information on the IRIS Registry. You can do so by submitting a Help Desk ticket (see aao.org/iris-registry/user-guide/submit-help-desk-ticket). If a new clinician's electronic records need to be integrated into the IRIS Registry, you must let the Academy know no later than Sept. 1. Also let the IRIS Registry know if any of your clinicians don't have to take part in MIPS, or if the low-volume exclusion applies but they decide to opt in to MIPS.

Speed up IRIS Registry communications. Whenever you contact the IRIS Registry or its vendors, make sure you include your practice's name and its IRIS Registry ID. Watch for emails from FIGmd, an IRIS Registry vendor.

Use These Five MIPS Resources

Make sure staff have access to do the following:

1. Use aao.org/medicare. This hub page links to member-only ophthalmic-specific resources.

2. Use aao.org/iris-registry. The IRIS Registry User Guide walks you through the key MIPS steps.

3. Read these Academy and AAOE news bulletins. To learn about the latest MIPS developments, watch for *Washington Report Express* (Thursdays), *Medicare Physician Payment Update* (first Saturday of each month), and, if you are an AAOE member, *Practice Management Express* (Sundays).

4. Use the email hotlines. Got a MIPS question? If you can't find your answer in this MIPS manual or in the resources listed above, you can email mips@aao.org or irisregistry@aao.org, (If you have technical problems with IRIS Registry–EHR integration, submit a help-desk ticket; learn how at aao.org/iris-registry/user-guide/submit-help-desk-ticket.)

5. Crowdsource MIPS answers via AAOE-Talk. AAOE members can use this listserv to find out how other practices are tackling MIPS: Go to aao.org/practice-management/listserv. Not an AAOE member? Join at aao.org/member-services/join-aaoe.

CMS HAS RAISED THE BAR WITH A 60-POINT PERFORMANCE THRESHOLD

What's New With 2021 MIPS Reporting

Each year, CMS makes changes to its MIPS regulations. Here are those most likely to impact ophthalmology practices.

Harder to Avoid the Penalty

Performance threshold is now 60 points. Your 2023 Medicare Part B payments will be penalized if your 2021 MIPS final score falls below a performance threshold of 60 points (see Tables 2A and 2B, page 12), up from 45 points last year.

You may need to update your MIPS strategy. You can't assume that you will avoid the penalty with the same measures and the same level of performance as last year.

Quality's weight reduced; cost's weight increased. Your MIPS final score is based on your weighted scores in up to four performance categories. The quality and cost performance categories are weighted at 40% and 20%, respectively, of your MIPS final score in 2021, compared with 45% and 15% in 2020. Note: In 2021, ophthalmologists who don't perform cataract surgery are likely to be excluded from the cost performance category, in which case cost's weight in the MIPS final score would be reallocated to quality in most reweighting scenarios (see Table 1, page 11).

What's New With Quality

Here are some of the biggest changes in quality reporting.

Attention small practices: You can no longer avoid the penalty with minimal reporting. Last year the performance threshold was a MIPS final score of 45 points. This meant that if you were in a small practice, and you were excluded from the cost and promoting interoperability performance categories, you could avoid the payment penalty by maxing out your 2020 improvement activities score and then doing minimal quality reporting—as little as reporting six measures just one time for just one patient.

That won't work in 2021. Now that you need a MIPS final score of 60 points to avoid the payment penalty, your quality score will need to be much higher. In 2021, because many claims-based measures are subject to extreme scoring limitations (see Table 8, page 36), it will be very difficult to avoid a payment penalty if you are reporting quality measures by claims. Indeed, if you don't have an EHR system, avoiding a penalty will be difficult even if you use the IRIS Registry (see page 38), though you can still try to minimize that penalty.

Eight IRIS Registry measures now have benchmarks. As a qualified clinical data registry (QCDR), the IRIS Registry can develop its own QCDR measures. It has developed 30 of these IRIS measures, eight of which now have benchmarks (see Table 7, page 34), up from five last year. These ophthalmology-specific measures can be reported only via the IRIS Registry. If you previously used claims to report quality measures, you may find that these QCDR measures provide a more feasible pathway to avoiding or minimizing the penalty.

Change to hospital readmission measure. The All-Cause Hospital Readmission (ACR) measure has been replaced with quality measure 479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the MIPS Eligible Clinician Groups. Few ophthalmologists are likely to meet the case minimum for this measure (see page 22).

Measure 12: Primary Open Angle (POAG): Optic Nerve Evaluation now only available for EHR-based reporting. You can no longer report measure 12 manually via the IRIS Registry or via claims. You can still report it via IRIS Registry–EHR integration, but you should check the changes to its measure specifications (see below).

Measure 419: Overuse of Imaging for the Evaluation of Primary Headache can no longer be reported by claims. The measure can still be reported manually via the IRIS Registry.

Double-check the measure specifications. Whichever quality measures you plan to report—even if you reported them last year—you should check the measure specifications to make sure you understand how the measures are performed, how your performance rate will be determined, and what documentation you should maintain. If you use the IRIS Registry, you can log in to it and download PDFs of the measure specifications. You also can visit aao.org/medicare/quality-reporting-measures and download a table that has links to the measure specifications. Each measure has a different set of specifications for each reporting mechanism.

The following quality measures, for example, have undergone substantive changes to their specifications for at least one collection type (quality measures can have different specifications depending on which reporting mechanism you use).

- Measure 1: Diabetes: Hemoglobin A1c Poor Control
- Measure 12: POAG: Optic Nerve Evaluation
- Measure 14: AMD: Dilated Macular Examination
- Measure 19: Diabetic Retinopathy: Communication With the Physician Managing Ongoing Diabetes Care
- Measure 110: Preventive Care and Screening: Influenza

Immunization
- Measure 117: Diabetes: Eye Exam
- Measure 128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan
- Measure 130: Documentation of Current Medications in Medical Record
- Measure 226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention
- Measure 236: Controlling High Blood Pressure
- Measure 238: Use of High-Risk Medications in Older Adults (previously known as Use of High-Risk Medications in *the Elderly*)
- Measure 265: Biopsy: Follow-Up

What's New With Promoting Interoperability (PI)

The biggest changes to the EHR-based performance category are a new alternate measure and new EHR certification.

New Health Information Exchange (HIE) measure. To get a score for PI in 2020, you had to perform (or claim exclusions for) two Support Electronic Referral Loops measures. You can still do that in 2021 (see Table 9, page 45), but you also have the option of performing a new option instead—the HIE Bi-Directional Exchange measure (see page 46). If you successfully report this measure, and attest that you did so, the measure will contribute 40 points toward your PI score. As with all PI measures, make sure that you document proof of your measure performance. CMS has said that clinicians can support their attestation for this measure with the following documentation: "Agreements with the organization providing them with health information exchange services; materials from the organization that provides their HIE services describing their services in a manner consistent with the attestation statements; or systems documentation from their EHR vendor describing their connection to the HIE."

New certification for EHR systems. In 2021 and 2022, you can still perform PI measures using an EHR system that is a 2015-edition CEHRT, but you also have the option of using one that is a 2015-edition Cures Update CEHRT (see page 43).

No plans to extend PI's minimum performance period. In the early years of MIPS, CMS had said that it would eventually extend PI's minimum performance period to the full calendar year. In the latest regulations, the agency announced that it has dropped those plans; this year, and in future performance years, the minimum performance period for PI is set at 90 consecutive days.

What's New With Improvement Activities

CMS has clarified the requirements for a COVID-19 activity that was introduced last year, and it also modified the descriptions for two improvement activities.

IA_ERP_3 has a new name: COVID-19 clinical data reporting with or without clinical trial. CMS launched this high-weighted improvement activity in March 2020, but the activity's initial name—COVID-19 clinical trials—proved to be misleading. Later in 2020, the agency renamed the activity to clarify that you don't have to be involved in a clinical trial. For more on this activity, see page 55.

IA_AHE_7: Comprehensive eye exams. CMS expanded its description of this medium-weighted activity to include promoting access to vision rehabilitation services. For more on this activity, see page 57.

IA_BE_4: Engagement of patients through improvements in patient portal. CMS has expanded the description of this medium-weighted activity. It has added language that:
- includes caregivers as potential portal users;
- clarifies that the portal's use should be bidirectional and its primary use should be clinical, not just administrative; and
- adds a list of examples of bidirectional, clinical use.

For more on this activity, see page 58.

What's New With Cost

Like last year, ophthalmologists are only likely to receive a cost score if they perform cataract surgery. However, there have been a few changes to cost, including the following.

An increased role for cost. The biggest change to the cost performance category involves its steadily increasing contribution to your MIPS final score. It's default weight in your MIPS final score was 15% last year, is 20% in 2021, and is slated to be 30% in 2022. (Quality's default weight, meanwhile, has been falling.)

Cataract surgery and telehealth services. Because of the increased use of telehealth during the COVID-19 pandemic, CMS has updated the specifications of cost measures, including the one for cataract surgery, to include the codes and costs associated with some telehealth services.

CMS continues to develop new cost measures that it might start using in future performance years. Last year, CMS field tested two episode-based cost measures that could be relevant to ophthalmology—one for diabetes and another for melanoma resection. Whenever a potential measure might impact ophthalmologists, the Academy will monitor the measure's development and alert CMS to any problems.

New Site for Reporting of MIPS Results

Until this year, CMS posted some MIPS scores on the Physician Compare website. The agency has now replaced that website with the Care Compare site (https://medicare.gov/care-compare). In early 2023, you will be able to review the agency's summary of your 2021 MIPS performance before it gets posted at Care Compare.

Watch Out for Further Changes!

This supplement reflects the Academy's understanding of the 2021 MIPS regulations at time of press, but CMS policies can change. For the latest MIPS news, check your email for the following:
- *Medicare Physician Payment Update* (first Saturday of each month)
- *Washington Report Express* (every Thursday)
- *Practice Management Express* (every Sunday for AAOE members)

KNOW THE BASICS

Your MIPS Final Score, Bonuses, and Penalties

Under MIPS, Medicare Part B payments are subject to a payment adjustment based on clinician performance, with your MIPS final score for 2021 determining whether your 2023 payment adjustment is positive (a bonus), neutral (no adjustment), or negative (a penalty).

Your MIPS Final Score

Your 2021 MIPS final score (0-100 points) is a composite score. As in past years, your MIPS final score will be based on your weighted scores in up to four performance categories. Their default weights are as follows:

- quality—40% (down from 45% in 2020)
- promoting interoperability—25%
- improvement activities—15%
- cost—20% (up from 15% in 2020)

What the weights mean. If your quality score is weighted at 40%, it can contribute a maximum of 40 points to your MIPS final score; for example, a quality score of 60% would contribute 24 points (60% of 40 points).

Get up to 5 bonus points for patient complexity. If you report MIPS data for at least one performance category, you may be eligible for a complex patient bonus.

CMS determines the complex patient bonus based on two indicators:

1. the average Hierarchical Condition Category (HCC) risk score of your patients; and
2. a "dual eligible" score, which is based on the proportion of beneficiaries eligible for both Medicare and Medicaid.

Note: For the 2020 performance year, because of the COVID-19 pandemic, CMS increased the maximum complex patient bonus from 5 points to 10 points. What about this year? At time of press, the agency was indicating that it would cap this bonus at the usual 5 points.

Calculating your MIPS final score. Your MIPS final score is the sum of your weighted performance category scores (0-100 points) plus your complex patient bonus (0-5 points). It is capped at 100 points,

Example. In a hypothetical example, a clinician scores 60% for quality, 80% for promoting interoperability, 100% for improvement activities, and 60% for cost. If the default weights of those four performance category scores apply, then they would contribute to her MIPS final score as follows:

- quality score of 60% contributes 24 points (60% of 40 points)
- promoting interoperability score of 80% contributes 20 points (80% of 25 points)
- improvement activities score of 100% contributes 15 points (100% of 15 points)
- cost score of 60% contributes 12 points (60% of 20 points)

If the clinician's complex patient bonus contributes 2 bonus points, then the MIPS final score would be 73 points (the sum of 24 + 20 + 15 + 12 + 2).

Reweighting Your Performance Categories

In some circumstances, CMS can reweight the performance categories. If CMS determines that you shouldn't be scored on a performance category, it can reduce that category's weight in your MIPS final score to zero and increase the weight of one or more of the other performance categories as shown in Table 1 (next page). Here are some common scenarios:

Promoting interoperability reweighted to zero. If you qualify for a promoting interoperability exception (see page 46)—because, for example, you are in a small practice and successfully apply for the "overwhelming barriers" exception—CMS can reduce the weight of that performance category to zero and increase quality's weight from 40% to 65%. A quality score of 60% would now contribute 39 points (60% of 65 points) to your MIPS final score.

Cost reweighted to zero. If you don't perform cataract surgery, then it is unlikely that you will meet the case minimum for any of this year's cost measures (see pages 65 and 66). If that's the case, then CMS will not factor cost into your MIPS final score. Instead, it will reduce cost's weight from 20% to zero and increase quality's weight from 40% to 55% and promoting interoperability's weight from 25% to 30%. A quality score of 60% would now contribute 33 points (60% of 55 points) to your MIPS final score, and a promoting interoperability score of 80% would contribute 24 points (80% of 30 points).

What if both cost and promoting interoperability are reweighted to zero? Your quality score would now have a weight of 85%, meaning that a quality score of 60% would contribute 51 points (60% of 85 points) to your MIPS final score.

Emergencies. CMS can reweight performance categories if it determines that "extreme and uncontrollable circumstances" apply (see page 16).

Table 1: How the Performance Categories Are Weighted

Your MIPS final score (0-100 points) is a composite score based on up to four performance category scores, which are weighted as shown below. For example, the default weight for promoting interoperability (PI) is 25%, meaning that it can contribute up to 25 points to your MIPS final score—in that case, a PI score of 80% would contribute 20 points (80% of 25 points) to your MIPS final score.

Default Weights		Weighting in MIPS Final Score			
		Quality	PI	Improvement Activities	Cost
You are scored on all four performance categories—no reweighting	Weight	40%	25%	15%	20%
	Points	0-40	0-25	0-15	0-20
Reweighting Scenarios		**Weighting in MIPS Final Score**			
		Quality	**PI**	**Improvement Activities**	**Cost**
Reweight One Performance Category to a Zero Weight					
No cost	Weight	55%	30%	15%	0%
	Points	0-55	0-30	0-15	0
No promoting interoperability (PI)	Weight	65%	0%	15%	20%
	Points	0-65	0	0-15	0-20
No quality	Weight	0%	65%	15%	20%
	Points	0	0-65	0-15	0-20
No improvement activities	Weight	55%	25%	0%	20%
	Points	0-55	0-25	0	0-20
Reweight Two Performance Categories to a Zero Weight					
No cost and no PI	Weight	85%	0%	15%	0%
	Points	0-85	0	0-15	0
No cost and no quality	Weight	0%	85%	15%	0%
	Points	0	0-85	0-15	0
No cost and no improvement activities	Weight	70%	30%	0%	0%
	Points	0-70	0-30	0	0
No PI and no quality	Weight	0%	0%	50%	50%
	Points	0	0	0-50	0-50
No PI and no improvement activities	Weight	80%	0%	0%	20%
	Points	0-80	0	0	0-20
No quality and no improvement activities	Weight	0%	80%	0%	20%
	Points	0	0-80	0	0-20
No Score for Three Performance Categories					
If CMS can only score you on one performance category, you would be assigned a MIPS final score of 60 points, which is enough to avoid the payment penalty (see Table 2A, next page).					
When might you qualify to have performance categories reweighted? CMS reweights performance categories if extreme and uncontrollable circumstances apply (see page 16), if a promoting interoperability exception applies (see page 46), or if you don't meet the case minimum for any of the cost measures.					

Assessed on How You Do During Each Category's Performance Period

Your score for a performance category will depend on how you perform over a performance period. The performance period for each performance category must take place between Jan. 1, 2021, and Dec. 31, 2021, and its length depends on the category:

- quality: 12 months (full calendar year)
- promoting interoperability: 90 consecutive days or longer (up to the full calendar year)
- improvement activities: typically 90 consecutive days or longer (up to the full calendar year)
- cost: 12 months (full calendar year)

You don't have to tackle promoting interoperability measures and improvement activities at the same time. Each of those two performance categories could have a different performance period. For example, you could pick June-August for improvement activities and September-November for promoting interoperability—but you would need to perform all your improvement activities within that June-August time frame and all your *scored* promoting interoperability measures within that September-November time frame, though they could also extend beyond that period.

Note: For the promoting interoperability performance category, the *unscored* Security Risk Analysis measure is an exception—it has to be performed during the calendar year, but it doesn't have to be performed during the same 90-day performance period as your scored promoting interoperability measures.

Reporting as a group? If you are reporting an improvement activity as a group, at least half of the group must perform the activity for 90 or more days, but they can each pick their own date range of 90 days or more.

Special Circumstances: When Clinicians Join a Practice Late in the Year

If you join a practice in the last three months of 2021, CMS will assume that you won't have enough measures available to you to participate as an individual in MIPS at that practice. What does this mean for your score at that practice? If you join a newly formed practice (established after Oct. 1, 2021) or if you join an established practice where the clinicians are reporting as individuals, CMS will award you a MIPS final score of 60 points, which is this year's performance threshold, meaning that you would get a neutral payment adjustment in 2023. But if you join an established practice that is reporting as a group and includes your National Provider Identifier in its group-level reporting, you would get its group score; your data after you join should be included in its group reporting.

CMS Determines Your Payment Adjustment

Bonus or penalty? Your 2021 MIPS final score (0-100 points) will impact your 2023 Medicare Part B payments as shown below.

If your MIPS final score is 15 points or less, you will incur the maximum –9% penalty. If you can't accumulate the 60 points to avoid the payment penalty, you should still evaluate what your practice can do to score more than 15 points and avoid the maximum –9% penalty.

If you score more than 15 points but less than 60 points, you will incur a negative payment adjustment. As shown in Table 2B, this penalty will be based on a linear sliding scale (the higher the score, the lower the penalty).

If you score 60 points, your payment adjustment will be neutral. You will get neither a penalty nor a bonus.

If you score more than 60 points, you will earn a positive payment adjustment. CMS funds this bonus with money

Table 2A: Bonuses and Penalties

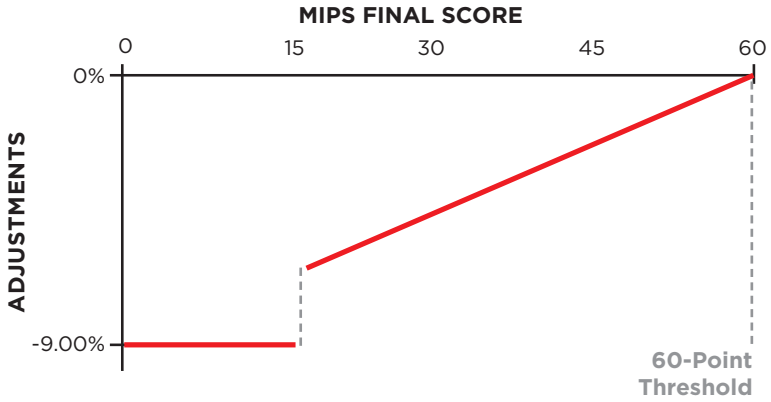
2021 MIPS Final Score	2023 Payment Adjustment
0-15 points	Maximum penalty of –9%
15.01-59.99 points	Penalty on a sliding scale (see Table 2B)
60 points	Neutral (no penalty, no bonus)
60.01-84.99 points	Initial bonus*
85-100 points	Initial bonus* + exceptional performance bonus†

* The initial bonus is based on a linear sliding scale—those who score 60.01 points get the lowest bonus; those who score 100 points get the highest.

† The exceptional performance bonus is based on a linear sliding scale—those who score 85 points get the lowest bonus; those who score 100 points get the highest.

Table 2B: Payment Penalty

If your 2021 MIPS final score is less than the 60-point performance threshold, your 2023 Medicare Part B payments will be reduced as shown below.



that it saves when it reduces payments to those who score less than 60 points.

If you score at least 85 points, you will also earn an additional positive payment adjustment for exceptional performance. These bonuses are funded by a $500-million bonus pool that will be used to reward exceptional performance.

Although CMS has set the negative payment adjustment (as shown in Table 2B), it doesn't yet know what the positive payment adjustments will be. The bonus for scoring more than 60 points (the initial bonus) will be funded by payment penalties. Consequently, CMS won't be able to estimate how much money is in the bonus pool—and how many clinicians will be entitled to money from that pool—until it has calculated the MIPS final scores of all MIPS participants, which can't happen until the performance year is over. Similarly, until CMS knows how many MIPS eligible clinicians have scored at least 85 points, and what scores they got, it won't know how far it has to stretch the $500-millon bonus pool for exceptional performance.

To date, the initial bonuses and the exceptional performance bonuses have been quite small.

Why is there a gap year between performance (2021) and payment adjustments (2023)? CMS needs time to process the MIPS data, determine final scores, perform targeted reviews, and calculate what the adjustment factors for bonuses will need to be in order to ensure budget neutrality.

CMS has steadily raised the bar. In 2017, the first year of MIPS, you only needed a MIPS final score of 3 points to avoid the payment penalty. This performance threshold increased to 15 points in 2018, 30 points in 2019, 45 points in 2020, and 60 points this year. Next year's performance threshold is slated to be set at a level where about half of MIPS eligible clinicians will get a bonus and half will get a penalty. How high would this performance threshold be? In 2019, CMS had estimated that the 2022 performance threshold could be 74.01 points, but the agency more recently said that it could be even higher than that.

How the Bonuses and Penalties Will Be Applied

You can report and be scored as an individual and/or as part of a group. If you are scored as an individual, CMS will use both your Taxpayer Identification Number (TIN) and National Provider Identifier (NPI) to distinguish you as a unique MIPS participant.

If you and your colleagues report as a group, the group's TIN will be used as your identifier for scoring purposes.

You also can report both ways and see which approach scores higher (see "Participate as an Individual or as a Group?" on page 16).

Your payment adjustments are always applied at the TIN/NPI level. CMS will apply the payment adjustments at the TIN/NPI level, and it will do so regardless of whether you were assigned a MIPS final score as an individual or as part of a MIPS group.

What if you move to another practice after 2021 is over? Your 2021 final score will determine your 2023 payment adjustment, and this is the case even if you move to a new practice after the 2021 performance year is over.

The payment adjustments will be applied throughout the year. In 2023, CMS will start applying a payment adjustment based on your 2021 MIPS final score. It will be applied throughout 2023 to your Medicare Part B remittances.

Table 2C: How the Bonuses Are Funded

2021 MIPS Final Score	2023 Payment Adjustment		Provenance of Bonus Dollars
0-15 points	–9% penalty (negative payment adjustment)	→	The negative payment adjustments reduce CMS expenditure. These savings go into a bonus pool that funds the initial bonuses (which are therefore budget neutral).
15.01-59.99 points	Payment penalty on a linear sliding scale, as shown in Table 2B (negative payment adjustment)	→	
60 points	Neutral (no payment adjustment)		
60.01-84.99 points	Initial bonus (payment adjustment)	←	Funded by the penalties, this initial bonus is paid on a linear sliding scale. (Those who score 60.01 points get the lowest bonus, those who score 100 points get the highest.)
85-100 points	Initial bonus (payment adjustment)	←	
	+ exceptional performance bonus (additional payment adjustment)	←	Funded by a separate $500-million bonus pool, this exceptional performance bonus is paid on a linear sliding scale. (Those who score 85 points get the lowest bonus, those who score 100 points get the highest.)

KNOW THE BASICS

Your MIPS Participation Status

Many aspects of your MIPS participation status are determined by CMS. For example: Are you eligible to participate in MIPS? Do you qualify for a MIPS exclusion? Is your practice deemed to be small or large?

But another important aspect of your MIPS status—whether you want to participate as an individual or as part of a group—is up to you and your practice.

Who Does (and Doesn't) Take Part in MIPS

Understand two related terms—*eligible clinicians* and *MIPS eligible clinicians.* Under the Quality Payment Program, which includes an advanced alternative payment model (APM) pathway and a MIPS pathway, certain clinicians are classified as eligible clinicians, and a subset of those—those classified as MIPS eligible clinicians—take part in MIPS.

If you are an eligible clinician, CMS will count you when it is determining practice size regardless of whether or not you are a MIPS eligible clinician (see "Small or Large Practice?" on next page).

Who are the *eligible clinicians*? You are considered an eligible clinician if 1) you have a unique TIN/NPI combination (for more on Tax Identification Numbers and National Provider Identifiers, see "Use of TINs and NPIs as Identifiers," page 16) and 2) you fall within one of these clinician types:

- physicians,
- optometrists,
- physician assistants,
- nurse practitioners,
- clinical nurse specialists,
- certified registered nurse anesthetists,
- clinical psychologists,
- physical therapists,
- occupational therapists,
- qualified speech-language pathologists,
- qualified audiologists, and
- registered dieticians or nutrition professionals.

Who are the *MIPS eligible clinicians*? You are considered a MIPS eligible clinician if:

- you are an eligible clinician and none of the exclusions (see below) apply to you, or
- you are an eligible clinician who decides to "opt in" to MIPS even though you fall below one or two (but not all three) of the low-volume thresholds (see "Exclusion 2," below).

(Note: When the MIPS regulations use the term MIPS eligible clinician, it doesn't just refer to individuals, it can also refer to a group that includes such an individual.)

MIPS Exclusions

Are you exempt from MIPS? You may be exempt from MIPS if at least one of the following three exclusions applies.

Exclusion 1—eligible clinicians new to Medicare. If you enroll in Medicare for the first time in 2021, and you have not previously submitted claims under Medicare, you will be exempt from the MIPS rules for the 2021 performance year.

Exclusion 2—eligible clinicians who are below the low-volume threshold. You will be exempt from MIPS if, during either of two 12-month time segments (see "MIPS Determination Period"), you:

- have allowed charges for covered Medicare Part B professional services of $90,000 or less; or
- provide covered professional services to no more than 200 Medicare Part B beneficiaries; or
- provide 200 or fewer covered professional services to Part B beneficiaries. (Note: If you see one beneficiary one time, that counts as one service; if you see a second patient five times, that would count as another five services.)

Two chances to meet the requirements of a low-volume exclusion. The fact that the MIPS determination period is composed of two time segments means that you have two chances to qualify for a low-volume exclusion: If you fall below the low-volume threshold for one time segment, you will be eligible for an exclusion—even if you exceed

MIPS Determination Period

The MIPS determination period is a 24-month assessment period. It consists of two time segments; for the 2021 performance year, these are as follows:

- Oct. 1, 2019–Sept. 30, 2020 (with 30-day claims run out)
- Oct. 1, 2020–Sept. 30, 2021 (no claims run out)

Why the MIPS determination period matters. CMS uses data from these two time segments to determine whether clinicians fall under any of the low-volume thresholds (see "Exclusion 2") and to see whether a practice should be assigned a special status, such as small practice (see next page) or rural practice (see page 49).

the threshold in the other time segment.

Low-volume threshold determinations are made at the individual level and at the group level. You could fall below the low-volume threshold at the individual-reporting level but would not be exempt from MIPS if reporting as part of a group that exceeds that threshold at the group level.

Exclusion 3—eligible clinicians who are qualifying participants (QPs) in advanced APMs. If you are participating in an advanced APM, you may be exempt from the MIPS rule if you satisfy the APM track's thresholds.

Low-Volume Clinicians Can Opt in to MIPS

Some low-volume clinicians will be able to opt in. If you fall below one or two—but not all three—of the low-volume exclusion thresholds, you have a choice of being exempt from MIPS or electing to opt in to the program. (This option isn't available if you fall below all three thresholds.)

How do you know if you are eligible for opt-in status? Use the QPP Participation Status tool (see "What's Your MIPS Participation Status?").

How do you opt in to MIPS? Assuming that CMS offers the same opt-in procedures as it has used in previous years, you will be able to opt in for performance year 2021 by signing into your account at qpp.cms.gov; the window for opting in would open in January 2022, when CMS opens the submission window for performance year 2021.

What are the consequences of opting in? If you opt in for the 2021 performance year, your 2023 payments will be subject to a MIPS payment adjustment based on your 2021 MIPS final score. You also will be eligible to have your data published on Care Compare (https://medicare.gov/care-compare), a website that CMS has set up to enable the public to see performance data on physicians who participate in Medicare. Once you have elected to opt in to MIPS for 2021, that decision is binding for that performance year.

An alternate option: Voluntary reporting. If you are excluded from MIPS, you can choose to voluntarily report. You will receive feedback reports, but—unlike those who choose to opt in—your 2023 payments won't be subject to a MIPS payment adjustment, and any quality data that you report won't be included when CMS calculates measure benchmarks. Note: If you voluntarily report, your performance information may appear on Care Compare; however, during the preview period in 2023 (see page 67), voluntary reporters can ask that their information not be publicly reported.

What's Your MIPS Participation Status?

Check your status. Use the QPP Participation Status tool at https://qpp.cms.gov/participation-lookup, where you can enter your 10-digit National Provider Identifier (NPI) to find out:

- if you are eligible to participate in MIPS;
- if any exclusions apply to you (and if so, whether you can opt in to MIPS); and
- if a special status—such as being in a small or rural practice—applies to you.

MIPS tip. If you are in multiple practices, make sure you scroll down to check your status at each practice.

Preliminary eligibility information published in late 2020. CMS uses two 12-month time segments (see "MIPS Determination Period," previous page) to assess clinicians' MIPS status. Since late 2020, you could use the QPP Participation Status tool to see your preliminary eligibility information, based on data from the first time segment (Oct. 1, 2019-Sept. 30, 2020).

Final eligibility information published in November 2021. CMS will reconcile data from the second time segment (Oct. 1, 2020-Sept. 30, 2021) and will then update the tool with your final eligibility information. If you qualify for an exclusion based on data from one time segment, you will be exempt—even if you don't qualify for the exclusion in the other time segment.

Use the QPP Participation Status tool to check your quarterly snapshots. During the determination period's second time segment (Oct. 1, 2020–Sept. 30, 2021), CMS will provide you with quarterly snapshots that will show—based on the data available at that point in time—what the agency's provisional status and eligibility determinations would be for you. Although the final determinations won't be made until after Sept. 30, 2021, these informational snapshots will give you a sense of what those final decisions are likely to be.

Small or Large Practice?

Practice size is determined by CMS based on the number of eligible clinicians in a practice:

- Small practices have 15 or fewer eligible clinicians.
- Large practices have 16 or more eligible clinicians.

CMS uses claims data to assign practice size. CMS determines how many eligible clinicians are in a practice by reviewing claims data during two 12-month time periods (see "MIPS Determination Period," previous page) and looking at the number of National Provider Identifiers (NPIs) associated with the practice's Taxpayer Identification Number (TIN). This would include NPIs of eligible clinicians who are not MIPS eligible clinicians—see "Who Does (and Doesn't) Take Part in MIPS," previous page.

Why practice size matters. CMS provides small practices with accommodations that can help them to boost their MIPS final score (see "Small Practices Get Some Breaks," page 17). For example, CMS doubles their score for each improvement activity, allows them to report quality measures via claims, adds a 6-point bonus to their quality score, gives them a 3-point floor on quality measures, and has created a promoting interoperability (PI) hardship exception for small practices facing "overwhelming barriers" that prevent them from meeting the PI requirements.

Is your practice small or large? CMS will post its practice size determinations online (see "What's Your MIPS Participation Status").

Use of TINs and NPIs as Identifiers

Taxpayer Identification Numbers (TINs) and National Provider Identifiers (NPIs) were developed by the Internal Revenue Service and CMS, respectively. A TIN is assigned to each practice for tax purposes, and NPIs are used to identify individual health care providers.

Individuals (TIN/NPI). CMS uses both your TIN and your NPI to distinguish you as a unique MIPS eligible clinician. If you have more than one TIN/NPI combination—for example, you work at multiple practices or you move to a new practice during the performance year—you will be assessed separately for each one.

Groups (TIN). If you and your colleagues decide to report as a group (see below), the group's TIN alone will—for reporting purposes—be your identifier for all four performance categories. Although groups report at the TIN level, payment adjustments will be applied at the individual TIN/NPI level. No registration is required to participate in MIPS as a group, unless you are using the CMS Web Interface (see page 22), which wasn't designed for ophthalmology.

Participate as an Individual or as a Group?

You can choose to take part in MIPS as an individual or as part of a group.

What is a group? For MIPS, a group consists of two or more eligible clinicians, each with their own NPI, who have each reassigned their billing rights to the same TIN. At least one of them must be a MIPS eligible clinician.

What is group-level reporting? In group-level reporting, clinicians pool their MIPS data and are scored at the TIN level; they'll all get the same 2021 MIPS final score and will receive the same payment adjustment in 2023. There are some advantages to reporting as a group: For example, if at least 50% of clinicians in a group satisfy the requirements for a particular improvement activity, then the group as a whole scores points for that activity. But there are also some caveats to group-level reporting. For example, there are limited circumstances in which you may be excused from the promoting interoperability performance category when reporting as an individual, but you wouldn't be excused when reporting as part of a group unless all the MIPS eligible clinicians in that group were also excused from promoting interoperability. A practice that opts to report as a group will be scored as a group for all four performance categories.

What if you report as an individual *and* as part of a group? CMS will calculate two MIPS final scores for you. For the first final score, CMS will evaluate you across all performance categories based on your individual-level reporting; the second final score will be based on group-level reporting. CMS will use the higher of those two MIPS final scores to determine your payment adjustments in 2023.

What is a virtual group? Solo practitioners and/or groups of 10 or fewer eligible clinicians can agree to form virtual groups for the purpose of MIPS reporting, scoring, and payment adjustment. In order to join a virtual group, a solo practitioner must be a MIPS eligible clinician and a group must have no more than 10 eligible clinicians (at least one of whom must be a MIPS eligible clinician). The virtual group must include two or more TINs. There was a Dec. 31, 2020, deadline for forming a virtual group for this year.

"Extreme and Uncontrollable" Circumstances

What if circumstances beyond your control limit your ability to participate in MIPS? You can apply to have your performance categories reweighted if you have difficulty reporting one or more performance categories due to "extreme and uncontrollable circumstances." CMS hasn't set a date for when it will start reviewing applications, but last year it started in the summer. The application period will close on Dec. 31, 2021.

What is considered extreme and uncontrollable? It must be a rare event that is entirely outside of the control of yourself and of the facility where you work. The circumstances must prevent you—either altogether or for an extended period of time—from collecting information that you need to submit for a performance category. For example, a fire that destroys the only facility where a clinician works could be considered extreme and uncontrollable, but the inability to renew a lease for that facility wouldn't. CMS will take into account the type of event, date of event, length of time over which the event took place, and other details that impact your ability to report each performance category.

During a widespread catastrophe, CMS may waive the application requirement for individuals. For example, if the Federal Emergency Management Agency declares a major disaster or public health emergency, CMS may decide to implement an automatic extreme and uncontrollable circumstances policy, which would mean that affected clinicians could have their performance categories reweighted without having to go through the application process. However, this automated reweighting would only be applied to individuals; if you are reporting as part of a group, your group would have to apply for the reweighting.

Note: In some years, CMS has not been able to publish a list of affected areas eligible for an automatic exemption before the end of the calendar year. If you are in a disaster zone, and your area hasn't yet been flagged as eligible for an automatic exemption, consider applying for an "extreme and uncontrollable circumstances" reweighting before you miss the Dec. 31 application deadline.

What about COVID-19? For the 2020 performance year, CMS—in a late about face—waived the application requirement for COVID-related hardships. Don't assume that it will also waive the application requirement for performance year 2021. If you want to reweight one or more performance categories to zero because of the pandemic, you should submit an "extreme and uncontrollable" circumstances hardship application.

How performance categories are reweighted. If CMS approves your application to reweight one or more performance categories to zero, the weight(s) would be reallocated as shown in Table 1 on page 11.

IMPORTANT: *Don't* submit data to CMS on performance categories that are accepted for reweighting. CMS will not reweight a performance category if you report data for it after the triggering extreme and uncontrollable event.

THE RULES AREN'T ONE SIZE FITS ALL

Small Practices Get Some Breaks

While tackling MIPS is burdensome for all MIPS eligible clinicians, it is particularly challenging for solo practitioners and small group practices. With that in mind, the MIPS rules provide small practices with some accommodations (see below). Even so, this year's 60-point threshold will make it *much harder* than last year for small practices to avoid the payment penalty, especially if they don't have an electronic health record (EHR) system (see page 38). Small practices can no longer avoid a penalty with minimal reporting of quality measures.

What Is a Small Practice?

A practice is designated as small if it has 15 or fewer eligible clinicians. Simple, right? Not quite. As described in "Small or Large Practice?" (page 15), CMS reviews claims data from two 12-month time segments (see "MIPS Determination Period," page 14) to determine how many eligible clinicians are associated with your practice.

Does CMS think your practice is small or large? You can check online (see "What's Your MIPS Participation Status?" on page 15).

Accommodations for Small Practices

Low-volume exclusion. You may be exempt from MIPS if you provided limited Medicare Part B services—in terms of allowed charges, patients seen, or actual covered services provided—over either of two 12-month segments of the MIPS determination period (see "Exclusion 2—eligible clinicians who are below the low-volume threshold," page 14).

Virtual groups. CMS developed the virtual group option for practices with 10 or fewer eligible clinicians. There was a Dec. 31, 2020, deadline for forming a virtual group for the 2021 performance year.

Quality—a 3-point floor for reporting a measure. Suppose you report on a quality measure, but you don't meet the 70%–data completeness criteria. If you are in a large practice, you would score 0 achievement points for that measure, but if you are in a small practice, and you report on at least one patient, you would score 3 achievement points. (See "Meet Quality's Data Submission Thresholds," page 20.)

Quality—a 6-point small practice bonus. When CMS determines your quality score, it will add 6 points to your numerator if you are in a small practice provided that you submit data on at least one quality measure. (For more on your quality score's numerator and denominator, see "How CMS Calculates Your Quality Score," page 24.)

Quality—can report via Medicare Part B claims. Clinicians in small practices have the option of reporting quality measures via claims, and they can do so whether participating in MIPS at the individual or at the group level.

One downside is that claims-based reporting is done in real time. This means that you may need to start early in the year in order to satisfy the 70%–data completeness criteria that is needed to score more than 3 achievement points for a measure.

Furthermore, many of the benchmarks for claims-based reporting have significant scoring limitations, which can make it hard to get a high achievement points total (see the "Achievement Points" column in Table 8, page 36).

An upside of reporting via claims is that you don't have to track the data-completeness totals (see page 33). This means that, you can score 3 achievement points for a measure with minimal reporting. Doing that for six quality measures, along with the 6-point bonus for small practices that report quality, would give you a quality score of 40%, which—if the default weights apply (see Table 1, page 11)—would contribute 16 points to your MIPS final score. This would leave you *far short* of the 60 points that you need to avoid a payment penalty, but you would at least avoid the maximum –9% penalty that is imposed on clinicians who score 15 points or less.

Improvement activities—score double. Clinicians with a special status, such as being in a small practice, only have to perform one high- or two medium-weighted activities to get a 100% score for the improvement activities performance category (see "How You Will Be Scored," page 49). This 100% score would contribute 15 points to your MIPS final score, assuming that the default weights apply (see Table 1, page 11). If your quality score also contributes 16 points to your MIPS final score, and you earn a complex patient bonus (see page 10), you will now have a 2021 MIPS final score of more than 31 points, which will reduce your 2023 penalty from –9% to just under –4.5%.

Promoting interoperability (PI) exception. If you are in a small practice, you can apply for a small practice exception if "overwhelming barriers" prevent you from meeting PI's requirements (see page 46); if approved, PI's weight in your MIPS final score would be reallocated to quality.

DECIDE HOW YOU WILL REPORT YOUR QUALITY DATA

Pick Your Quality Collection Type(s)

Your MIPS reporting options—or collection types, as CMS calls them—will depend, in part, on whether you have an electronic health record (EHR) system. For example, the IRIS Registry offers two reporting options, one of which requires an EHR system.

In a small practice? Now that the MIPS performance threshold is 60 points (see Table 2A, page 12), avoiding a penalty will involve reporting much more quality data than in the past, and that reporting will be especially onerous if you aren't reporting via EHR (see page 38).

Which collection type(s) should you pick? After reading about the options below, review Tables 4, 5, and 6 (on pages 25, 28, and 31) to see which quality measures are available for each collection type. Many measures are subject to significant scoring limitations when reported via claims (see Table 8, page 36), which means that it will be very difficult to avoid the penalty with claims-based reporting.

New to IRIS Registry Reporting?

Report MIPS quality measures via IRIS Registry–EHR integration:

- Sign up for integration and select measures for mapping by June 1. (If you started, but didn't complete, the integration process last year, June 1 is also the deadline for notifying FIGmd that you want to complete integration this year.)
- Complete the integration process by Aug. 1.
- Request mapping refinements for selected measures by Sept. 30.
- E-sign a data release consent form by Jan. 31, 2022.
- Press the "Submit" button to send data to CMS by Jan. 31, 2022.

If you want to manually report MIPS via the IRIS Registry:

- Sign up for manual reporting by Oct. 31. (If you sign up for integrated IRIS Registry–EHR reporting of quality measures, you do not have to sign up separately for manual reporting.)
- Get step-by-step instructions on how to enter data at aao.org/iris-registry/user-guide/getting-started.
- Finish manually entering MIPS data by Jan. 31, 2022.
- E-sign a data release consent form by Jan. 31, 2022.
- Press the "Submit" button to send data to CMS by Jan. 31, 2022.

Got questions? If the IRIS Registry User Guide doesn't answer your questions, email irisregistry@aao.org. For technical questions—e.g., on data mapping—submit a help desk ticket (aao.org/iris-registry/user-guide/submit-help-desk-ticket).

Option 1: Report Quality Measures via IRIS Registry–EHR Integration

The most efficient way to report quality measures is to integrate your EHR system with the IRIS Registry. Once you have done that, an automated process can extract MIPS quality data from your EHRs.

The quality measures available to you may depend on your EHR. Up to 43 quality measures are available to report via IRIS Registry–EHR integration (see Table 4, page 25), including 30 ophthalmic measures that were developed specifically for the IRIS Registry. However, you can only report a measure if the IRIS Registry is able to extract the relevant data elements from your EHR system—so the quality measures that are available to you may depend on your EHR system. Furthermore, you only can use integrated reporting if your EHR system is a 2015-edition or a 2015-edition Cures Update certified EHR technology (CEHRT). To find out which CEHRTs have been integrated with the IRIS Registry, visit aao.org/iris-registry/ehr-systems.

Select which quality measures you want to report. You should report at least six measures, but can report more than that. The Academy urges you to include all the IRIS Registry–developed measures (see next page) that you have data for. The more data CMS gets on these measures, the more likely they are to acquire MIPS benchmarks.

Report on all relevant patients. For each measure that you report, include both Medicare and non-Medicare patients.

Start checking your quality data. Make sure that data from your EHR system are being transferred over to the IRIS Registry correctly. If you suspect a problem, you can work with staff from the IRIS Registry vendor (FIGmd) to make any necessary adjustments. Also be on the lookout for workflow problems. For example, is information being entered into the EHR correctly? The earlier in the year you address such problems, the less likely they are to impact your MIPS reporting.

Used this reporting option in 2020 but are now changing to a new EHR system? Notify the IRIS Registry about your move to a new system no later than June 15. If you delay, you might not be able to complete data mapping in time for 2021 reporting.

Option 2: Report Quality Measures Manually via the IRIS Registry

Each year, hundreds of practices have entered their MIPS quality data manually via the IRIS Registry. Some of them have no EHR system; others have one but haven't integrated it with the IRIS Registry.

Choose from 55 quality measures. These 55 measures (see Table 5, page 28) include 30 ophthalmology-specific measures that were developed by the IRIS Registry.

Report on all relevant patients. If you report a measure manually via the IRIS Registry, you should do so on both Medicare and non-Medicare patients.

Throughout the year, enter quality data at the individual-clinician level. It won't be until January 2022, when you get ready to hit the "submit" button that sends your data to CMS, that you decide whether to report as an individual or as part of a group.

Start entering quality data ASAP. If you enter data for quality measures regularly throughout the year, you can identify areas of underperformance while you still have time to do something about it.

Track the data-completeness totals. For each measure that you report, you also need to report the total number of patients eligible for the measure and, if the measure definition includes exceptions, the total number of patients excepted (see page 33). Contact the vendor of your billing system to see if they can provide instructions on running the appropriate reports.

The IRIS Registry Developed Its Own Ophthalmology-Specific Quality Measures

As a qualified clinical data registry (QCDR), the IRIS Registry has been able to develop its own quality measures. These measures have an "IRIS" prefix (e.g., IRIS1).

Up to 30 ophthalmology-specific quality measures for IRIS Registry users. You can report on any of the 30 QCDR measures manually, but the measures available for integrated IRIS Registry–EHR reporting may depend on what data can be extracted from your EHR system.

Benchmarks available for eight QCDR measures. There are already benchmarks for IRIS1, IRIS6, IRIS13, IRIS23, IRIS43, IRIS44, IRIS48, and IRIS50. After the 2021 performance year is over, CMS will see if there is enough 2021 performance data to retroactively create reliable benchmarks for the other 22 QCDR measures.

Option 3: Report Quality Measures via Medicare Part B Claims

It will be difficult to avoid a payment penalty if you report quality via claims. See Table 6 (page 31) for the 13 claims-based measures that are most relevant to ophthalmology. To explore all the claims-based measures, go to https://qpp.cms.gov/mips/explore-measures/quality-measures.

You must be in a small practice. Clinicians in large practices can't report via claims; clinicians in small practices can do so—and can do so whether reporting as a group or as individuals. To learn how CMS determines practice size, see "Small or Large Practice?" (page 15).

What do you report? You only report on Medicare Part B patients and—unlike manual reporting via the IRIS Registry—you don't need to report on the data-completeness totals.

When do you report? Report measures in real time using the CMS 1500 form. For detailed instructions, see aao.org/medicare/claims-reporting-guide.

You Can Report via Multiple Collection Types

You can, for example, report two measures via claims and four *different* measures via the IRIS Registry.

But suppose you report six measures by Medicare Part B claims and you also report the *same* six measures manually via the IRIS Registry. For each measure, CMS will calculate scores for both collection types and then assign you the higher of those two scores—so your final quality score could, for example, be based on five measures that you reported via the IRIS Registry and one measure that you reported via claims.

What if you switch collection types? Suppose, for example, you report a measure via claims from January through June and then switch to reporting it manually via the IRIS Registry from July through December. CMS will not aggregate your data from both collection types. It will score you separately for each collection type.

Note: When you report via more than one collection type, you must use the same identifier each time (see "Use of TINs and NPIs as Identifiers," page 16).

Other Reporting Options

Via your EHR vendor. Some EHR vendors may offer a reporting option, but they won't include the QCDR measures.

Consider reporting quality at the group level. There are some advantages to reporting as a group. Suppose, for example, a practice consists of four cataract subspecialists and a pediatric ophthalmologist. The latter might find it a challenge to report on six quality measures, but doing so wouldn't be a problem for the group as a whole.

If you're in an accountable care organization (ACO), you should still report MIPS quality measures in case your ACO's reporting is unsuccessful. If the ACO is successful in its MIPS reporting, CMS can ignore the quality measures that you reported. But if your ACO is unsuccessful in its MIPS reporting, your independent quality reporting can safeguard you from the –9% payment adjustment in 2023.

Facility-based scoring isn't an option for most ophthalmologists. Facility-based scoring will only be available to you if you provide at least 75% of your covered professional services at an inpatient hospital (place of service [POS] code: 21), an on-campus outpatient hospital (POS code: 22), or an emergency room (POS code: 23), with at least one service at an inpatient hospital or emergency room. This is based on claims submitted between Oct. 1, 2019, and Sept. 30, 2020.

What if you are eligible for facility-based scoring but you also do your own MIPS reporting? CMS will assign you the facility's score for quality and cost unless your separate MIPS submission earns you a higher combined score for those two performance categories.

WATCH OUT FOR MEASURES THAT HAVE SCORING LIMITATIONS

How to Report Quality Measures

Of the four MIPS performance categories, quality can contribute the most to your MIPS final score. Its default weight is 40% of that score, meaning that it would contribute up to 40 points to it, but that weight can be increased in certain cases (see Table 1, page 11).

Reporting Quality Measures

Report at least one outcome measure. A measure that is listed as an intermediate outcome measure or a patient-reported outcome measure would count for this purpose.

If no outcome measure is available, you must report another high-priority measure instead. Alternative high-priority quality measures include appropriate use, care coordination, efficiency, patient experience, patient safety, and opioid-related measures.

Report at least six quality measures (including the one mentioned above). Your quality score will be based on your achievement points for up to six quality measures, plus high-priority and CEHRT bonus points (see page 22), and your quality improvement percent score (see page 24).

Table 4 (page 25) and Table 5 (page 28) show the quality measures that you can report via IRIS Registry–EHR integration or via IRIS Registry manual reporting, with the caveat that you can only report a quality measure via integrated reporting if the IRIS Registry is able to extract the relevant data from your EHR.

Table 6 (page 31) shows the 13 claims-based measures that are most relevant to ophthalmology, but there are many more. (Explore them all at https://qpp.cms.gov/mips/explore-measures/quality-measures; make sure you select "2021" as the performance year and "Medicare Part B claims measures" as the collection type.)

What if you report on more than six quality measures? If you report on seven or more measures, CMS will determine which six of those measures will give you the highest number of measure achievement points based on your performance rates, with the caveat that one of them must be an outcome measure. Furthermore, if you report high-priority quality measures, the high-priority bonus point(s) for those measures can contribute to your score regardless of whether they are among the six measures that contribute to your measure achievement score.

If you report manually via the IRIS Registry, you need additional data on patient counts. When you report a quality measure manually via a Qualified Clinical Data Registry (QCDR), such as the IRIS Registry, you must include 1) the number of patients eligible for that measure and 2) for measures that include exceptions, the number of patients for whom the exception applies (see page 33).

Report more than six quality measures to give yourself a margin of error. In case you run into a problem with one of your quality measures, you can hedge your bets by reporting more than six of them. Suppose, for example, you are reporting a measure that doesn't yet have a benchmark. Once the performance year is over, CMS will attempt to calculate a benchmark for that measure. But if it doesn't have enough data to create a reliable benchmark, you won't be able to score more than 3 achievement points for that measure.

Meet Quality's Data Submission Thresholds

When you report a measure, you must meet both the case minimum requirement and the data completeness criteria in order to earn achievement points based on your performance rate (see page 21) and, for a high priority measure, earn bonus points (see page 22).

The case minimum: Report on at least 20 patients. The exception is the Hospital-Wide Readmission (HWR) measure (see page 22), which has a 200-patient case minimum.

The data completeness criteria: Report on at least 70% of denominator-eligible patients. For each measure that you report, submit data on at least 70% of denominator-eligible patients who were seen during the entire 2021 calendar year.

Who are the denominator-eligible patients? That

Quality 101

Default weight in MIPS final score: 40%.
Performance period: Full calendar year.
Reporting requirements: Aim to report on at least six quality measures. At least one of the six measures must be an outcome measure (or, if no outcome measure is available to you, another type of high priority measure).
Collection types: You can report via IRIS Registry–EHR integration, manually via the IRIS Registry, and/or via your EHR vendor. Small practices—but not large practices—can report via Medicare Part B claims.

depends on the quality measure as well as on what collection type you are using to report that measure. Suppose, for example, you are reporting measure 117: Diabetes: Eye Exam. The denominator-eligible patients for that measure would be those with diabetes who are 18-75 years old. If you could report this measure via claims, you would just include Medicare patients. (Update: On June 30, CMS suppressed this measure for claims-based reporting.) If reporting via the IRIS Registry, include Medicare and non-Medicare patients. Your reporting will indicate what percentage of those patients had an eye screening for diabetic retinal disease. (Read each measure's denominator criteria. When you are logged in to the IRIS Registry, you can download PDFs of each quality measure. You also can download measure specifications at aao.org/medicare/quality-reporting-measures. Measure specifications may differ depending on the collection type.)

What if you don't meet the case minimum requirement for a reported measure? You score 3 achievement points for it, provided you meet the 70%–data completeness criteria.

What if you don't satisfy the data completeness criteria for a reported measure? If you are in a large practice, you score no points; if in a small practice, you score 3 achievement points provided that you report on at least one patient.

Do Not Cherry-Pick Your Patients

If you report on fewer than 100% of patients, do not cherry-pick. If you report on a measure for fewer than 100% of applicable patients, you must not cherry-pick patients with the goal of boosting your performance rate. The MIPS regulations address this when they state that if "quality data are submitted selectively such that the submitted data are unrepresentative of a MIPS eligible clinician or group's performance, any such data would not be true, accurate, or complete." In an audit, you'd be failed for cherry picking.

Scoring—Your Performance Rate Will Be Compared Against a Benchmark

Did you report enough data for a measure? When you report a quality measure, CMS first determines whether you met the case minimum requirement (at least 20 patients) and the data completeness criteria (at least 70% of applicable patients). If you did, CMS will see how your performance rate stacks up against the measure's benchmark as shown below.

Benchmarks are typically based on historical performance data. CMS used 2019 performance data to try to establish 2021 benchmarks for quality measures.

A quality measure can have up to three different benchmarks. Quality measures typically have separate benchmarks for claims-based reporting, for reporting via manual data entry into a registry portal, and for EHR-based reporting (whether via IRIS Registry integration or via your EHR vendor). However, the IRIS Registry's QCDR measures (e.g., IRIS44: Visual Field Progression in Glaucoma) have the same benchmark regardless of whether you are reporting via manual entry or via IRIS Registry–EHR integration.

Also, some measures can't be reported by all collection types and therefore have fewer than three benchmarks. For example, measure 374: Closing the Referral Loop, can't be reported via claims.

Your achievement score (3-10 points) for a measure will depend on how your performance compares against the measure's benchmark. Each benchmark is broken into deciles. Assuming no scoring limitations apply (see next page), if your performance rate falls within:

- deciles 1 or 2, you score 3 achievement points
- deciles 3 through 9, your score will depend on where you fall within that decile (e.g., if you fall in the third decile, you can earn between 3.0 and 3.9 achievement points)
- decile 10, you score 10 achievement points.

ICD-10 Turbulence and Changes in Clinical Guidelines

During the course of the year, a quality measure may be impacted by "significant changes" to its clinical guidelines, to its measure specifications, or to relevant codes (e.g., updates or deletions of ICD-10, CPT, or HCPCS codes). This can mean that continued adherence to the measure's original specifications—as defined at the start of the performance year—could result in "patient harm" and/or "misleading results" on performance quality. In such cases, CMS may truncate the performance period for that measure or suppress the measure altogether, depending on when in the year the changes take place.

Truncation or suppression? If a quality measure has been impacted by a significant change, are there nine consecutive months of performance data that are unaffected by that change? If there are, then CMS will assess clinician performance for that measure based on a truncated nine-month performance period. If there aren't, then CMS will suppress the measure altogether.

Truncation example. Each year, on Oct. 1, CMS implements changes to the ICD-10 codes. These diagnosis codes are used to determine which patients are eligible for each quality measure. If the Oct. 1 changes to the ICD-10 code set have significant repercussions for a measure's performance rate, CMS can score you on that measure based on your performance from Jan. 1 to Sept. 30.

What if a measure is suppressed? Clinicians aren't scored on suppressed quality measures. If you submitted data on a quality measure before it was suppressed—because, for example, you reported it by claims—1) you wouldn't score points for that measure, and 2) when CMS calculates your quality score it would reduce your denominator by 10 points (so you wouldn't be penalized for reporting the suppressed measure).

UPDATE. On June 30, CMS announced that it was suppressing Measures 1 and 117 for claims-based reporters. If other measures or suppressed or scored on a truncated performance period, CMS will notify clinicians as soon as it can and no later than Jan. 2, 2022.

Warning—Some Benchmarks Are Subject to Scoring Limitations

Scoring "stalls" for some benchmarks due to high performance rates. The scoring for some benchmarks approaches maximum performance before the ninth decile. If, for example, you use the IRIS Registry to manually report measure 374: Closing the Referral Loop, the relevant benchmark reaches a 99.99% performance rate at the seventh decile (see Table 3A, next page). You can still earn 10 achievement points with a 100% performance rate, but with a less-than-perfect performance, scoring stalls at 6.9 achievement points.

A 7-point cap for some benchmarks. Once a quality benchmark is in its second year of being "topped out" it becomes subject to a 7-point cap.

What is a topped out benchmark? CMS considers a benchmark to be topped out if there is limited opportunity for improvement. For example, a process-based measure is considered topped out if the median performance rate was at least 95%. CMS is concerned that such benchmarks provide very little room for improvement for most of the MIPS eligible clinicians who use those measures.

The end of the line for some topped out benchmarks. Once a benchmark is topped out for three consecutive performance years, CMS will consider eliminating it in the fourth year. Furthermore, if CMS finds that a benchmark is extremely topped out (e.g., average performance rate of a process-based measure is 98% or higher), it may eliminate it the following year.

What if there is no benchmark? If there were not enough performance data from 2019 to establish a reliable benchmark for a measure, or if the measure didn't exist in 2019, CMS will try to establish a benchmark retroactively using 2021 performance data. However, CMS won't assign a benchmark to a measure unless at least 20 clinicians or groups submit performance data that meet the two data submission thresholds.

If CMS is unable to establish a benchmark for a measure, you won't be able to earn more than 3 achievement points for reporting that measure.

Scoring—Some Benchmarks Are "Flat"

CMS has applied flat benchmarks to these two measures:

- Measure 1: Diabetes: Hemoglobin A1c (HBA1c) Poor Control (>9%). Measure 1 has a flat benchmark when reported by Medicare Part B claims. (Update: On June 30, CMS suppressed this measure when reported via claims.)
- Measure 236: Controlling High Blood Pressure. Measure 236 has a flat benchmark when reported by claims or manually via the IRIS Registry but not when reported via IRIS Registry–EHR integration.

What is a flat benchmark? Most benchmarks are based on historic performance rates. By contrast, flat benchmarks are based on a simple formula.

When an inverse measure (e.g., measure 1) has a flat benchmark, a performance rate of 10% or less earns you 10 achievement points; a performance rate of 10.01%-20% earns you 9 achievement points, etc.

For a flat benchmark that isn't an inverse measure, a performance rate of at least 90% earns you 10 achievement points; a performance rate of 80%-89.9% earns you 9 achievement points, etc.

Why did CMS introduce flat benchmarks? CMS was concerned that using the standard performance-based benchmarks for measures 1 and 236 may have motivated clinicians to reduce blood sugar or blood pressure to levels that might be too low for patients with certain medical conditions.

Scoring—Bonuses for High-Priority Measures and CEHRT

In addition to scoring achievement points based on your performance rate, you may also be able to score bonus points for high-priority measures and for using a CEHRT.

Bonus points for reporting high-priority measures. You get no bonus points for your first high-priority measure, but for additional high-priority measures, you get:

- 2 points for an outcome or patient experience measure, and
- 1 point for an appropriate use, care coordination, efficiency, patient safety, or opioid-related measure.

You must meet the data submission thresholds. To score high-priority bonus point(s) for a measure, your reporting for it must meet both the case minimum requirement (at least 20 patients) and the data completeness criteria (at least 70% of denominator-eligible patients)

What Is the CMS Web Interface?

The CMS Web Interface is used by some big practices that provide primary care services. It has its own reporting requirements and its own set of quality measures (mostly primary care–based). It is only available to practices that have at least 25 eligible clinicians reporting quality data. The registration period for this option usually opens in spring and closes in early summer. CMS has said that 2021 is the last year for this option.

The HWR Measure for Large Practices

It is very unlikely that you will be scored on quality measure 479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the MIPS Eligible Clinician Groups. This measure only applies to large groups (16 or more eligible clinicians) that meet the case minimum requirement of 200 cases involving patients who are at least 65 years old. Such practices don't need to report this measure; they will be evaluated based on Medicare administrative claims data. This new measure replaces quality measure 458: All-Cause Hospital Readmission (ACR).

Table 3A: Scoring "Stalls" for Some Benchmarks (Updated July 2021)

Measure 374: Closing the Referral Loop. Measure 374 has one benchmark for reporting via IRIS Registry–EHR integration and another for reporting manually via the IRIS Registry. If you report manually, your achievement points score stalls at 6.9 points for a 99.99% performance rate, but it jumps to 10 points with a 100% performance rate. This benchmark is based on 2019 performance data, and high numbers of manual reporters had a 100% performance rate that year. (Note: This measure is not available for claims-based reporting.)

Decile	IRIS Registry			
	Integrated EHR Reporting		Manual Reporting (No EHR Needed)	
	Performance Rate (%)	Points	Performance Rate (%)	Points
d3	9.72-16.97	3.0–3.9	60.00-77.54	3.0–3.9
d4	16.98-25.50	4.0–4.9	77.55-92.30	4.0–4.9
d5	25.51-34.92	5.0–5.9	92.31-97.54	5.0–5.9
d6	34.93-46.42	6.0–6.9	97.55-99.99	6.0–6.9
d7	46.43-59.99	7.0–7.9	100	10
d8	60.00-74.59	8.0–8.9	100	10
d9	74.6-89.65	9.0–9.9	100	10
d10	≥89.66	10	100	10
Summary	3-10 points		3-6.9 points or, with 100% performance rate, 10 points	
Notes			Topped out	

Table 3B: Examples of 7-Point Cap (Updated July 2021)

Measure 117: Diabetes: Eye Exam. Update: In June, after CMS realized that it hadn't updated its systems, the agency suppressed (see page 21) measure 117 when reported via claims. It can still be reported via the IRIS Registry.

Decile	IRIS Registry				Medicare Part B Claims-Based Reporting	
	Integrated EHR Reporting		Manual Reporting (No EHR Needed)			
	Performance Rate (%)	Points	Performance Rate (%)	Points	Performance Rate (%)	Points
d3	12.00-20.54	3.0–3.9	89.93-96.67	3.0–3.9	~~0.75-97.82~~	~~3.0–3.9~~
d4	20.55-30.68	4.0–4.9	96.68-98.85	4.0–4.9	~~97.83-99.99~~	~~4.0–4.9~~
d5	30.69-44.81	5.0–5.9	98.86-99.69	5.0–5.9	~~100~~	~~7~~
d6	44.82-69.39	6.0–6.9	99.97-99.99	6.0–6.9	~~100~~	~~7~~
d7	69.40-94.16	7.0–7.9	100	7	~~100~~	~~7~~
d8	94.17-98.42	8.0–8.9	100	7	~~100~~	~~7~~
d9	98.43-99.92	9.0-9.9	100	7	~~100~~	~~7~~
d10	≥99.93	10	100	7	~~100~~	~~7~~
Summary	3-10 points		3-7 points		In June, CMS suppressed this measure for claims-based reporting.	
Notes			Topped out, 7-point cap			

and you also need to have a performance rate that is greater than zero.

You can score high-priority bonus points for measures that don't contribute to your measure achievement points total. If you report more than six quality measures, CMS will base your total measure achievement points on the six measures that have the highest achievement points scores, but you also can earn high-priority bonus points for quality measures that aren't among those six.

Note: There is no bonus point for the first high-priority measure because you are required to report at least one outcome measure (or, if no outcome measure is available, an alternate high-priority measure).

Bonus points for using CEHRT. You can earn 1 bonus point for each measure that you report electronically, even if you don't meet the data submission thresholds. This can include measures reported via IRIS Registry–EHR integration or your EHR vendor. However, you must use either a 2015-edition CEHRT or a 2015-edition Cures Update CEHRT to collect your measure data, and you must meet CMS' criteria for "end-to-end electronic reporting."

Up to 12 (or 14) bonus points. Your high-priority bonus is typically capped at 6 points or—in the unlikely event that you are scored on the HWR measure (see page 22)—7 points. The CEHRT bonus is capped in the same way.

Scoring—You Can Earn an Improvement Percent Score

If you score more achievement points for quality measures in 2021 than you did in 2020, you may be able to earn a quality improvement percent score.

CMS checks whether your score for measure performance has improved. CMS compares your 2021 performance with your 2020 performance to determine your improvement percent score. In doing so, the agency only takes into account achievement points, not bonus points. For each of the two years, it assigns you a quality performance category achievement percent score, which it calculates by dividing your total measure achievement points by your total available measure achievement points. (Note: When making its calculation, CMS sets a floor of 30% for your 2020 quality performance.)

How CMS determines your improvement percent score. Your improvement percent score = ([your increase in quality performance category achievement percent score from 2020 to 2021] ÷ your 2020 quality performance category achievement percent score) × 10.

The improvement percent score is capped at 10%. If you doubled your measure achievement points, you would get the maximum score of 10%.

You can't get a negative score. If your performance declined, your improvement percent score would be 0%.

How CMS Calculates Your Quality Score

This can be described as a five-step process.

1. Achievement points: CMS determines your total measure achievement points, which is the sum of your achievement points for up to six quality measures that you reported plus—if applicable—your score for the HWR measure (see "The HWR Measure for Large Practices," page 22).

2. Measure bonus points: CMS determines your total measure bonus points (see "Scoring—Bonuses for High-Priority Measures and CEHRT," page 22).

3. Numerator: CMS calculates your numerator, which is your total measure achievement points plus your total measure bonus points plus—if you are in a small practice that submits data on at least one quality measure—a 6-point small practice bonus.

4. Denominator: CMS calculates your denominator, also known as your total available measure achievement points, which—assuming that you had at least six quality measures available to report—is 60 (or 70 if the HWR measure also applies). In limited circumstances, CMS may determine that you have fewer than six quality measures to report and can reduce that denominator accordingly.

5. CMS does the math: CMS divides your numerator by your denominator, turns the resulting fraction into a percentage, and then your improvement percent score (see above) is added.

The resulting percentage is your quality performance category percent score, which is capped at 100%. Unless your performance categories are reweighted (see "Table 1: How the Performance Categories Are Weighted," page 11), it contributes up to 40 points to your MIPS final score. For example, if your quality score is 60%, it would contribute 24 points (60% of 40 points).

Which Quality Measures Should You Report?

See what measures you should be focusing on. Skim Tables 4, 5, and/or 6 on pages 25, 28, and 31, respectively. Look for measures where you are most likely to 1) satisfy the case minimum of 20 patients, 2) satisfy the 70%–data completeness criteria, and 3) achieve a high performance rate. Also be mindful of measures that have scoring limitations—such as score-stalling or a 7-point cap—or that don't yet have a benchmark.

Understand the measure specifications. Familiarize yourself with the measures that you expect to be scored on and make sure that you are performing and documenting them in line with their current specifications. If you report via the IRIS Registry, you can access detailed measure specifications via your dashboard. You can also download measures specifications from the Quality Clinical Measure Specification and Benchmark Table at aao.org/medicare/quality-reporting-measures. Note: A measure can have different sets of specifications for different collection types.

Ask the practice's clinicians to review their performance. Throughout the year, give each care provider his or her own IRIS Registry report. Encourage them to review their performance across the quality measures.

Tables 4-6: Quality Measures at a Glance

Column 1—ID: Measure Name. If a measure ID has the "QCDR" prefix, that means that the measure was developed by the IRIS Registry specifically for ophthalmology. Eight QCDR measures now have benchmarks, up from five last year.

Column 2—High-Priority Measures (Bonus Points). You need to report at least one outcome or intermediate outcome measure. You can then earn up to 6 bonus points for additional high-priority measures (see page 22), provided you meet the two data submission thresholds (see page 20).

Column 3—Achievement Points. Watch for benchmarks where scoring is subject to a 7-point cap and/or scoring "stalls" (see Table 3B, page 23). Also be mindful of measures that don't yet have a benchmark for your collection type (see "What if there is no benchmark?" on page 22). For more detailed benchmark information on the QCDR and claims-based measures, see pages 34 and 36, respectively. You also can visit aao.org/medicare/benchmarks for a PDF that provides a decile-by-decile breakdown of benchmark data for measures in Tables 4, 5, and 6.

Column 4—Notes. The final column flags benchmarks that have noteworthy characteristics, including the following:

- A 7-point cap is applied to benchmarks that are in their second year of being topped out.
- Topped out benchmarks have an average performance rate that is very high (or, for inverse measures, very low) and may be discontinued in a future performance year.
- Inverse measures are those where a lower performance rate earns you more achievement points.
- A flat benchmark is not based on performance data; instead, it is based on a simple formula (see page 22).

Table 4: Reporting via IRIS Registry–EHR Integration (Updated July 2021)

For tips on interpreting this chart, see above. Also see Table 7 (page 34) for QCDR measure benchmarks.

Meet two data submission thresholds. If your reporting for a quality measure satisfies both the case minimum requirement (20 patients) and the data completeness criteria (70% of denominator-eligible patients), your performance rate will be compared against a benchmark (if the measure has one), and you can earn the achievement points indicated below (see column 3).

Understand the measures. Detailed measure specifications can be downloaded from the Quality Clinical Measure Specification and Benchmark Table at aao.org/medicare/quality-reporting-measures or via the IRIS Registry dashboard.

Important caveat: You can only report a measure if the relevant data elements are available for extraction from your EHR system. Check with staff from the IRIS Registry vendors to work on mapping for any of these measures.

ID: Measure Name	High-Priority Measure (Bonus Points)	Achievement Points	Notes
Preventive Health Measures			
110: Preventive Care and Screening: Influenza Immunization		No benchmark	
111: Pneumococcal Vaccination Status for Older Adults		3-10 points	
117: Diabetes: Eye Exam		3-10 points	See Table 3B (page 23) for benchmark data
128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up Plan		3-10 points	
130: Documentation of Current Medications in the Medical Record	Patient safety (+1 point)	3-7 points	Topped out, 7-point cap
226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention		No benchmark	
236: Controlling High Blood Pressure	Intermediate outcome (+2 points)	3-10 points	
238: Use of High-Risk Medications in Older Adults	Patient safety (+1 point)	No benchmark	Inverse measure
318: Falls: Screening for Future Fall Risk	Patient safety (+1 point)	3-10 points	

374: Closing the Referral Loop	Care coordination (+1 point)	3-10 points	See page 23 for benchmark data.
Resource Use and Opioid Management			
IRIS26: Avoidance of Routine Antibiotic Use Before or After Intravitreal Injections	Efficiency (+1 point)	No benchmark	Inverse measure
IRIS52: Postoperative Opioid Management Following Ocular Surgery	Opioid-related (+1 points)	No benchmark	
Cataract/Anterior Segment			
191: Cataracts: 20/40 or Better Visual Acuity Within 90 Days Following Cataract Surgery	Outcome (+2 points)	3-10 points	
IRIS54: Complications After Cataract Surgery	Outcome (+2 points)	No benchmark	Inverse measure
IRIS59: Regaining Vision After Cataract Surgery	Outcome (+2 points)	No benchmark	
Also see IRIS55 and IRIS60, under "Glaucoma."			
Cornea/External Disease			
IRIS1: Endothelial Keratoplasty: Postoperative Improvement in Best Corrected Visual Acuity to 20/40 or Better	Outcome (+2 points)	3-10 points	
IRIS38: Endothelial Keratoplasty: Dislocation Requiring Surgical Intervention	Outcome (+2 points)	No benchmark	Inverse measure
Also see IRIS52 under "Resource Use and Opioid Management."			
Glaucoma			
12: Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation		3-10 points	
~~**IRIS2:** Intraocular Pressure (IOP) Reduction~~	~~Intermediate outcome (+2 points)~~	~~No benchmark~~	Not an option for 2021.
IRIS39: IOP Reduction Following Trabeculectomy or an Aqueous Shunt Procedure	Outcome (+2 points)	No benchmark	
IRIS43: IOP Reduction Following Laser Trabeculoplasty	Outcome (+2 points)	3-10 points	
IRIS44: Visual Field Progression in Glaucoma	Outcome (+2 points)	3-10 points	Inverse measure
IRIS55: Visual Acuity Improvement Following Cataract Surgery and Minimally Invasive Glaucoma Surgery	Outcome (+2 points)	No benchmark	
IRIS60: Visual Acuity Improvement Following Cataract Surgery Combined With a Trabeculectomy or an Aqueous Shunt Procedure	Outcome (+2 points)	No benchmark	
Neuro-Ophthalmology			
IRIS56: Adult Diplopia: Improvement of Ocular Deviation or Absence of Diplopia or Functional Improvement	Outcome (+2 points)	No benchmark	
IRIS57: Idiopathic Intracranial Hypertension: Improvement of Mean Deviation or Stability of Mean Deviation	Outcome (+2 points)	No benchmark	
Oculofacial Plastics/Reconstructive			
IRIS5: Surgery for Acquired Involutional Ptosis: Patients With an Improvement of Marginal Reflex Distance (MRD)	Outcome (+2 points)	No benchmark	

IRIS6: Acquired Involutional Entropion: Normalized Lid Position After Surgical Repair	Outcome (+2 points)	3-6.9 points or, with a 100% performance rate, 10 points	
Also see IRIS52 under "Resource Use and Opioid Management."			
Pediatric Ophthalmology and Strabismus			
IRIS48: Adult Surgical Esotropia: Post-operative Alignment	Outcome (+2 points)	3-10 points	
IRIS49: Surgical Pediatric Esotropia: Post-operative Alignment	Outcome (+2 points)	No benchmark	
IRIS50: Amblyopia: Interocular Visual Acuity	Outcome (+2 points)	3-10 points	
Refractive Surgery			
IRIS23: Refractive Surgery: Patients With a Postoperative Uncorrected Visual Acuity (UCVA) of 20/20 or Better Within 30 Days	Outcome (+2 points)	3-10 points	
IRIS24: Refractive Surgery: Patients With a Postoperative Correction Within ± 0.5 Diopter (D) of the Intended Correction	Outcome (+2 points)	No benchmark	
Retina/Vitreous			
Retina: Age-Related Macular Degeneration (AMD)			
IRIS45: Exudative AMD: Loss of Visual Acuity	Outcome (+2 points)	No benchmark	
Also see IRIS26, under "Resource Use and Opioid Management."			
Retina: Diabetic Retinopathy (DR) and Diabetic Macular Edema (DME)			
19: Diabetic Retinopathy: Communication With the Physician Managing On-going Diabetes Care	Care coordination (+1 point)	3-10 points	
IRIS13: Diabetic Macular Edema: Loss of Visual Acuity	Outcome (+2 points)	3-10 points	
IRIS58: Improved Visual Acuity After Vitrectomy for Complications of Diabetic Retinopathy Within 120 Days	Outcome (+2)	No benchmark	
Retina: Epiretinal Membrane			
IRIS41: Improved Visual Acuity After ERM Treatment Within 120 Days	Outcome (+2 points)	No benchmark	
Retina: Macular Hole			
IRIS46: Evidence of Anatomic Closure of Macular Hole Within 90 Days After Surgery as Documented by OCT	Outcome (+2 points)	No benchmark	
Uveitis/Immunology			
IRIS17: Acute Anterior Uveitis: Post-treatment Grade 0 Anterior Chamber Cells	Outcome (+2 points)	No benchmark	
IRIS35: Improvement of Macular Edema in Patients With Uveitis	Outcome (+2 points)	No benchmark	
IRIS51: Acute Anterior Uveitis: Post-Treatment Visual Acuity	Outcome (+2 points)	No benchmark	
IRIS53: Chronic Anterior Uveitis: Post-Treatment Visual Acuity	Outcome (+2 points)	No benchmark	

Table 5: Reporting Manually via the IRIS Registry (Updated July 2021)

For tips on interpreting this chart, see page 25. Also see Table 7 (page 34) for QCDR measure benchmarks.

Meet two data submission thresholds. If your reporting for a quality measure satisfies both the case minimum requirement (20 patients) and the data completeness criteria (70% of denominator-eligible patients), your performance rate will be compared against a benchmark (if the measure has one), and you can earn the achievement points indicated below (see column 3).

Understand the measures. Detailed measure specifications can be downloaded from the Quality Clinical Measure Specification and Benchmark Table at aao.org/medicare/quality-reporting-measures or via the IRIS Registry dashboard.

ID: Measure Name	High-Priority Measure (Bonus Points)	Achievement Points	Notes
Preventive Health Measures			
1: Diabetes: Hemoglobin A1c Poor Control (>9%)	Intermediate outcome (+2 points)	3-10 points	Inverse measure
110: Preventive Care and Screening: Influenza Immunization		No benchmark	
111: Pneumococcal Vaccination Status for Older Adults		3-10 points	
117: Diabetes: Eye Exam		3-7 points	Topped out, 7-point cap; see page 23 for benchmark data
128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan		3-10 points	
130: Documentation of Current Medications in the Medical Record	Patient safety (+1 point)	3-7 points	Topped out, 7-point cap
154: Falls: Risk Assessment	Patient safety (+1 point)	3-5.9 or, with 100% performance rate, 7	Topped out, 7-point cap
226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention		No benchmark	
236: Controlling High Blood Pressure	Intermediate outcome (+2 points)	3-10 points	Flat benchmark
238: Use of High-Risk Medications in Older Adults	Patient safety (+1 point)	No benchmark	Inverse measure
317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented		No benchmark	
374: Closing the Referral Loop	Care coordination (+1 point)	3-6.9 points or, with a 100% performance rate, 10 points	See page 23 for benchmark data
402: Tobacco Use and Help With Quitting Among Adolescents		3-7 points	Topped out, 7-point cap
Resource Use and Opioid Management			
IRIS26: Avoidance of Routine Antibiotic Use Before or After Intravitreal Injections	Efficiency (+1 point)	No benchmark	Inverse measure
IRIS52: Postoperative Opioid Management Following Ocular Surgery	Opioid-related (+1 points)	No benchmark	

Cataract/Anterior Segment			
191: Cataracts: 20/40 or Better Visual Acuity Within 90 Days Following Cataract Surgery	Outcome (+2 points)	3-7.9 points or, with a 100% performance rate, 10 points	
389: Cataract Surgery: Difference Between Planned and Final Refraction	Outcome (+2 points)	3-8.9 or, with 100% performance rate, 10	
IRIS54: Complications After Cataract Surgery	Outcome (+2 points)	No benchmark	Inverse measure
IRIS59: Regaining Vision After Cataract Surgery	Outcome (+2 points)	No benchmark	
Also see IRIS55 and IRIS60, under "Glaucoma."			
Cornea/External Disease			
IRIS1: Endothelial Keratoplasty: Postoperative Improvement in Best Corrected Visual Acuity to 20/40 or Better	Outcome (+2 points)	3-10 points	
IRIS38: Endothelial Keratoplasty: Dislocation Requiring Surgical Intervention	Outcome (+2 points)	No benchmark	Inverse measure
Also see IRIS52, under "Resource Use and Opioid Management."			
Glaucoma			
141: Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% or Documentation of a Plan of Care	Outcome (+2 points)	3-7.9 points or, with a 100% performance rate, 10 points	
~~**IRIS2:** Intraocular Pressure (IOP) Reduction~~	~~Intermediate outcome (+2 points)~~	~~No benchmark~~	Not an option for 2021.
IRIS39: IOP Reduction Following Trabeculectomy or an Aqueous Shunt Procedure	Outcome (+2 points)	No benchmark	
IRIS43: IOP Reduction Following Laser Trabeculoplasty	Outcome (+2 points)	3-10 points	
IRIS44: Visual Field Progression in Glaucoma	Outcome (+2 points)	3-10 points	Inverse measure
IRIS55: Visual Acuity Improvement Following Cataract Surgery and Minimally Invasive Glaucoma Surgery	Outcome (+2 points)	No benchmark	
IRIS60: Visual Acuity Improvement Following Cataract Surgery Combined With a Trabeculectomy or an Aqueous Shunt Procedure	Outcome (+2 points)	No benchmark	
Neuro-Ophthalmology			
419: Overuse of Imaging for the Evaluation of Primary Headache	Efficiency (+1 point)	3-10 points	Inverse measure, topped out
IRIS56: Adult Diplopia: Improvement of Ocular Deviation or Absence of Diplopia or Functional Improvement	Outcome (+2 points)	No benchmark	
IRIS57: Idiopathic Intracranial Hypertension: Improvement of Mean Deviation or Stability of Mean Deviation	Outcome (+2 points)	No benchmark	
Oculofacial Plastics/Reconstructive			
137: Melanoma: Continuity of Care—Recall System	Care coordination (+1 point)	3-4.9 points or, with a 100% performance rate, 10 points	
138: Melanoma: Coordination of Care	Care coordination (+1 point)	3-5.9 or, with 100% performance rate, 7	Topped out, 7-point cap

265: Biopsy Follow-Up	Care coordination (+1 point)	3-5.9 or, with 100% performance rate, 7	Topped out, 7-point cap
397: Melanoma Reporting	Care coordination (+1 point)	3 points or, with a 100% performance rate, 7 points	Topped out, 7-point cap
IRIS5: Surgery for Acquired Involutional Ptosis: Patients With an Improvement of MRD	Outcome (+2 points)	No benchmark	
IRIS6: Acquired Involutional Entropion: Normalized Lid Position After Surgical Repair	Outcome (+2 points)	3-6.9 points or, with a 100% performance rate, 10 points	
Also see IRIS52, under "Resource Use and Opioid Management."			
Pediatric Ophthalmology and Strabismus			
IRIS48: Adult Surgical Esotropia: Postoperative Alignment	Outcome (+2 points)	3-10 points	
IRIS49: Surgical Pediatric Esotropia: Postoperative Alignment	Outcome (+2 points)	No benchmark	
IRIS50: Amblyopia: Interocular Visual Acuity	Outcome (+2 points)	3-10 points	
Refractive Surgery			
IRIS23: Refractive Surgery: Patients With a Postoperative Uncorrected Visual Acuity (UCVA) of 20/20 or Better Within 30 Days	Outcome (+2 points)	3-10 points	
IRIS24: Refractive Surgery: Patients With a Postoperative Correction Within ± 0.5 Diopter (D) of the Intended Correction	Outcome (+2 points)	No benchmark	
Retina/Vitreous			
Retina: Age-Related Macular Degeneration (AMD)			
14: AMD: Dilated Macular Examination		3-7 points	Topped out, 7-point cap
IRIS45: Exudative AMD: Loss of Visual Acuity	Outcome (+2 points)	No benchmark	
Also see IRIS26, under "Resource Use and Opioid Management."			
Retina: Diabetic Retinopathy (DR) and Diabetic Macular Edema (DME)			
19: Diabetic Retinopathy: Communication With the Physician Managing On-going Diabetes Care	Care coordination (+1 point)	3-7 points	Topped out, 7-point cap
IRIS13: Diabetic Macular Edema: Loss of Visual Acuity	Outcome (+2 points)	3-10 points	
IRIS58: Improved Visual Acuity After Vitrectomy for Complications of Diabetic Retinopathy Within 120 Days	Outcome (+2)	No benchmark	
Retina: Epiretinal Membrane			
IRIS41: Improved Visual Acuity After ERM Treatment Within 120 Days	Outcome (+2)	No benchmark	
Retina: Macular Hole			
IRIS46: Evidence of Anatomic Closure of Macular Hole Within 90 Days After Surgery as Documented by OCT	Outcome (+2 points)	No benchmark	
Retina: Retinal Detachment			
384: Adult Primary Rhegmatogenous Retinal Detachment: No Return to the Operating Room Within 90 Days of Surgery	Outcome (+2 points)	3-3.9 points or, with a 100% performance rate, 10 points	

385: Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery	Outcome (+2 points)	No benchmark	
Uveitis/Immunology			
IRIS17: Acute Anterior Uveitis: Post-Treatment Grade 0 Anterior Chamber Cells	Outcome (+2 points)	No benchmark	
IRIS35: Improvement of Macular Edema in Patients With Uveitis	Outcome (+2 points)	No benchmark	
IRIS51: Acute Anterior Uveitis: Post-Treatment Visual Acuity	Outcome (+2 points)	No benchmark	
IRIS53: Chronic Anterior Uveitis: Post-Treatment Visual Acuity	Outcome (+2 points)	No benchmark	

Table 6: Reporting via Medicare Part B Claims (Updated July 2021)

For tips on interpreting this chart, see page 25. Also see Table 8 (page 36) for claims-based benchmarks.

Meet two data submission thresholds. If your reporting for a quality measure satisfies both the case minimum requirement (20 patients) and the data completeness criteria (70% of denominator-eligible patients), your performance rate will be compared against a benchmark (if the measure has one), and you can earn the achievement points indicated below (see column 3).

Understand the measures. Detailed measure specifications can be downloaded from the Quality Clinical Measure Specification and Benchmark Table at aao.org/medicare/quality-reporting-measures or via the IRIS Registry dashboard.

ID: Measure Name	High-Priority Measure (Bonus Points)	Achievement Points	Notes
Preventive Health Measures			
1: Diabetes: Hemoglobin A1c Poor Control (>9%)	Intermediate outcome (+2 points)	3-10 points	Inverse measure, flat benchmark
110: Preventive Care and Screening: Influenza Immunization		No benchmark	
111: Pneumococcal Vaccination Status for Older Adults		3-8.9 or, with 100% performance rate, 10	
117: Diabetes: Eye Exam		3-3.9 points or, with a 100% performance rate, 7 points	Topped out, 7-point cap
128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up Plan		3-5.9 points or, with 100% performance rate, 7 points	Topped out, 7-point cap
130: Documentation of Current Medications in the Medical Record	Patient safety (+1 point)	3-4.9 points or, with a 100% performance rate, 7 points	Topped out, 7-point cap
154: Falls: Risk Assessment	Patient safety (+1 point)	3-3.9 points or, with a 100% performance rate, 7 points	Topped out, 7-point cap
226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention		No benchmark	

236: Controlling High Blood Pressure	Intermediate outcome (+2 points)	3-10 points	Flat benchmark
317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented		No benchmark	
Glaucoma			
141: Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% or Documentation of a Plan of Care	Outcome (+2 points)	3 points or, with a 100% performance rate, 10 points	
Oculofacial Plastics/Reconstructive			
397: Melanoma Reporting	Care coordination (+1 point)	3 points or, with a 100% performance rate, 7 points	Topped out, 7-point cap
Retina/Vitreous			
Retina: Age-Related Macular Degeneration (AMD)			
14: AMD: Dilated Macular Examination		3 points or, with a 100% performance rate, 7 points	Topped out, 7-point cap

SEE IF YOU CAN GET THIS DATA FROM YOUR BILLING SYSTEM

IRIS Registry: Manual Reporters Will Need Their Data-Completeness Totals

Since 2018, CMS has required practices that report quality measures manually through registries to submit data-completeness totals for each quality measure reported. (Note: This is different from the 70%–data completeness criteria described on page 20.)

What data-completeness total(s) must you submit for each quality measure? For each quality measure that you report manually via the IRIS Registry, do the following:

- Report the total number of patients seen during the year (from all payers) who were eligible for the measure
- If the measure includes an exception, report the total number of patients excepted from the measure

If you are reporting manually via the IRIS Registry, you won't be able to submit a measure's quality data to CMS without including the total number of eligible patients and, if applicable, the total number of excepted patients. Even if you want to report the measure for just one patient, CMS will want to know how many patients the measure could have been reported on over the calendar year.

Contact the vendor of your billing system. Many practices will be able to readily collect the eligible patient totals from their billing systems. Contact your billing system vendor and ask for instructions on how to run the appropriate reports.

Find out which patients would be eligible for each of your quality measures. At the IRIS Registry dashboard, you can view detailed measure specifications of each quality measure that you plan to report. The detailed measure descriptions include the denominator criteria that indicate which patients qualify for each measure.

Report the Eligible Totals

Get the total number of eligible patients for quality measures. After determining the denominator criteria, use your billing system to run a report of patients who meet those criteria. This will give you the total number of patients eligible for the measure. (Note: Run these reports after the end of the calendar year.)

Example: Determining the total number of eligible patients for Measure 12: Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation. Run a report in your billing system for the date range "1/1/21-12/31/21." Apply a filter for the following:

- Diagnosis of POAG (using ICD-10 codes outlined in the measure specification)
- Eligible CPT codes billed during the 2021 calendar year (using CPT codes outlined in the measure specifications)
- Date of birth, so that only patients age 18 years and older are included. If your system doesn't have this functionality, you can print out the report using the diagnosis- and CPT code–criteria and then remove patients who do not meet the measure's age criteria.

Report the Exceptions

Get the total number of patient exceptions for a quality measure. Some quality measures have exceptions. These are often medical- or patient-related. For example, there may be a medical reason why you can't perform an optic nerve evaluation on a POAG patient. Such exceptions should be supported by documentation. It may be difficult to run a report in your billing system to produce this total, and it may require manual counting.

Some quality measures do not have exceptions. Of the quality measures that can be manually reported via the IRIS Registry, the following do not have exceptions: Measures 1, 111, 117, 141, 191, 236, 238, 374, 384, 385, 389, 402, and the manually reported measures developed by the IRIS Registry (IRIS1, IRIS2, etc.).

Can't Get These Totals Electronically?

Some practices collect data manually by adding a MIPS worksheet to the charts. If you are not able to use your billing system to collect the number of patients eligible for a quality measure and/or the number excepted from the measure, you can use a manual approach for gathering this information. For example, some practices set up a manual system at the start of the year: They create a quality measure worksheet that they place in every patient's chart. This worksheet asks for all the information that is needed for the measures that the practice plans to report, and staff are trained to fill it out at each patient visit. This data can be used to calculate the eligible patients and exceptions.

Some practices keep up with their MIPS data entry throughout the year. Some practices manually enter 100% of eligible patients into the IRIS Registry throughout the year on a daily, weekly, or monthly basis. Both the eligible totals and the patient exception totals will be captured during that reporting, and the practice will have them on hand in early 2022 when it is time to submit its quality data to CMS.

Table 7: Benchmarks for QCDR Measures (Updated July 2021)

Benchmarks. The eight IRIS Registry QCDR measures below have benchmarks for performance year 2021 based on quality performance data from performance year 2019. The same benchmarks apply regardless of whether you are reporting via IRIS Registry–EHR integration or manually via the IRIS Registry web portal.

The other 22 IRIS Registry QCDR measures don't yet have a benchmark, but CMS will attempt to create benchmarks for them based on this year's performance data (see "What if there is no benchmark?" on page 22).

ID: Measure Name	High-Priority Measure (Bonus Points)	Achievement Points		Benchmark Decile (d)		
				d1 & d2	d3	
IRIS1: Endothelial Keratoplasty: Postoperative Improvement in Best Corrected Visual Acuity to 20/40 or Greater	Outcome (+2 points)	3-10 points	Performance rate:	<38.74%	38.75%-46.14%	
			Achievement points:	3.0	3.0-3.9	
IRIS6: Acquired Involutional Entropion: Normalized Lid Position After Surgical Repair	Outcome (+2 points)	3-6.9 points or, with a 100% performance rate, 10 points	Performance rate:	<91.74%	91.74%-93.85%	
			Achievement points:	3.0	3.0-3.9	
IRIS13: Diabetic Macular Edema: Loss of Visual Acuity	Outcome (+2 points)	3-10 points	Performance rate:	<70.84%	70.84%-82.47%	
			Achievement points:	3.0	3.0-3.9	
IRIS23: Refractive Surgery: Patients With a Postoperative Uncorrected Visual Acuity (UCVA) of 20/20 or Better	Outcome (+2 points)	3-10 points	Performance rate:	<68.75%	68.75%-75.33%	
			Achievement points:	3.0	3.0-3.9	
IRIS43: IOP Reduction Following Laser Trabeculoplasty	Outcome (+2 points)	3-10 points	Performance rate:	<21.43%	21.43%-27.49%	
			Achievement points:	3.0	3.0-3.9	
IRIS44: Visual Field Progression in Glaucoma	Outcome (+2 points)	3-10 points	Performance rate:	>15.65%	15.65%-14.02%	
			Achievement points:	3.0	3.0-3.9	
IRIS48: Adult Surgical Esotropia: Postoperative Alignment	Outcome (+2 points)	3-10 points	Performance rate:	<2.86%	2.86%-4.41%	
			Achievement points:	3.0	3.0-3.9	
IRIS50: Amblyopia: Interocular Visual Acuity	Outcome (+2 points)	3-10 points	Performance rate:	<42.86%	42.86%-47.61%	
			Achievement points:	3.0	3.0-3.9	

Scoring. Provided that your reporting for a measure meets the two data submission thresholds (see page 20), you can 1) earn achievement points based on your performance rate, as shown below, and 2) earn bonus point(s) (see column 2) for reporting a high-priority measure. Note: Because you must report at least one outcome (or intermediate outcome) measure, you don't earn high-priority bonus points on your first such measure. (For more on bonuses, see "Scoring—Bonuses for High-Priority Measures and CEHRT," page 22).

	Benchmark Decile (d)							Notes
	d4	d5	d6	d7	d8	d9	d10	
	46.15% -48.71%	48.72%- 55.87%	55.88%- 56.39%	56.4%- 66.98%	66.99%- 71.78%	71.79%- 79.99%	≥80.00%	
	4.0-4.9	5.0-5.9	6.0-6.9	7.0-7.9	8.0-8.9	9.0-9.9	10.0	
	93.86%- 95.69%	95.7%- 98.27%	98.28%- 99.99%	100%				
	4.0-4.9	5.0-5.9	6.0-6.9	10.0				
	82.48%- 87.43%	87.44%- 88.74%	88.75%- 89.86%	89.87%- 92.24%	92.25%- 93.87%	93.88%- 98.07%	≥98.08%	
	4.0-4.9	5.0-5.9	6.0-6.9	7.0-7.9	8.0-8.9	9.0-9.9	10.0	
	75.34%- 79.91%	79.92%- 83.01%	83.02%- 87.79%	87.8%-89.18%	89.19%- 94.11%	94.12%- 95.8%	≥95.81%	
	4.0-4.9	5.0-5.9	6.0-6.9	7.0-7.9	8.0-8.9	9.0-9.9	10.0	
	27.5%- 30.52%	30.53%- 33.32%	33.33%- 38.97%	38.98%- 62.85%	62.86%- 70.96%	70.97%- 85.70%	≥85.71%	
	4.0-4.9	5.0-5.9	6.0-6.9	7.0-7.9	8.0-8.9	9.0-9.9	10.0	
	14.01%- 13.13%	13.12%- 11.84%	11.83%- 10.85%	10.84%- 9.53%	9.52%- 8.84%	8.83%- 2.34%	≤2.33%	Inverse measure
	4.0-4.9	5.0-5.9	6.0-6.9	7.0-7.9	8.0-8.9	9.0-9.9	10.0	
	4.42%- 6.0%	6.01%- 7.69%	7.7%- 15.6%	15.61%- 22.61%	22.62%- 31.24%	31.25%- 37.32%	≥37.33%	
	4.0-4.9	5.0-5.9	6.0-6.9	7.0-7.9	8.0-8.9	9.0-9.9	10.0	
	47.62%- 53.32%	53.33%- 56.51%	56.52%- 57.88%	57.89%- 67.56%	67.57%- 68.17%	68.18%- 68.96%	≥68.97%	
	4.0-4.9	5.0-5.9	6.0-6.9	7.0-7.9	8.0-8.9	9.0-9.9	10.0	

Table 8: Benchmarks for Medicare Part B Claims–Based Measures (Updated July 2021)

Of the scores of quality measures available for claims-based reporting, the 13 below are most likely to be relevant to ophthalmology practices. For 10 of these 13 measures, CMS had enough data from 2019 claims-based reporting to create benchmarks for this year.

Scoring. If your reporting for a measure meets the two data submission thresholds (see page 20), you can 1) earn achievement points based on your performance rate, as shown below, and 2) earn bonus point(s) (see column 2) for reporting a high-priority measure. Note: Because you must report at least one outcome (or intermediate outcome) measure, you don't earn high-priority bonus points on your first such measure. (For more information on bonuses, including the bonus

ID: Measure Name	High-Priority Measure (Bonus Points)	Achievement Points		Benchmark Decile (d)		
				d1 & d2	d3	
~~**1:** Diabetes: Hemoglobin A1c Poor Control (>9%)~~	~~Intermediate outcome (+2 points)~~	~~3-10 points~~	~~Performance rate:~~	~~>79.99%~~	~~79.99%-70.01%~~	
			~~Achievement points:~~	~~3.0~~	~~3.0~~	
14: AMD: Dilated Macular Examination		3 points or, with a 100% performance rate, 7 points	Performance rate:	<100%		
			Achievement points:	3.0		
110: Preventive Care and Screening: Influenza Immunization		No benchmark	Performance rate:			
			Achievement points:			
111: Pneumonia Vaccination Status for Older Adults		3-8.9 points or, with a 100% performance rate, 10 points	Performance rate:	<68.68%	68.68%-76.31%	
			Achievement points:	3.0	3.0-3.9	
~~**117:** Diabetes: Eye Exam~~		~~3-3.9 points or, with a 100% performance rate, 7 points~~	~~Performance rate:~~	~~<0.75%~~	~~0.75%-97.82%~~	
			~~Achievement points:~~	~~3.0~~	~~3.0-3.9~~	
128: Preventive Care and Screening: Body Mass Index (BMI)		3-5.9 points or, with a 100% performance rate, 7 points	Performance rate:	<91.47%	91.47%-98.57%	
			Achievement points:	3.0	3.0-3.9	
130: Documentation of Current Medications in the Medical Record	Patient safety (+1 point)	3-4.9 points or, with a 100% performance rate, 7 points	Performance rate:	<99.67%	99.67%-99.93%	
			Achievement points:	3.0	3.0-3.9	
141: POAG: Reduction of IOP by 15% or Documentation of a Plan of Care	Outcome (+2 points)	3 points or, with a 100% performance rate, 10 points	Performance rate:	<100%		
			Achievement points:	3.0		
154: Falls: Risk Assessment	Patient safety (+1 point)	3-3.9 points or, with a 100% performance rate, 7 points	Performance rate:	<99.07%	99.07%-99.99%	
			Achievement points:	3.0	3.0-3.9	

caps, see "Scoring—Bonuses for High-Priority Measures and CEHRT," page 22).

Scoring limitations for some benchmarks. Watch out for benchmarks where large numbers of MIPS participants attained a perfect performance rate in 2019. For measure 141, for example 70% of claims-based reporters had a 100% performance rate in 2019. Consequently, scoring stalls at decile 3, which means that a 99.99% performance rate only earns you 3.9 achievement points, though you can still score 10 achievement points for a 100% performance rate.

Furthermore, some benchmarks are subject to a 7-point cap, which means that you can't earn more than 7 achievement points.

<table>
<tr><th colspan="8">Benchmark Decile (d)</th><th>Notes</th></tr>
<tr><th></th><th>d4</th><th>d5</th><th>d6</th><th>d7</th><th>d8</th><th>d9</th><th>d10</th><th></th></tr>
<tr><td></td><td>~~70.00%-60.01%~~</td><td>~~60.00%-50.01%~~</td><td>~~50.00%-40.01%~~</td><td>~~40.00%-30.01%~~</td><td>~~30.00%-20.01%~~</td><td>~~20.00%-10.01%~~</td><td>~~≤10%~~</td><td rowspan="2">CMS suppressed this measure for claims in 2021.</td></tr>
<tr><td></td><td>~~4.0~~</td><td>~~5.0~~</td><td>~~6.0~~</td><td>~~7.0~~</td><td>~~8.0~~</td><td>~~9.0~~</td><td>~~10.0~~</td></tr>
<tr><td colspan="8">100%</td><td rowspan="2">7-point cap, topped out</td></tr>
<tr><td colspan="8">7.0</td></tr>
<tr><td colspan="8">CMS will attempt to create a benchmark based on 2021 performance data.</td><td rowspan="2"></td></tr>
<tr><td colspan="8">If there aren't enough 2021 performance data to create a reliable benchmark, you won't be able to score more than 3 achievement points.</td></tr>
<tr><td></td><td>76.32%-82.46%</td><td>82.47%-87.56%</td><td>87.57%-93.08%</td><td>93.09%-97.89%</td><td>97.9%-99.99%</td><td colspan="2">100%</td><td rowspan="2"></td></tr>
<tr><td></td><td>4.0-4.9</td><td>5.0-5.9</td><td>6.0-6.9</td><td>7.0-7.9</td><td>8.0-8.9</td><td colspan="2">10.0</td></tr>
<tr><td></td><td>~~97.83%-99.99%~~</td><td colspan="6">~~100%~~</td><td rowspan="2">CMS suppressed this measure for claims in 2021.</td></tr>
<tr><td></td><td>~~4.0-4.9~~</td><td colspan="6">~~7.0~~</td></tr>
<tr><td></td><td>98.58%-99.72%</td><td>99.73%-99.99%</td><td colspan="5">100%</td><td rowspan="2">7-point cap, topped out</td></tr>
<tr><td></td><td>4.0-4.9</td><td>5.0-5.9</td><td colspan="5">10.0</td></tr>
<tr><td></td><td>99.94%-99.99%</td><td colspan="6">100%</td><td rowspan="2">7-point cap, topped out</td></tr>
<tr><td></td><td>4.0-4.9</td><td colspan="6">7.0</td></tr>
<tr><td colspan="8">100%</td><td rowspan="2"></td></tr>
<tr><td colspan="8">10.0</td></tr>
<tr><td colspan="8">100%</td><td rowspan="2">7-point cap, topped out</td></tr>
<tr><td colspan="8">7.0</td></tr>
</table>

Continued on page 38.

Table 8: Benchmarks for Medicare Part B Claims–Based Measures

ID: Measure Name	High-Priority Measure (Bonus Points)	Achievement Points		Benchmark Decile (d)		
				d1 & d2	d3	
226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention		No benchmark	Performance rate:			
			Achievement points:			
236: Controlling High Blood Pressure	Intermediate outcome (+2 points)	3-10 points	Performance rate:	<20%	20%-29.99%	
			Achievement points:	3.0	3.0	
317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented		No benchmark	Performance rate:			
			Achievement points:			
397: Melanoma Reporting	Care coordination (+1 point)	3 points or, with a 100% performance rate, 7 points	Performance rate:	<100%		
			Achievement points:	3.0		

IT IS NOW MUCH HARDER TO AVOID THE PAYMENT PENALTY

Are You In a Small Practice With No EHR?

It is now much harder for clinicians to avoid the MIPS payment penalty, and this is especially true if you are in a small practice without an electronic health record (EHR) system.

Greater Challenges

Small practices without EHR might be able to get a MIPS final score of more than 15 points, and thus avoid the maximum penalty of –9%. However, avoiding a penalty altogether will be a big challenge. The reasons include the following:

Performance threshold raised to 60 points. To avoid a future payment penalty, your MIPS final score must meet or exceed the year's performance threshold. This year's performance threshold is 60 points, up from 45 points last year (see Table 2A, page 12). Small practices without an EHR system are likely to feel the greatest negative impact. Previously, such practices could avoid the penalty by submitting minimal data on six quality measures and also maxing out their score for the improvement activities performance category. While small practices will still earn 3 achievement points toward their quality score for doing minimal reporting on a measure (e.g., reporting the measure one time on one patient), the new performance threshold means that they need to do more than that to avoid the payment penalty.

What does it take to earn more than 3 achievement points for a quality measure? Like last year, to earn more than 3 points for a quality measure, small practices must meet the two data submission thresholds—reporting on 1) at least 20 patients and 2) at least 70% of denominator-eligible patients (see page 20). This will be less onerous for practices that have an EHR system and have integrated it with the IRIS Registry. If you are reporting manually via the IRIS Registry, you will also have to track your data-completeness totals (see page 33).

Claims-based quality measures must be reported in real time. Small practices—but not large practices—can still report quality measures via claims. However, if you are reporting via claims, you do your reporting throughout the year when you submit your requests for payments. This means that you will probably need to start reporting early in the year if you want to report on 70% of denominator-eligible patients, which is a prerequisite for earning more than 3 achievement points for a measure (see above).

Significant scoring limitations for quality measures that are reported via claims. When a quality measure isn't subject to any scoring limitations, you can earn up to 10 achievement points for it. But this year, many of the measures most relevant to ophthalmology are subject to score "stalling" and,

Benchmark Decile (d)							Notes
d4	d5	d6	d7	d8	d9	d10	
CMS will attempt to create a benchmark based on 2021 performance data.							No benchmark
If there aren't enough 2021 performance data to create a reliable benchmark, you won't be able to score more than 3 achievement points.							
30%-39.99%	40%-49.99%	50%-59.99%	60%-69.99%	70%-79.99%	80%-89.99%	≥90%	Flat benchmark
4.0	5.0	6.0	7.0	8.0	9.0	10.0	
CMS will attempt to create a benchmark based on 2021 performance data.							No benchmark
If there aren't enough 2021 performance data to create a reliable benchmark, you won't be able to score more than 3 achievement points.							
100%							7-point cap, topped out
7.0							

in some cases, a 7-point cap when reported via claims (see Table 8, above). For example, even if you have an extremely high performance rate of 99.99% for measure 14 (a retina measure) or measure 141 (a glaucoma measure), you would only earn 3.9 achievement points for each of them; a performance rate of 100% would earn you 7 points for measure 14 and 10 points for measure 141.

Measure 12—optic nerve evaluation in cases of primary open-angle glaucoma—can only be reported via EHR. Measure 12 can no longer be reported manually via the IRIS Registry or via claims. This is because its benchmarks for those two reporting mechanisms had been "topped out" (see page 22) for three consecutive years.

Avoiding the Penalty

If you are in a small practice without an EHR system, one route to attaining a MIPS final score of at least 60 points, and thus avoiding the penalty, would be as follows:

- Max out your score for the improvement activities performance category, which would then contribute 15 points to your MIPS final score.
- Be approved for a promoting interoperability (PI) hardship exception (see page 46), which would mean PI's weight in your MIPS final score would be reassigned to quality (increasing quality's weight from 40% of your MIPS final score to 65%; see Table 1, page 11).
- Meet the two data submission thresholds (see page 20) for at least six quality measures.
- Given that you don't know what your score will be for the cost performance category, you should aim to score an average of 6.02 points for each quality measure. This—together with the 6-point small practice bonus for reporting quality—will give you a quality score of 70.20%. If quality is weighted at 65% of your MIPS final score, then a quality score of 70.20% will contribute 45.63 points (70.20% of 65 points) to your MIPS final score. Along with your 15 points for maxing out the improvement activities performance category, plus a possible complex patient bonus, you will score more than enough to avoid the penalty.
- If you don't perform cataract surgery, then you may be excluded from the cost performance category (see pages 65 and 66). If you are excluded from both cost and PI, quality's weight in your MIPS final score would be 85% (see Table 1, page 11), and you would now need an average of 4.6 points for each of six quality measures, along with a 100% score for improvement activities to avoid the payment penalty.

Bottom line. Given the scoring limitations for many quality measures, particularly those reported by claims, it will be difficult for small practices without EHR systems to avoid the payment penalty. However, their MIPS reporting can reduce the penalty and mitigate its impact on reimbursement in 2023. By attaining a MIPS final score of more than 15 points, they can avoid the maximum –9% penalty, and the closer they get to 60 points the smaller their penalty will be (see Table 2B, page 12).

Interested in adopting an EHR system? EHR technology can provide multiple benefits for streamlined workflow and documentation, as well as for electronically reporting quality for MIPS. For more on EHRs, visit aao.org/practice-management/electronic-health-records/ehrs.

WHAT COULD SHE SEE THIS YEAR?

EYLEA®
(aflibercept) Injection
For Intravitreal Injection

Inspired by a real patient with DME.

375 MATH TESTS

IMPORTANT SAFETY INFORMATION
CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

- Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA.
- Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.
- There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA compared with 1.5% (9 out of 595) in patients treated with ranibizumab; through 96 weeks, the incidence was 3.3% (60 out of 1824) in the EYLEA group compared with 3.2% (19 out of 595) in the ranibizumab group. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

REGENERON

777 Old Saw Mill River Road, Tarrytown, NY 10591

EYLEA ACHIEVED RAPID, SUSTAINED OUTCOMES IN DME

Demonstrated efficacy outcomes in VISTA and VIVID, phase 3 anti-VEGF trials in DME (N=862)[1]

Mean change in BCVA (ETDRS letters) at Year 1 from baseline[1-5,*]

	Initial Gains (Month 5)		Primary Endpoint (Year 1)		Prespecified Exploratory Endpoint (Year 3)	
	VISTA	VIVID	VISTA	VIVID	VISTA	VIVID
EYLEA Q4	+10.3 (n=154)	+9.3 (n=136)	+12.5 (n=154)	+10.5 (n=136)	+10.4 (n=154)	+10.3 (n=136)
EYLEA Q8†	+9.9 (n=151)	+9.3 (n=135)	+10.7 (n=151)	+10.7 (n=135)	+10.5 (n=151)	+11.7 (n=135)
Control	+1.8 (n=154)	+1.8 (n=132)	+0.2 (n=154)	+1.2 (n=132)	+1.4 (n=154)	+1.6 (n=132)

P<0.01 vs control at Year 1.

The analyses of these exploratory endpoints were not multiplicity protected and are descriptive only.

Year 2 data was consistent with results seen in Year 1.[5]

VISTA and VIVID study designs: Two randomized, multicenter, double-masked, controlled clinical studies in which patients with DME (N=862; age range: 23-87 years, with a mean of 63 years) were randomized and received: 1) EYLEA 2 mg Q8 following 5 initial monthly doses; 2) EYLEA 2 mg Q4; or 3) macular laser photocoagulation (control) at baseline and then as needed. From Week 100, laser control patients who had not received EYLEA rescue treatment received EYLEA as needed per re-treatment criteria. Protocol-specified visits occurred every 28 (±7) days.[1]

In both clinical studies, the primary efficacy endpoint was the mean change from baseline in BCVA at Week 52, as measured by ETDRS letter score.[1]

*Last observation carried forward; full analysis set.
†Following 5 initial monthly doses.

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

anti-VEGF, anti–vascular endothelial growth factor; BCVA, best-corrected visual acuity; ETDRS, Early Treatment Diabetic Retinopathy Study; Q4, every 4 weeks; Q8, every 8 weeks.

ADVERSE REACTIONS

- Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis and retinal detachment.
- The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.
- Patients may experience temporary visual disturbances after an intravitreal injection with EYLEA and the associated eye examinations. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

INDICATIONS

EYLEA® (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).

References: 1. EYLEA® (aflibercept) Injection full U.S. Prescribing Information. Regeneron Pharmaceuticals, Inc. August 2019. **2.** Korobelnik JF, Do DV, Schmidt-Erfurth U, et al. Intravitreal aflibercept for diabetic macular edema. *Ophthalmology.* 2014;121(11):2247-2254. doi:10.1016/j.ophtha.2014.05.006 **3.** Brown DM, Schmidt-Erfurth U, Do DV, et al. Intravitreal aflibercept for diabetic macular edema: 100-week results from the VISTA and VIVID studies. *Ophthalmoogy.* 2015;122(10):2044-2052. doi:10.1016/j.ophtha.2015.06.017 **4.** Data on file. Regeneron Pharmaceuticals, Inc. **5.** Heier JS, Korobelnik JF, Brown DM, et al. Intravitreal aflibercept for diabetic macular edema: 148-week results from the VISTA and VIVID studies. *Ophthalmology.* 2016;123(11):2376-2385. doi:10.1016/j.ophtha.2016.07.032

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

04/2021
EYL.21.03.0211

EYLEA®
(aflibercept) Injection
For Intravitreal Injection

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

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

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

4 CONTRAINDICATIONS

4.1 Ocular or 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

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

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

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

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

	CRVO		BRVO	
Adverse Reactions	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

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

Less common adverse reactions reported in <1% of the patients treated with EYLEA were hypersensitivity, retinal detachment, retinal tear, corneal edema, and injection site hemorrhage.
Safety data observed in 269 patients with nonproliferative diabetic retinopathy (NPDR) through week 52 in the PANORAMA trial were consistent with those seen in the phase 3 VIVID and VISTA trials (see Table 3 above).

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy
Risk Summary
Adequate and well-controlled studies with EYLEA have not been conducted in pregnant women. Aflibercept produced adverse embryofetal effects in rabbits, including external, visceral, and skeletal malformations. A fetal No Observed Adverse Effect Level (NOAEL) was not identified. At the lowest dose shown to produce adverse embryofetal effects, systemic exposures (based on AUC for free aflibercept) were approximately 6 times higher than AUC values observed in humans after a single intravitreal treatment at the recommended clinical dose [*see Animal Data*].
Animal reproduction studies are not always predictive of human response, and it is not known whether EYLEA can cause fetal harm when administered to a pregnant woman. Based on the anti-VEGF mechanism of action for aflibercept, treatment with EYLEA may pose a risk to human embryofetal development. EYLEA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

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

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

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

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

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

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

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

REGENERON

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

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

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

EYL.20.09.0052

YOU NEED A CERTIFIED EHR SYSTEM FOR THIS PERFORMANCE CATEGORY

How to Report Promoting Interoperability

Promoting interoperability (PI) is the MIPS performance category that is based on your use of electronic health records (EHRs). Its default weight in your MIPS final score is 25%, meaning that it can contribute up to 25 points to it. However, if you are excused from PI (see page 46), that weight would typically be reallocated to the quality performance category (see Table 1, page 11).

Your EHR System Must Be a CEHRT

You must use either a 2015-edition CEHRT or—new for 2021—a 2015-edition Cures Update CEHRT. To participate in the MIPS PI performance category, you'll need a certified EHR technology (CEHRT) that has either 2015-edition certification or 2015-edition Cures Update certification.

If you use a modular EHR system, you can use a mixture of 2015-edition modules and 2015-edition Cures Update modules. (Note: Starting in 2023, CMS plans to make the 2015-edition Cures Update certification mandatory for PI.)

What is 2015-edition Cures Update certification? In 2020, the 21st Century Cures Act created the 2015-editon Cures Update certification, which is an update of the 2015-edition certification. The updates include changes that are intended to improve interoperability between different EHR systems.

Check your EHR system's certification. To check the certification status of an EHR product at any given time, visit the Certified Health IT Product List (CHPL) at https://chpl.healthit.gov/#/search. (Make a note of your system's CHPL ID#; you will need this when you report your PI performance to CMS.)

What if your EHR system's certification is still pending? CMS recognizes that some vendors may be providing upgraded EHR systems to practices while certification is still pending. If this is the case with your EHR system, you may still be able to satisfy the CEHRT requirement provided:

- your EHR system has 2015-edition or 2015-edition Cures Update functionality for all 90+ days of your PI performance period, and
- CMS grants the certification by the last day of that performance period.

Promoting Interoperability 101

Default weight in MIPS final score: 25%.

Performance period: The same 90+ consecutive days for all scored measures, but the unscored Security Risk Analysis can be performed at any time of the calendar year.

Performance requirements: Meet the following requirements:

- Use an EHR system that has 2015-edition or 2015–edition Cures Update certification (see above), and provide CMS with your EHR system's CHPL identification code;
- perform the unscored Security Risk Analysis measure;
- perform and report—or, where applicable, claim an exclusion for—all the mandatory scored measures;
- make three attestations (regarding the Security Risk Analysis, Prevention of Information Blocking, and ONC Direct Review); and
- document your performance in case of an audit.

Collection types: Like last year, you can report your PI measures manually via the IRIS Registry, via the CMS QPP attestation portal, or possibly via your EHR vendor (check that your vendor offers this option, and ask about deadlines and fees).

Warning: You'll get a PI score of 0% if you submit conflicting data or conflicting attestations on PI measures. (This could happen, for example, if you report PI twice using two different collection types and submit different information each time.)

Not everybody has to take part in PI. In some cases, you may be excused from performing the PI measures (see page 46).

Understand How PI Is Structured

PI is arranged around four objectives: 1) e-Prescribing; 2) Health Information Exchange (HIE); 3) Provider to Patient Exchange; and 4) Public Health and Clinical Data Exchange. Each objective has at least one measure associated with it (see Table 9, page 45).

Fall short with even just one measure and your PI score will be 0%. In order to earn any score for the PI performance category, you must either 1) report or, if an exclusion is available, 2) claim an exclusion for all the required measures. If you fail to do that, your PI score will be 0% and will contribute 0 points to your MIPS final score. (Note: When you report a numerator, it must be at least 1.)

You may be able to claim exclusions for some measures. Exclusions are available for most of the

PI measures (see Table 10, page 47). For example, there is an exclusion available for the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure. If you qualify for and claim this exclusion, the 20 points available for it would be reallocated to another measure.

Not all PI measures have exclusions. There is no exclusion for the Provide Patients Electronic Access to Their Health Information measure. The e-Prescribing objective's opioid-related bonus measure is optional in 2021, and therefore doesn't need an exclusion. There also is no exclusion for the new HIE Bi-Directional Exchange measure, but you can opt to report the two Support Electronic Referral Loops measures instead.

Performance Period Is At Least 90 Days

Pick a performance period of at least 90 continuous days and no more than the calendar year.

Pick your date range. You must use the same performance period—i.e., same start date and same end date—for each of the scored PI measures that you report.

The Security Risk Analysis can be done on a separate schedule. The unscored Security Risk Analysis doesn't have to be done during the performance period that you are using for the scored PI measures. It can be performed at any time during the 2021 calendar year. However, it must be an analysis of the same 2015-edition or 2015-edition Cures Update CEHRT that is being used to perform the scored measures.

Last day to start performing PI measures is Oct. 3. Don't wait till October; make sure you allow yourself some leeway in case you run into any problems.

What you should be doing early in the year. Make sure you understand the PI measures and know what you need to do to meet their requirements. Read the measure descriptions and documentation suggestions at aao.org/medicare/promoting-interoperability/measures. Your EHR system should allow you to run PI reports; run them to see what your performance rates are. If performance rates seem low, try to pinpoint the source of the problem—are data being entered into the right field? Do you need to make changes to workflow? If any physicians have joined your practice this year, make sure they are included in the reports.

Document measure performance. Make sure your documentation includes dates, so you can show that you met the performance period requirements. You won't need to provide this when you report your PI measures, but you should keep it for six years in case you are audited.

Three Critical Attestations

You must submit "yes" for these three attestations. Failure to do so will result in a PI score of 0%.

Submit "yes" to attest that you performed the Security Risk Analysis. The Security Risk Analysis must be documented (in case of an audit), it must be done at some point during the 2021 performance year, and it must involve an analysis of the CEHRT that you have in place during your 90-day PI performance period, but it doesn't have to take place during that 90-day performance period. This Security Risk Analysis is also a HIPAA requirement.

Submit "yes" for the Prevention of Information Blocking attestation. Attest "yes" to three statements about how you have implemented and used your EHR system. This requirement reflects a CMS concern that practices might "knowingly and willfully" take action to limit and restrict the compatibility or interoperability of CEHRT.

Submit "yes" for the ONC Direct Review attestation. The ONC—otherwise known as the Office of National Coordinator for Health Information Technology—is responsible for certifying EHR systems as CEHRTs, and for monitoring CEHRTs to make sure they continue to meet their certification requirements. Occasionally, ONC may need to conduct a "direct review" of a vendor's EHR product (for example, if ONC has a reasonable belief that faults within the EHR system may present a risk to public health). By submitting "yes" to this attestation, you agree to cooperate in such a review.

How You Will Be Scored

For some PI measures, scoring is based on your performance rate. You can, for example, score up to 10 points for the e-Prescribing measure; if your performance rate is 82%, you would score 8 points. (Note: In calculating this point score, CMS typically rounds off to the nearest whole number. The exception is when the nearest whole number is 0 points; provided you have reported on at least one patient, CMS will round up to 1 point.)

Your performance rate is based on a numerator and a denominator. For the e-Prescribing measure, to continue the example, the denominator is the number of prescriptions written during the performance period for drugs that require prescriptions and the numerator is the number of those prescriptions that were 1) generated, 2) queried for a drug formulary, and 3) transmitted electronically using a certified EHR. You need a numerator of at least 1 to successfully report the measure. (For information on the numerators and denominators of the performance rate–based measures, see the detailed measure descriptions at aao.org/medicare/promoting-interoperability/measures; for tips on the Provide Patients Electronic Access to Their Health Information measure, see aao.org/practice-management/article/mips-tips-provide-patients-electronic-access.)

Scoring is not performance rate–based for measures in the Public Health and Clinical Data Exchange objective. For the five measures that involve reporting to registries or public health agencies, you attest "yes" or "no" to indicate whether you are actively engaged with registries or public health agencies. Scoring for this objective is on a pass/fail basis, with 10 points for a pass and 0 points for a fail. To pass, either 1) provide two "yes" responses or 2) provide one "yes" response and claim one exclusion. If you provide no "yes" responses but claim two exclusions, the 10 points will be reallocated to the Provider to Patient Exchange objective. Note: To be actively engaged with a registry or agency, you must be either sending production data to the entity or in the process of moving toward doing so. (For a more complete definition of active engagement, see the detailed measure descriptions

at aao.org/medicare/promoting-interoperability/measures.)

Scoring is not performance-rate based for the Query of Prescription Drug Monitoring Program (PDMP) bonus measure. CMS had initially designed this as a performance-rate based measure, but a lack of EHR-PDMP integration meant that clinicians would have to track their numerator and denominator manually or develop custom reports. Consequently, CMS changed this to a measure that requires a "yes" or "no" attestation. Attesting "yes" indicates that "for at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician then used data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law." You can earn 10 bonus points for this measure (up from 5 points in 2020).

Scoring is not performance-rate based for the new Health Information Exchange (HIE) Bi-Directional Exchange measure. This measure can be reported instead of the two Support Electronic Referral Loops measures. To score 40 points on this measure, you must report "yes" on three attestations (see page 46); if you report "no" on one or more of those attestations, you will score 0 points for the measure.

Table 9: Promoting Interoperability (PI)—at a Glance

To get a PI score of more than 0%, you must perform the following steps:
❶ have 2015-edition or 2015-edition Cures Update CEHRT;
❷ submit a "Yes" for the Security Risk Analysis attestation;
❸ submit a "Yes" for the Prevention of Information Blocking attestation;
❹ submit a "Yes" for the ONC Direct Review attestation; and meet the reporting requirements for ❺; ❻ or ❼; ❽; and ❾, as shown below. (The measures listed below must be performed for a performance period of at least 90 consecutive days.)

Objective	Reporting Requirements	2020 PI Measure	What You Report	Points
e-Prescribing	❺ Report a numerator of at least 1 or claim an exclusion for this measure.	e-Prescribing	Report performance rate (numerator/ denominator)	Up to 10
	This bonus measure is optional.	Query of Prescription Drug Monitoring Program (PDMP)	Attest "yes" or "no"	0 or 10 (bonus)
Health Information Exchange (HIE) [Perform either ❻ or ❼]	❻a Report a numerator of at least 1 or claim an exclusion for this measure.	Support Electronic Referral Loops by *Sending* Health Information	Report performance rate (numerator/ denominator)	Up to 20
	❻b Report a numerator of at least 1 or claim an exclusion for this measure.	Support Electronic Referral Loops by *Receiving and Reconciling* Health Information	Report performance rate (numerator/ denominator)	Up to 20
	❼ Attest that your EHR supports bi-directional exchange of health information.	HIE Bi-Directional Exchange	Three "yes" or "no" attestations (see page 46)	0 or 40
Provider to Patient Exchange	❽ Report a numerator of at least 1 for this measure.	Provide Patients Electronic Access to Their Health Information	Report performance rate (numerator/ denominator)	Up to 40
Public Health and Clinical Data Exchange	❾ Do one of the following: (a) Report two measures, or (b) report one measure for two different clinical data registries or public health agencies, or (c) report one measure and claim one exclusion, or (d) claim two exclusions.	Immunization Registry Reporting	Attest "yes" or "no"	0 or 10
		Electronic Case Reporting	Attest "yes" or "no"	
		Public Health Registry Reporting	Attest "yes" or "no"	
		Clinical Data Registry Reporting	Attest "yes" or "no"	
		Syndromic Surveillance Reporting	Attest "yes" or "no"	
2021 PI score is sum of your measure scores (capped at 100 points, and reported as a percentage)				0%-100%
Contribution to MIPS final score. If PI is weighted at 25% of your MIPS final score (which is the default weight), it can contribute up to 25 points to your MIPS final score (0-100 points).				

Reporting PI as a Group

If the MIPS eligible clinicians in your practice are reporting a performance category as a group, they must aggregate their performance data across the group's TIN (see "Use of TINs and NPIs as Identifiers," page 16). However, for the PI performance category, you would only use the performance data of those clinicians for whom you have data in a CEHRT.

Some Clinicians May Be Excused From PI

In limited circumstances, you may be excused from PI reporting. Typically, if you don't report PI measures, your PI score will be 0% and your maximum MIPS final score would be 75 points. However, there are some exceptions (see below). If you qualify for an exception, you would be excused from reporting PI measures. Some PI exceptions must be applied for, while others are automatic.

What happens if you are excused from PI? If CMS excuses you from reporting PI, the performance category's weight within your MIPS final score could be reduced to 0%. If PI is the only performance category that is being reweighted to 0%, its weight is transferred to the quality performance category, which would now be weighted at 65%, meaning quality would contribute up to 65 points toward your MIPS final score. If more than one performance category is being reweighted to 0%, weights are reallocated as shown in "Table 1: How the Performance Categories Are Weighted" (page 11).

Warning: If you do any PI reporting for the 2021 performance year, you will have waived your right to any exception from PI. Suppose you qualify for a PI exception, but you report PI measures anyway. CMS will assume that you decided to participate in PI, will assign you a PI score, and will give PI a weight of 25% in your MIPS final score.

Caveat for group-level reporting. If you are participating in MIPS as part of a group, you won't be excused from PI unless all MIPS eligible clinicians in the group are excused.

Some PI Exceptions Must Be Applied For

You may apply for a significant hardship exception. CMS has described several circumstances in which you can apply for the significant hardship exception:

- insufficient internet connectivity and insurmountable barriers prevented you from obtaining sufficient access;
- extreme and uncontrollable circumstances that caused your CEHRT to become unavailable (see page 16), including disaster, practice closure, severe financial distress (e.g., bankruptcy or debt restructuring), and vendor issues;
- you have no control over whether CEHRT is available (you must be able to show that more than 50% of your patient encounters occurred in locations where you had no control over the availability of CEHRT);
- you're using a decertified EHR system that lost its certification in 2020 or 2021 (note: you must be able to show a good-faith effort to replace it with a CEHRT ahead of the performance period, and you can't be granted this exception for more than five years); and/or
- you're in a small practice and you can demonstrate that there are "overwhelming barriers" that prevent you from complying with the PI requirements.

Note: If your practice lacks an EHR system, that is not enough, in and of itself, to excuse you from PI.

Submit your application by Dec. 31, 2021. In past years, CMS opened the application process in August. It will post a link at at https://qpp.cms.gov/mips/exception-applications. For some Academy guidance on the application process, visit aao.org/medicare/promoting-interoperability/exceptions. Note: If you applied for this exception in 2020 and it was approved, the approval doesn't roll over to 2021—you need to reapply.

Some PI Exceptions Are Automatic

You're in a disaster zone. If your practice is in an area that CMS has identified as being affected by extreme and uncontrollable circumstances (see page 16), CMS may excuse you from MIPS provided you don't report any MIPS data.

Certain types of MIPS eligible clinicians qualify for automatic reweighting. These include the following clinician types:

- hospital-based clinicians,
- ambulatory surgical center (ASC)–based clinicians,
- non–patient-facing clinicians,
- physician assistants,
- nurse practitioners,
- clinical nurse specialists,
- certified registered nurse anesthetists,
- physical therapists,
- occupational therapists,
- qualified speech-language pathologists, or
- registered dietitians or nutrition professionals.

New for 2021: HIE Bi-Directional Exchange Measure

For this year's HIE objective, you have a choice of PI measures: You can either report (or claim exclusions for) the two Support Electronic Referral Loops measures or report the new HIE Bi-Directional Exchange measure.

To earn all 40 points for the new HIE Bi-Directional Exchange measure, you must attest "yes" to these three statements:

1. You participate in an HIE in order to enable secure, bi-directional exchange to occur for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period in accordance with applicable law and policy.
2. The HIE that you participate in is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and does not engage in exclusionary behavior when determining exchange partners.
3. You use the functions of CEHRT to support bi-directional exchange with an HIE.

If you report "no" on one or more of those attestations, you earn 0 points for the measure.

Table 10: PI Measure Exclusions—at a Glance

Exclusions available for some measures. If you successfully claim an exclusion for a PI measure, the points available for that measure will be reassigned to one or more other PI measures as shown below (see column 5).

Objective	2021 PI Measure	Points	Exclusion	Point Reallocation if Exclusion(s) Applies
e-Prescribing	e-Prescribing	Up to 10	Exclusion: Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.	Five points to each of the Supporting Electronic Referral Loops measures.
	Query of Prescription Drug Monitoring Program (PDMP)	0 or 10 (bonus)	No exclusion is needed for this optional bonus measure.	
Health Information Exchange (HIE) Note: New for 2021, you either report (or submit exclusions for) the two Support Electronic Referral Loops measures or you report the HIE Bi-Directional Exchange measure.	Support Electronic Referral Loops by *Sending* Health Information	Up to 20	Exclusion: Any MIPS eligible clinician who transfers a patient to another setting or refers a patient [a combined total of] fewer than 100 times during the performance period.	The 20 points (or 40 points if you claim an exclusion for both HIE measures) would be distributed to the Provide Patients Electronic Access to Their Health Information measure.
	Support Electronic Referral Loops by *Receiving and Reconciling* Health Information	Up to 20	Exclusion: Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient [a combined total of] fewer than 100 times during the performance period.	The 20 points would be redistributed to the Support Electronic Referral Loops by *Sending* Health Information measure.
	HIE Bi-Directional Exchange	0 or 40	No exclusion available.	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	Up to 40	No exclusion available.	
Public Health and Clinical Data Exchange	Immunization Registry Reporting	0 or 10	Each measure has its own exclusion; for the exact exclusion criteria for each measure see aao.org/medicare/promoting-interoperability/measures. Generally speaking, the exclusions are based on these criteria: 1) Does not diagnose or directly treat any disease or condition associated with an agency/registry in their jurisdiction during the performance period. 2) Operates in a jurisdiction for which no agency/registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the performance period.	If you attest to one measure and claim one exclusion, the 10 points would remain with this objective. If you claim two exclusions, the 10 points would be redistributed to the Provide Patients Electronic Access to Their Health Information measure.
	Electronic Case Reporting			
	Public Health Registry Reporting			
	Clinical Data Registry Reporting			
	Syndromic Surveillance Reporting			

Continued on page 48.

Table 10: PI Measure Exclusions—at a Glance (continued)

Objective	2020 PI Measure	Points	Exclusion	Point Reallocation if Exclusion(s) Applies
Public Health and Clinical Data Exchange (continued)			3) Operates in a jurisdiction where no agency/registry for which the MIPS eligible clinician is eligible has declared readiness to receive electronic registry transactions as of six months prior to the start of the performance period.	

Table 11: PI's Scoring Methodology—an Example

PI scoring in action. The example below shows how numerators and denominators are used to calculate performance rates, which are themselves used to determine your measure scores. For detailed descriptions of what will fall within the numerator and denominator of the performance rate–based measures, see the measure listings at aao.org/medicare/promoting-interoperability/measures.

Objective	2020 PI Measure	Points Available	Numerator/ Denominator	Performance Rate	Points Scored
e-Prescribing	e-Prescribing	Up to 10	200/250	80%	80% of 10 = 8
	Query of Prescription Drug Monitoring Program (PDMP)	Didn't report this optional measure.			
Health Information Exchange	Support Electronic Referral Loops by *Sending* Health Information	Up to 20	135/185	73%	73% of 20 = 15
	Support Electronic Referral Loops by *Receiving and Reconciling* Health Information	Up to 20	145/175	83%	83% of 20 = 17
	HIE Bi-Directional Exchange	Didn't choose this option; reported the two Support Electronic Referral Loops measures instead.			
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	Up to 40	350/500	75%	75% of 40 = 30
Public Health and Clinical Data Exchange	Immunization Registry Reporting	0 or 10	Claimed exclusion	N/A	10
	Electronic Case Reporting				
	Public Health Registry Reporting				
	Clinical Data Registry Reporting		Has integrated EHR with IRIS Registry; attested "yes"	N/A	
	Syndromic Surveillance Reporting				
Total points available:		110	Total points scored:		80
2021 PI score is sum of your measure scores (capped at 100 points, and reported as a percentage)					80%

Contribution to MIPS final score. If PI is weighted at 25% of your MIPS final score (which is the default weight), it can contribute up to 25 points to your MIPS final score—e.g., a PI score of 80% contributes 20 points (80% of 25).

MAX OUT YOUR SCORE FOR THIS PERFORMANCE CATEGORY

How to Succeed With Improvement Activities

Improvement activities is one of four performance categories that can contribute to your MIPS final score. Its default weight is 15% of that score, which means that it can contribute up to 15 points to it.

This performance category is largely the same as last year, but there have been changes to two improvement activities (see "2021 Versus 2020," next page). You also should note that you can still use the COVID-19 improvement activity that CMS introduced last April—IA_ERP_3: COVID-19 clinical data reporting with or without clinical trial (page 55).

How You Will Be Scored

Scoring for this performance category is the same as in 2020. To max out your score, you will need to successfully perform one to four performance activities—the amount that you need to perform depends on how those activities are weighted, as well as the size and location of your practice (see "Who scores double?" below).

You typically need to perform each activity for at least 90 consecutive days.

How many points do you get for an improvement activity? This depends on 1) how the activity is weighted and 2) whether you're able to double the score.

If an activity's weight is:

- medium—it scores 10 points (double score is 20 points)
- high—it scores 20 points (double score is 40 points)

Improvement Activities 101

Default weight in MIPS final score: 15%.

Performance period: At least 90 continuous days.

How to score 100%: Practices with a special status—such as small or rural practices—should perform one high-weighted activity *or* two medium-weighted activities. Other practices should perform two high-weighted activities *or* one high-weighted and two medium-weighted activities *or* four medium-weighted activities.

Document your performance: Make sure you include dates.

Group reporting: If your practice is reporting as a group, each improvement activity must be performed by at least 50% of the group's clinicians.

Who scores double? MIPS participants can score double for an improvement activity if they have one of these special statuses:

- small practice (fewer than 16 eligible clinicians; see "Small or Large Practice?" on page 15),
- rural practice (zip codes will be considered rural based on the most recent Federal Office of Rural Health Policy data files on eligible zip codes, not the HRSA Area Health Resource File dataset as CMS had incorrectly stated prior to the 2020 performance year),
- practice that is in a geographic health professional shortage area (HPSA), or
- non–patient-facing MIPS clinicians.

Are you a non–patient-facing clinician? Probably not. Few ophthalmologists are likely to fall within this category. You are designated a non–patient-facing MIPS clinician if you bill Medicare for no more than 100 patient-facing encounter codes—including Medicare telehealth services—in a designated period.

Check whether CMS doubles your score. To see if you fall within one of the special status categories, use the CMS Participation Status tool. (See "What's Your MIPS Participation Status?" on page 15.)

Maximum score is capped at 40 points. If you don't have a special status that doubles your score, you can accrue the maximum score of 40 points by performing either:

- two high-weighted activities (2 × 20 points)
- two medium-weighted activities (2 × 10 points) and one high-weighted activity (1 × 20 points), or
- four medium-weighted activities (4 × 10 points).

If you are eligible to score double, you can accrue 40 points by performing:

- one high-weighted activity (1 × 40 points) or
- two medium-weighted activities (2 × 20 points).

Each improvement activity is all or nothing. You won't score points for an improvement activity unless it is performed for the required time—typically a minimum of 90 consecutive days—and you satisfy all of its requirements. You do not score partial credit for reporting a partially performed activity.

Some MIPS participants will automatically get credit. MIPS eligible clinicians (and groups) who are practicing as part of an accredited patient-centered medical home (or comparable specialty practice) will automatically score 40

points (the maximum score); those who are participating as part of an advanced alternative payment model (APM) will automatically score a minimum of 20 points (half the maximum score). Few ophthalmologists are expected to fall within these two categories in 2021.

Your improvement activities score (0-40 points) is turned into a percentage, which contributes up to 15 points to your MIPS final score. CMS divides your total number of points by 40 and turns the resulting fraction into a percentage (e.g., a score of 40 points would be 100%). This contributes up to 15 points to your MIPS final score (e.g., a score of 100% would contribute 15 points).

Decide How You Will Report

Decide how you will attest. You can attest to your improvement activities performance via the IRIS Registry, the CMS QPP portal, or possibly your EHR vendor (ask your vendor whether it offers this option and what fees are involved).

Attest that you successfully completed improvement activities. However you decide to attest, it is your responsibility to attest that you appropriately completed the improvement activities that you choose to perform. If you attest via a third party (e.g., the IRIS Registry), the third party simply reports to CMS what you attested—the third party is not confirming that you did in fact complete those activities.

Group-level reporting. Practices that report as a group will only score points for an improvement activity if at least 50% of the practice's clinicians meet the reporting requirements of that activity (e.g., in a practice of nine, at least five).

2021 Versus 2020

What's new with improvement activities for 2021? CMS changed the rules governing the development of new improvement activities, making it easier to add new activities during an emergency, such as a pandemic.

The agency also removed one improvement activity—IA_CC_5: Partner in patients hospital engagement network—because it involved participation in a program that ended last year.

For ophthalmologists, the most relevant changes involve updates to the descriptions of the following two improvement activities.

IA_BE_4: Engagement of patients through implementation of improvements in patient portal. Language was added to 1) include caregivers as potential portal users; 2) clarify that the portal should be used for bi-directional information exchange between a physician and patient or caregiver; and 3) clarify that, for the purpose of this activity, primary use of the portal should be clinical rather than administrative. The new language also includes clinical, rather than administrative, examples of portal use.

IA_AHE_7: Comprehensive eye exam. The description of this improvement activity has been expanded to include the promotion of vision rehabilitation services.

They must do each activity for a performance period of at least 90 consecutive days, but they don't all have to do it during the same date range.

Select, Perform, and Document Your Activities

MIPS includes more than 100 improvement activities, but many of them aren't suitable for ophthalmologists.

Which improvement activities are most relevant to ophthalmology? The IRIS Registry supports reporting of the 62 improvement activities that are most meaningful for ophthalmology practices (see Table 12, page 51).

Select which activities you will perform. To score 100% on this performance category, the number of improvement activities that you need to perform can range from one to four, depending on the activities' weights and whether you score double (see "How You Will Be Scored," previous page).

Some improvement activities were designed for QCDRs, such as the IRIS Registry. The improvement activities performance category seeks to leverage the capability of qualified clinical data registries (QCDRs). For example, IRIS Registry–EHR integration facilitates performance of these activities:

- IA_PM_7: Use of QCDR for feedback reports that incorporate population health (high weighted)
- IA_PSPA_7: Use of QCDR data for ongoing practice assessment and improvements (medium weighted)

Get credit for MIPS *and* MOC. You can design and implement a quality improvement project that meets the requirements of the medium-weighted Maintenance of Certification (MOC) improvement activity. But you will need to submit your proposed project to the American Board of Ophthalmology (ABO) no later than Aug. 31 for its approval. For further information, visit the ABO's website at https://abop.org/IRIS or see the IRIS Registry guide at aao.org/iris-registry/maintenance-of-certification.

The performance period is typically 90 days. In order to score points for an improvement activity, you—or at least 50% of your colleagues, if you are reporting as part of a group or virtual group—must perform that activity for the performance period, which is typically at least 90 consecutive days. When groups perform an activity, each clinician can choose his or her own 90-day period within the 2021 calendar year.

Document your improvement activities. Ensure that you're ready for a future audit by maintaining documentation that shows you performed the improvement activities for which you are claiming credit. CMS has published suggested documentation for each improvement activity (for detailed web pages that list CMS' documentation suggestions for all the activities that can be reported via the IRIS Registry, go to aao.org/medicare/improvement-activities).

In case of an audit, can you prove that improvement activities were performed for at least 90 days? When you document your performance of improvement activities, make sure you include dates so you can prove that you performed the activities for at least 90 days.

You should maintain this documentation for at least six years. In 2019, a CMS contractor started contacting practices to conduct the first ever MIPS audits.

Table 12: Improvement Activities—at a Glance

Which improvement activities should you perform? The IRIS Registry supports reporting of the 62 improvement activities that are most relevant to ophthalmology. To determine which of those would be most appropriate for your practice, review the activity descriptions in Table 13 (page 54), as well as the detailed specifications and documentation suggestions at aao.org/medicare/improvement-activities.

	ID#	Improvement Activity	Notes
HIGH-WEIGHTED ACTIVITIES			
		Achieving Health Equity	
page 54	IA_AHE_1	Engagement of new Medicaid patients and follow-up	No EHR required
	IA_AHE_3	Promote use of patient-reported outcome tools	No EHR required
	IA_AHE_6	Provide education opportunities for new clinicians	No EHR required
		Beneficiary Engagement	
page 54	IA_BE_6	Collection and follow-up on patient experience and satisfaction data on beneficiary engagement	No EHR required
	IA_BE_14	Engage patients and families to guide improvement in the system of care	No EHR required
		Emergency Response and Preparedness	
55	IA_ERP_2	Participation in a 60-day or greater effort to support domestic or international humanitarian needs	No EHR required
	IA_ERP_3	COVID-19 clinical data reporting with or without clinical trial	Facilitated by IRIS Registry–EHR integration
		Expanded Practice Access	
55	IA_EPA_1	Provide 24/7 access to MIPS eligible clinicians or groups who have real-time access to patient's medical record	No EHR required
		Patient Safety and Practice Assessment	
page 56	IA_PSPA_6	Consultation of the Prescription Drug Monitoring Program	No EHR required
	IA_PSPA_11	Participation in CAHPS or other supplemental questionnaire	No EHR required
	IA_PSPA_22	CDC Training on CDC's guideline for prescribing opioids for chronic pain*	No EHR required
	IA_PSPA_23	Completion of CDC training on antibiotic stewardship*	No EHR required
	IA_PSPA_31	Patient medication risk education	No EHR required
	IA_PSPA_32	Use of CDC guideline for clinical decision support to prescribe opioids for chronic pain via clinical decision support	
		Population Management	
page 57	IA_PM_3	Rural Health Clinic (RHC), Indian Health Service Medium Management (HIS), or Federally Qualified Health Center (FQHC) quality improvement activities	No EHR required
	IA_PM_7	Use of QCDR for feedback reports that incorporate population health	Facilitated by IRIS Registry–EHR integration

* You can only select IA_PSPA_22 once every four years. The same is true for IA_PSPA_23.

MEDIUM-WEIGHTED ACTIVITIES			
	ID#	Improvement Activity	Notes
Achieving Health Equity			
page 57	IA_AHE_5	MIPS eligible clinician leadership in clinical trials or CBPR [community-based participatory research]	No EHR required
	IA_AHE_7	Comprehensive eye exams	No EHR required
Beneficiary Engagement			
57	IA_BE_1	Use of certified EHR to capture patient reported outcomes	
page 58	IA_BE_3	Engagement with QIN-QIO to implement self-management training programs [Quality Innovation Network-Quality Improvement Organization]	No EHR required
	IA_BE_4	Engagement of patient through implementation of improvements in patient portal	
	IA_BE_5	Enhancements/regular updates to practice websites/tools that also include considerations for patients with cognitive disabilities	No EHR required
	IA_BE_12	Use evidence-based decision aids to support shared decision-making.	No EHR required
	IA_BE_13	Regularly assess the patient experience of care through surveys, advisory councils and/or other mechanisms	No EHR required
	IA_BE_15	Engagement of patients, family, and caregivers in developing a plan of care	
	IA_BE_16	Evidenced-based techniques to promote self-management into usual care	No EHR required
	IA_BE_17	Use of tools to assist patient self-management	No EHR required
Care Coordination			
page 59	IA_CC_1	Implementation of use of specialist reports back to referring clinician or group to close referral loop	No EHR required
	IA_CC_2	Implementation of improvements that contribute to more timely communication of test results	No EHR required
	IA_CC_7	Regular training in care coordination	No EHR required
	IA_CC_8	Implementation of documentation improvements for practice/process improvements	No EHR required
	IA_CC_9	Implementation of practices/processes for developing regular individual care plans	No EHR required
	IA_CC_12	Care coordination agreements that promote improvements in patient tracking across settings	No EHR required
	IA_CC_13	Practice improvements for bilateral exchange of patient information	
60	IA_CC_14	Practice improvements that engage community resources to support patient health goals	No EHR required
	IA_CC_18	Relationship-centered communication	No EHR required
Emergency Response and Preparedness			
60	IA_ERP_1	Participation on Disaster Medical Assistance Team, registered for 6 months.	No EHR required

Expanded Practice Access			
page 60	IA_EPA_2	Use of telehealth services that expand practice access	No EHR required
	IA_EPA_3	Collection and use of patient experience and satisfaction data on access	No EHR required
	IA_EPA_4	Additional improvements in access as a result of QIN/QIO T A [Quality Innovation Network-Quality Improvement Organization technical assistance]	No EHR required
	IA_EPA_5	Participation in user testing of the Quality Payment Program website (https://qpp.cms.gov/)	No EHR required
Patient Safety and Practice Assessment			
page 61	IA_PSPA_1	Participation in an AHRQ-listed patient safety organization	
	IA_PSPA_2	Participation in MOC Part IV	No EHR required; IRIS Registry –EHR integration required for Academy/ABO option
	IA_PSPA_4	Administration of the AHRQ Survey of Patient Safety Culture	No EHR required
	IA_PSPA_7	Use of QCDR data for ongoing practice assessment and improvements	Facilitated by IRIS Registry–EHR integration
	IA_PSPA_8	Use of patient safety tools	No EHR required
page 62	IA_PSPA_9	Completion of the AMA STEPS Forward program	No EHR required
	IA_PSPA_12	Participation in private payer CPIA [clinical practice improvement activities]	No EHR required
	IA_PSPA_13	Participation in Joint Commission Evaluation Initiative	No EHR required
	IA_PSPA_16	Use of decision support and standardized treatment protocols	No EHR required
	IA_PSPA_17	Implementation of analytic capabilities to manage total cost of care for practice population	No EHR required
	IA_PSPA_18	Measurement and improvement [of quality] at the practice and panel level	No EHR required
	IA_PSPA_19	Implementation of formal quality improvement methods, practice changes, or other practice improvement processes	No EHR required
page 63	IA_PSPA_20	Leadership engagement in regular guidance and demonstrated commitment for implementing practice improvement changes	No EHR required
	IA_PSPA_21	Implementation of fall screening and assessment programs	No EHR required
	IA_PSPA_25	Cost display for laboratory and radiographic orders	No EHR required
	IA_PSPA_26	Communication of unscheduled visit for adverse drug event and nature of event	No EHR required
	IA_PSPA_28	Completion of an accredited safety or quality improvement program	No EHR required
Population Management			
63	IA_PM_5	Engagement of community for health status improvement	No EHR required
page 64	IA_PM_6	Use of toolsets or other resources to close healthcare disparities across communities	No EHR required
	IA_PM_11	Regular review practices in place on targeted patient population needs	No EHR required
	IA_PM_17	Participation in population health research	No EHR required

Table 13: Improvement Activity Descriptions

The IRIS Registry supports reporting of the 62 improvement activities that are most relevant to ophthalmology—16 of those are high-weighted (see below) and 46 are medium-weighted (see page 57).

Select your improvement activities carefully. To determine which improvement activities would be right for your practice, review the descriptions below and see the detailed specifications, including documentation suggestions, at aao.org/medicare/improvement-activities.

These descriptions are drawn from CMS materials. The descriptions below are based on CMS materials available at time of press, but you should check online for updates before performing your improvement activities.

Make sure your documentation includes dates. In case of a future audit, your documentation should show that an improvement activity was performed for the 90-day (or longer) performance period.

HIGH-WEIGHTED IMPROVEMENT ACTIVITIES

Achieving Health Equity

IA_AHE_1: Engagement on new Medicaid patients and follow-up

Scoring: High weighted.
Notes: No EHR required.
Description: Seeing new and follow-up Medicaid patients in a timely manner, including individuals dually eligible for Medicaid and Medicare. A timely manner is defined as within 10 business days for this activity.

IA_AHE_3: Promote use of patient-reported outcome tools

Scoring: High weighted.
Notes: No EHR required.
Description: Demonstrate performance of activities for employing patient-reported outcome (PRO) tools and corresponding collection of PRO data such as the use of PHQ-2 or PHQ-9, PROMIS instruments, patient-reported Wound-Quality of Life (QoL), patient-reported Wound Outcome, and patient-reported Nutritional Screening.

IA_AHE_6: Provide education opportunities for new clinicians

Scoring: High weighted.
Notes: No EHR required.
Description: MIPS eligible clinicians acting as a preceptor for clinicians-in-training (such as medical residents/fellows, medical students, physician assistants, nurse practitioners, or clinical nurse specialists) and accepting such clinicians for clinical rotations in community practices in small, underserved, or rural areas.
CMS note: CMS has said that "this activity is intended to support clinicians-in-training in community practices in small, underserved, or rural areas, not metropolitan areas."

Beneficiary Engagement

IA_BE_6: Collection and follow-up on patient experience and satisfaction data on beneficiary engagement

Scoring: High weighted.
Notes: No EHR required.
Description: Collection and follow-up on patient experience and satisfaction data on beneficiary engagement, including development of improvement plan.

IA_BE_14: Engage patients and families to guide improvement in the system of care

Scoring: High weighted.
Notes: No EHR required.
Description: Engage patients and families to guide improvement in the system of care by leveraging digital tools for ongoing guidance and assessments outside the encounter, including the collection and use of patient data for return-to-work and patient quality of life improvement.

Platforms and devices that collect patient-generated health data (PGHD) must do so with an active feedback loop, either providing PGHD in real or near-real time to the care team, or generating clinically endorsed real or near-real time automated feedback to the patient, including patient-reported outcomes (PROs).

Examples include patient engagement and outcomes tracking platforms, cellular or web-enabled bi-directional systems, and other devices that transmit clinically valid objective and subjective data back to care teams.

Because many consumer-grade devices capture PGHD (for example, wellness devices), platforms or devices eligible for this improvement activity must be, at a minimum, endorsed and offered clinically by care teams to patients to automatically send ongoing guidance (one way). Platforms and devices that additionally collect PGHD must do so with an active feedback loop, either providing PGHD in real or near-real time to the care team, or generating clinically endorsed real or near-real time automated feedback to the patient (e.g., automated patient-facing instructions based on glucometer readings).

Therefore, unlike passive platforms or devices that may collect but do not transmit PGHD in real or near-real time to clinical care teams, active devices and plat-

forms can inform the patient or the clinical care team in a timely manner of important parameters regarding a patient's status, adherence, comprehension, and indicators of clinical concern.

Emergency Response and Preparedness

IA_ERP_2: Participation in a 60-day or greater effort to support domestic or international humanitarian needs

Scoring: High weighted.
Notes: No EHR required.
Description: Participation in domestic or international humanitarian volunteer work. Activities that simply involve registration are not sufficient. MIPS eligible clinicians and groups attest to domestic or international humanitarian volunteer work for a period of a continuous 60 days or greater.

IA_ERP_3: COVID-19 clinical data reporting with or without clinical trial

Scoring: High weighted.
Notes: Was introduced on March 31, 2020. Initially was called "COVID-19 Clinical Trials," but was renamed to clarify that you don't have to be participating in a clinical trial. The goal of this improvement activity is to support innovation and improve the collection of COVID-19–related data that clinicians have available to them and to develop best practices that can drive improvements in patient care.
Description: To receive credit for this improvement activity, a MIPS eligible clinician or group must:
1) participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study; or
2) participate in the care of patients diagnosed with COVID-19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID-19 research. Data would be submitted to the extent permitted by applicable privacy and security laws.

Examples of COVID-19 clinical trials may be found on the U.S. National Library of Medicine website at https://clinicaltrials.gov/ct2/results?cond=COVID-19. In addition, examples of COVID-19 clinical data registries may be found on the National Institute of Health website at https://search.nih.gov/search?utf8=%E2%9C%93&affiliate=nih&query=COVID19+registries&commit=Search.

For purposes of this improvement activity, clinical data registries must meet the following requirements: 1) the receiving entity must declare that they are ready to accept data as a clinical registry; and 2) be using the data to improve population health outcomes. Most public health agencies and clinical data registries declare readiness to accept data from clinicians via a public online posting. Clinical data registries should make publically available specific information on what data the registry gathers, technical requirements or specifications for how the registry can receive the data, and how the registry may use, re-use, or disclose individually identifiable data it receives. For purposes of credit toward this improvement activity, any data should be sent to the clinical data registry in a structured format, which the registry is capable of receiving. A MIPS-eligible clinician may submit the data using any standard or format that is supported by the clinician's health IT systems, including but not limited to, certified functions within those systems. Such methods may include, but are not limited to, a secure upload function on a web portal, or submission via an intermediary, such as a health information exchange. To ensure interoperability and versatility of the data submitted, any electronic data should be submitted to the clinical data registry using appropriate vocabulary standards for the specific data elements, such as those identified in the United States Core Data for Interoperability (USCDI) standard adopted in 45 CFR 170.213.

Expanded Practice Assess

IA_EPA_1: Provide 24/7 access to MIPS eligible clinicians or groups who have real-time access to patient's medical record

Scoring: High weighted.
Notes: No EHR required.
Description: Provide 24/7 access to MIPS eligible clinicians, groups, or care teams for advice about urgent and emergent care (e.g., MIPS eligible clinician and care team access to medical record, cross-coverage with access to medical record, or protocol-driven nurse line with access to medical record) that could include one or more of the following:
• Expanded hours in evenings and weekends with access to the patient medical record (e.g., coordinate with small practices to provide alternate hour office visits and urgent care);
• Use of alternatives to increase access to care team by MIPS eligible clinicians and groups, such as e-visits, phone visits, group visits, home visits and alternate locations (e.g., senior centers and assisted living centers); and/or
• Provision of same-day or next-day access to a consistent MIPS eligible clinician, group or care team when needed for urgent care or transition management.

Patient Safety and Practice Assessment	
IA_PSPA_6: Consultation of the Prescription Drug Monitoring Program	
Scoring: High weighted. **Notes:** No EHR required. **Description:** Clinicians would attest to reviewing the patients' history of controlled substance prescription using state prescription drug monitoring program (PDMP) data prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription lasting longer than three days. Clinicians must attest to 75% review of applicable patient's history performance.	
IA_PSPA_11: Participation in CAHPS or other supplemental questionnaire	
Scoring: High weighted. **Notes:** No EHR required. **Description:** Participation in the Consumer Assessment of Healthcare Providers and Systems Survey [www.ahrq.gov/cahps] or other supplemental questionnaire items (e.g., Cultural Competence or Health Information Technology supplemental item sets).	
IA_PSPA_22: CDC Training on CDC's guideline for prescribing opioids for chronic pain	
Scoring: High weighted. **Notes:** No EHR required. **Description:** Completion of all the modules of the Centers for Disease Control and Prevention (CDC) course "Applying CDC's Guideline for Prescribing Opioids" that reviews the 2016 "Guideline for Prescribing Opioids for Chronic Pain."	**CMS note:** This activity may be selected once every four years, to avoid duplicative information given that some of the modules may change on a year by year basis but over four years there would be a reasonable expectation for the set of modules to have undergone substantive change, for the improvement activities performance category score.
IA_PSPA_23: Completion of CDC training on antibiotic stewardship	
Scoring: High weighted. **Notes:** No EHR required. **Description:** Completion of all modules of the Centers for Disease Control and Prevention antibiotic stewardship course. **CMS note:** This activity may be selected once every four years, to avoid duplicative information given that some of the modules may change on a year by year basis but over four years there would be a reasonable expectation for the set of modules to have undergone substantive change, for the improvement activities performance category score.	
IA_PSPA_31: Patient medication risk education	
Scoring: High weighted. **Notes:** No EHR required. **Description:** In order to receive credit for this activity, MIPS eligible clinicians must provide both written and verbal education regarding the risks of concurrent opioid and benzodiazepine use for patients who are prescribed both benzodiazepines and opioids. Education must be completed for at least 75% of qualifying patients and occur: 1) at the time of initial co-prescribing and again following greater than six months of co-prescribing of benzodiazepines and opioids, or 2) at least once per MIPS performance period for patients taking concurrent opioid and benzodiazepine therapy.	
IA_PSPA_32: Use of CDC guideline for clinical decision support to prescribe opioids for chronic pain via clinical decision support	
Scoring: High weighted. **Notes:** Visit www.cdc.gov/drugoverdose/prescribing/guideline.html to read the guidelines that underpin this improvement activity. **Description:** In order to receive credit for this activity, MIPS eligible clinicians must utilize the Centers for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain via clinical decision support (CDS). For CDS to be most effective, it needs to be built directly into the clinician workflow and support decision making on a specific patient at the point of care. Specific examples of how the guideline could be incorporated into a CDS workflow include, but are not limited to: electronic health record (EHR)–based prescribing prompts, order sets that require review of guidelines before prescriptions can be entered, and prompts requiring review of guidelines before a subsequent action can be taken in the record.	

Population Management

IA_PM_3: Rural Health Clinic (RHC), Indian Health Service Medium Management (HIS), or Federally Qualified Health Center (FQHC) quality improvement activities

Scoring: High weighted.
Notes: No EHR required.
Description: Participating in a Rural Health Clinic (RHC), Indian Health Service Medium Management (IHS), or Federally Qualified Health Center (FQHC) in ongoing engagement activities that contribute to more formal quality reporting, and that include receiving quality data back for broader quality improvement and benchmarking improvement which will ultimately benefit patients.

Participation in Indian Health Service, as an improvement activity, requires MIPS eligible clinicians and groups to deliver care to federally recognized American Indian and Alaska Native populations in the United States and in the course of that care implement continuous clinical practice improvement including reporting data on quality of services being provided and receiving feedback to make improvements over time.

IA_PM_7: Use of QCDR for feedback reports that incorporate population health

Scoring: High weighted.
Notes: Facilitated by IRIS Registry–EHR integration.
Description: Use of a QCDR to generate regular feedback reports that summarize local practice patterns and treatment outcomes, including for vulnerable populations.

MEDIUM-WEIGHTED IMPROVEMENT ACTIVITIES

Achieving Health Equity

IA_AHE_5: MIPS eligible clinician leadership in clinical trials or CBPR [community-based participatory research]

Scoring: Medium weighted.
Notes: No EHR required.
Description: MIPS eligible clinician leadership in clinical trials, research alliances, or community-based participatory research (CBPR) that identify tools, research, or processes that can focuses on minimizing disparities in healthcare access, care quality, affordability, or outcomes.

IA_AHE_7: Comprehensive eye exams

Scoring: Medium weighted.
Notes: CMS updated the description for 2021.
EHR Required: No EHR required.
Description: To receive credit for this activity, MIPS eligible clinicians must promote the importance of a comprehensive eye exam, which may be accomplished by any one or more of the following:

- providing literature,
- facilitating a conversation about this topic using resources such as the "Think About Your Eyes" campaign,
- referring patients to resources providing no-cost eye exams, such as the American Academy of Ophthalmology's EyeCare America and the American Optometric Association's VISION USA, or
- promoting access to vision rehabilitation services as appropriate for individuals with chronic vision impairment.

This activity is intended for:
1) non-ophthalmologists/optometrists who refer patients to an ophthalmologist/optometrist;
2) ophthalmologists/optometrists caring for underserved patients at no cost; or
3) any clinician providing literature and/or resources on this topic.

This activity must be targeted at underserved and/or high-risk populations that would benefit from engagement regarding their eye health with the aim of improving their access to comprehensive eye exams or vision rehabilitation services.

Help ECA: The Academy's EyeCare America program helps seniors who have not had a medical eye exam in three or more years, and those at increased risk for glaucoma, access eye care. You can make a big difference in the lives of these patients with a minimal time commitment and without leaving your office. To find out how it works, visit aao.org/volunteer.

Beneficiary Engagement

IA_BE_1: Use of certified EHR to capture patient reported outcomes

Scoring: Medium weighted.
Description: In support of improving patient access, performing additional activities that enable capture of patient reported outcomes (e.g., home blood pressure, blood glucose logs, food diaries, at-risk health factors such as tobacco or alcohol use, etc.) or patient activation measures through use of certified EHR technology, containing this data in a separate queue for clinician recognition and review.

IA_BE_3: Engagement with QIN-QIO to implement self-management training programs [Quality Innovation Network-Quality Improvement Organization]

Scoring: Medium weighted.
Notes: No EHR required.
Description: Engagement with a Quality Innovation Network-Quality Improvement Organization, which may include participation in self-management training programs such as diabetes.

IA_BE_4: Engagement of patient through implementation of improvements in patient portal

Scoring: Medium weighted.
Notes: CMS updated the description for 2021.
Description: To receive credit for this activity, MIPS eligible clinicians must provide access to an enhanced patient/caregiver portal that allows users (patients or caregivers and their clinicians) to engage in bidirectional information exchange. The primary use of this portal should be clinical and not administrative.

Examples of the use of such a portal include, but are not limited to: brief patient reevaluation by messaging; communication about test results and follow up; communication about medication adherence, side effects, and refills; blood pressure management for a patient with hypertension; blood sugar management for a patient with diabetes; or any relevant acute or chronic disease management.

IA_BE_5: Enhancements/regular updates to practice websites/tools that also include considerations for patients with cognitive disabilities

Scoring: Medium weighted.
Notes: No EHR required.
Description: Enhancements and ongoing regular updates and use of websites/tools that include consideration for compliance with section 508 of the Rehabilitation Act of 1973 or for improved design for patients with cognitive disabilities. Refer to the CMS website on Section 508 of the Rehabilitation Act (https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/Section508/index.html?redirect=/InfoTechGenInfo/07_Section508.asp) that requires that institutions receiving federal funds solicit, procure, maintain and use all electronic and information technology (EIT) so that equal or alternate/comparable access is given to members of the public with and without disabilities. For example, this includes designing a patient portal or website that is compliant with section 508 of the Rehabilitation Act of 1973.

IA_BE_12: Use evidence-based decision aids to support shared decision-making

Scoring: Medium weighted.
Notes: No EHR required.
Description: Use evidence-based decision aids to support shared decision-making.

IA_BE_13: Regularly assess the patient experience of care through surveys, advisory councils and/or other mechanisms

Scoring: Medium weighted.
Notes: No EHR required.
Description: Regularly assess the patient experience of care through surveys, advisory councils and/or other mechanisms.

IA_BE_15: Engagement of patients, family, and caregivers in developing a plan of care

Scoring: Medium weighted.
Notes: CMS says that you can use an "electronic platform to systematically capture patient preferences/value through validated patient experience measure instrument."
Description: Engage patients, family, and caregivers in developing a plan of care and prioritizing their goals for action, documented in the electronic health record (EHR) technology.

IA_BE_16: Evidenced-based techniques to promote self-management into usual care

Scoring: Medium weighted.
Notes: No EHR required.
Description: Incorporate evidence-based techniques to promote self-management into usual care, using techniques such as goal setting with structured follow-up, Teach Back, action planning or motivational interviewing.

IA_BE_17: Use of tools to assist patient self-management

Scoring: Medium weighted.
Notes: No EHR required.
Description: Use tools to assist patients in assessing their need for support for self-management (e.g., the Patient Activation Measure or How's My Health).

Care Coordination

IA_CC_1: Implementation of use of specialist reports back to referring clinician or group to close referral loop

Scoring: Medium weighted.
Notes: No EHR required.
Description: Performance of regular practices that include providing specialist reports back to the referring individual MIPS eligible clinician or group to close the referral loop or where the referring individual MIPS eligible clinician or group initiates regular inquiries to specialist for specialist reports which could be documented or noted in the EHR technology.

Academy tip: This improvement activity involves regularly taking certain actions when you are receiving the referral and when you are the referring clinician:
• When you receive referrals, provide specialist reports back to the MIPS-eligible clinician or group to close the referral loop.
• When you are referring, initiate regular inquiries to the specialist for specialist reports that could be documented or noted in the EHR.

IA_CC_2: Implementation of improvements that contribute to more timely communication of test results

Scoring: Medium weighted.
Notes: No EHR required.
Description: Timely communication of test results defined as timely identification of abnormal test results with timely follow-up.

Academy tip: The CMS specifications for this activity don't define "timely." The Academy recommends using the definition that was in place for the EHR meaningful use program; communicate abnormal test results within four business days of receiving them.

IA_CC_7: Regular training in care coordination

Scoring: Medium weighted.
Notes: No EHR required.
Description: Implementation of regular care coordination training.
CMS note: The main goal of care coordination is to meet patients' needs and preferences in the delivery of high-quality, high-value health care. This means that the patients' needs and preferences are known and communicated, and that this information is used to guide the delivery of safe, appropriate, and effective care.

IA_CC_8: Implementation of documentation improvements for practice/process improvements

Scoring: Medium weighted.
Notes: No EHR required.
Description: Implementation of practices/processes that document care coordination activities (e.g., a documented care coordination encounter that tracks all clinical staff involved and communications from date patient is scheduled for outpatient procedure through day of procedure).

IA_CC_9: Implementation of practices/processes for developing regular individual care plans

Scoring: Medium weighted.
Notes: No EHR required.
Description: Implementation of practices/processes, including a discussion on care, to develop regularly updated individual care plans for at-risk patients that are shared with the beneficiary or caregiver(s). Individual care plans should include consideration of a patient's goals and priorities, as well as desired outcomes of care.

IA_CC_12: Care coordination agreements that promote improvements in patient tracking across settings

Scoring: Medium weighted.
Notes: No EHR required.
Description: Establish effective care coordination and active referral management that could include one or more of the following:
• Establish care coordination agreements with frequently used consultants that set expectations for documented flow of information and MIPS eligible clinician or MIPS eligible clinician group expectations between settings. Provide patients with information that sets their expectations consistently with the care coordination agreements;
• Track patients referred to specialist through the entire process; and/or
• Systematically integrate information from referrals into the plan of care.

IA_CC_13: Practice improvements for bilateral exchange of patient information

Scoring: Medium weighted.
Notes: For information on OpenNotes, read "The OpenNotes Movement—Why Clinicians Are Sharing Notes With Patients" (*EyeNet*, June 2016) at aao.org/eyenet/archive.
Description: Ensure that there is bilateral exchange of necessary patient information to guide patient care, such as Open Notes, that could include one or more of the following:
• Participate in a Health Information Exchange if available; and/or
• Use structured referral notes.

IA_CC_14: Practice improvements that engage community resources to support patient health goals

Scoring: Medium weighted.
Notes: No EHR required.
Description: Develop pathways to neighborhood/community-based resources to support patient health goals that could include one or more of the following:
• Maintain formal (referral) links to community-based chronic disease self-management support programs, exercise programs, and other wellness resources with the potential for bidirectional flow of information; and provide a guide to available community resources.
• Including through the use of tools that facilitate electronic communication between settings;
• Screen patients for health-harming legal needs;
• Screen and assess patients for social needs using tools that are preferably health IT enabled and that include to any extent standards-based, coded question/field for the capture of data as is feasible and available as part of such tool; and/or
• Provide a guide to available community resources.

IA_CC_18: Relationship-centered communication

Scoring: Medium weighted.
Notes: No EHR required.
Description: In order to receive credit for this activity, MIPS eligible clinicians must participate in a minimum of eight hours of training on relationship-centered care tenets such as making effective open-ended inquiries; eliciting patient stories and perspectives; listening and responding with empathy; using the ART (ask, respond, tell) communication technique to engage patients, and developing a shared care plan. The training may be conducted in formats such as, but not limited to: interactive simulations practicing the skills above, or didactic instructions on how to implement improvement action plans, monitor progress, and promote stability around improved clinician communication.

Emergency Response and Preparedness

IA_ERP_1: Participation on Disaster Medical Assistance Team, registered for six months

Scoring: Medium weighted.
Notes: No EHR required.
Description: Participation in Disaster Medical Assistance Teams, or Community Emergency Responder Teams. Activities that simply involve registration are not sufficient. MIPS eligible clinicians and MIPS eligible clinician groups must be registered for a minimum of six months as a volunteer for disaster or emergency response.

Expanded Practice Access

IA_EPA_2: Use of telehealth services that expand practice access

Scoring: Medium weighted.
Notes: No EHR required.
Description: Use of telehealth services and analysis of data for quality improvement, such as participation in remote specialty care consults or teleaudiology pilots [or teleophthalmology pilots] that assess ability to still deliver quality care to patients.
CMS note: For the purposes of this improvement activity, telehealth services include a "real time" interaction and may be obtained over the phone, online, etc., and are not limited to the Medicare reimbursed telehealth service criteria.

IA_EPA_3: Collection and use of patient experience and satisfaction data on access

Scoring: Medium weighted.
Notes: No EHR required.
Description: Collection of patient experience and satisfaction data on access to care and development of an improvement plan, such as outlining steps for improving communications with patients to help understanding of urgent access needs.
Academy tip: Make sure the survey results include dates for each administered survey.

IA_EPA_4: Additional improvements in access as a result of QIN-QIO technical assistance [Quality Innovation Network–Quality Improvement Organization]

Scoring: Medium weighted.
Notes: No EHR required.
Description: As a result of Quality Innovation Network–Quality Improvement Organization technical assistance, performance of additional activities that improve access to services or improve care coordination (for example, investment of on-site diabetes educator).

IA_EPA_5: Participation in user testing of the Quality Payment Program website (https://qpp.cms.gov/)

Scoring: Medium weighted.
Notes: No EHR required.
Description: User participation in the Quality Payment Program website testing is an activity for eligible clini-

cians who have worked with CMS to provide substantive, timely, and responsive input to improve the CMS Quality Payment Program website through product user-testing that enhances system and program accessibility, readability and responsiveness as well as providing feedback for developing tools and guidance thereby allowing for a more user-friendly and accessible clinician and practice Quality Payment Program website experience.
CMS note: Email CMSQPPFeedback@Ketchum.com to participate in feedback sessions.

Patient Safety and Practice Assessment

IA_PSPA_1: Participation in an AHRQ-listed patient safety organization

Scoring: Medium weighted.
Description: Participation in an AHRQ-listed patient safety organization.
CMS note: To see which patient safety organizations are listed by the Agency for Healthcare Research and Quality, visit www.pso.ahrq.gov/listed.

IA_PSPA_2: Participation in MOC Part IV

Scoring: Medium weighted.
Notes: While there are options for perfoming this improvement activity without EHR, you can only implement the Academy/ABO option if you have an EHR system that has been integrated with the IRIS Registry.
Description: In order to receive credit for this activity, a MIPS eligible clinician must participate in Maintenance of Certification (MOC) Part IV. Maintenance of Certification (MOC) Part IV requires clinicians to perform monthly activities across practice to regularly assess performance by reviewing outcomes addressing identified areas for improvement and evaluating the results.

Some examples of activities that can be completed to receive MOC Part IV credit are: the American Board of Internal Medicine (ABIM) Approved Quality Improvement (AQI) Program, National Cardiovascular Data Registry (NCDR) Clinical Quality Coach, Quality Practice Initiative Certification Program, American Board of Medical Specialties Practice Performance Improvement Module or American Society of Anesthesiologists (ASA) Simulation Education Network, for improving professional practice including participation in a local, regional or national outcomes registry or quality assessment program; specialty-specific activities including Safety Certification in Outpatient Practice Excellence (SCOPE); American Psychiatric Association (APA) Performance in Practice modules.

IA_PSPA_4: Administration of the AHRQ Survey of Patient Safety Culture

Scoring: Medium weighted.
Notes: No EHR required.
Description: Administration of the Agency for Healthcare Research and Quality (AHRQ) Survey of Patient Safety Culture and submission of data to the comparative database (refer to AHRQ Survey of Patient Safety Culture website http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/index.html).
CMS note: This activity may be selected once every four years, to avoid duplicative information given that some of the modules may change on a year by year basis but over four years there would be a reasonable expectation for the set of modules to have undergone substantive change, for the improvement activities performance category score.

The SOPS Medical Office Survey has a total of 58 items and it takes approximately 10 to 15 minutes to complete.

IA_PSPA_7: Use of QCDR data for ongoing practice assessment and improvements

Scoring: Medium weighted.
Notes: IRIS Registry–EHR integration facilitates performance of this improvement activity.
Description: Participation in a qualified clinical data registry (QCDR) and use of QCDR data for ongoing practice assessment and improvements in patient safety, including:
• Performance of activities that promote use of standard practices, tools and processes for quality improvement (for example, documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups);
• Use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire, MD Anderson Symptom Inventory, and/or SF-12/VR-12 functional health status assessment);
• Use of standardized processes for screening for social determinants of health such as food security, employment, and housing;
• Use of supporting QCDR modules that can be incorporated into the certified EHR technology; or
• Use of QCDR data for quality improvement such as comparative analysis across specific patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcomes.

IA_PSPA_8: Use of patient safety tools

Scoring: Medium weighted.
Notes: No EHR required.
Description: In order to receive credit for this activity, a MIPS eligible clinician must use tools that assist specialty practices in tracking specific measures that are meaningful to their practice.

Some examples of tools that could satisfy this activity are: a surgical risk calculator; evidence based protocols, such as Enhanced Recovery After Surgery (ERAS) protocols; the Centers for Disease Control (CDC) Guide for Infection Prevention for Outpatient Settings predictive algorithms; and the opiate risk tool (ORT) or similar tool.

IA_PSPA_9: Completion of the AMA STEPS Forward program

Scoring: Medium weighted.
Notes: No EHR required.
Description: Completion of the American Medical Association's STEPS Forward program [https://edhub.ama-assn.org/steps-forward].

IA_PSPA_12: Participation in private payer CPIA [clinical practice improvement activities]

Scoring: Medium weighted.
Notes: No EHR required.
Description: Participation in designated private payer clinical practice improvement activities.

IA_PSPA_13: Participation in Joint Commission Evaluation Initiative

Scoring: Medium weighted.
Notes: No EHR required.
Description: Participation in Joint Commission Ongoing Professional Practice Evaluation initiative.

IA_PSPA_16: Use of decision support and standardized treatment protocols

Scoring: Medium weighted.
Description: Use decision support and standardized treatment protocols to manage workflow in the team to meet patient needs.

IA_PSPA_17: Implementation of analytic capabilities to manage total cost of care for practice population

Scoring: Medium weighted.
Notes: No EHR required.
Description: In order to receive credit for this activity, a MIPS eligible clinician must conduct or build the capacity to conduct analytic activities to manage total cost of care for the practice population. Examples of these activities could include:
1. Train appropriate staff on interpretation of cost and utilization information;
2. Use available data regularly to analyze opportunities to reduce cost through improved care.

An example of a platform with the necessary analytic capability to do this is the American Society for Gastrointestinal (GI) Endoscopy's GI Operations Benchmarking Platform.

IA_PSPA_18: Measurement and improvement [of quality] at the practice and panel level

Scoring: Medium weighted.
Notes: No EHR required.
Description: Measure and improve quality at the practice and panel level, such as the American Board of Orthopaedic Surgery (ABOS) Physician Scorecards, that could include one or more of the following:
• Regularly review measures of quality, utilization, patient satisfaction and other measures that may be useful at the practice level and at the level of the care team or MIPS eligible clinician or group (panel); and/or
• Use relevant data sources to create benchmarks and goals for performance at the practice level and panel level.
CMS note: Surveys should be administered by a third-party survey administrator/vendor.

IA_PSPA_19: Implementation of formal quality improvement methods, practice changes, or other practice improvement processes

Scoring: Medium weighted.
Notes: No EHR required.
Description: Adopt a formal model for quality improvement and create a culture in which all staff actively participates in improvement activities that could include one or more of the following, such as:
• Participation in multisource feedback;
• Train all staff in quality improvement methods;
• Integrate practice change/quality improvement into staff duties;
• Engage all staff in identifying and testing practices changes;
• Designate regular team meetings to review data and plan improvement cycles;
• Promote transparency and accelerate improvement by sharing practice level and panel level quality of care, patient experience and utilization data with staff;
• Promote transparency and engage patients and families by sharing practice level quality of care, patient experience and utilization data with patients and families, including activities in which clinicians act upon patient experience data;
• Participation in Bridges to Excellence;
• Participation in American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program.

IA_PSPA_20: Leadership engagement in regular guidance and demonstrated commitment for implementing practice improvement changes

Scoring: Medium weighted.
Notes: No EHR required.
Description: Ensure full engagement of clinical and administrative leadership in practice improvement that could include one or more of the following:
• Make responsibility for guidance of practice change a component of clinical and administrative leadership roles;
• Allocate time for clinical and administrative leadership for practice improvement efforts, including participation in regular team meetings; and/or
• Incorporate population health, quality and patient experience metrics in regular reviews of practice performance.

IA_PSPA_21: Implementation of fall screening and assessment programs

Scoring: Medium weighted
EHR Required: No EHR required.
Description: Implementation of fall screening and assessment programs to identify patients at risk for falls and address modifiable risk factors (e.g., clinical decision support/prompts in the electronic health record that help manage the use of medications, such as benzodiazepines, that increase fall risk).

IA_PSPA_25: Cost display for laboratory and radiographic orders

Scoring: Medium weighted.
Notes: No EHR required.
Description: Implementation of a cost display for laboratory and radiographic orders, such as costs that can be obtained through the Medicare clinical laboratory fee schedule.

IA_PSPA_26: Communication of unscheduled visit for adverse drug event and nature of event

Scoring: Medium weighted.
Notes: No EHR required.
Description: A MIPS eligible clinician providing unscheduled care (such as an emergency room, urgent care, or other unplanned encounter) attests that, for greater than 75% of case visits that result from a clinically significant adverse drug event, the MIPS eligible clinician provides information, including through the use of health IT to the patient's primary care clinician regarding both the unscheduled visit and the nature of the adverse drug event within 48 hours. A clinically significant adverse event is defined as a medication-related harm or injury such as side-effects, supratherapeutic effects, allergic reactions, laboratory abnormalities, or medication errors requiring urgent/emergent evaluation, treatment, or hospitalization.

IA_PSPA_28: Completion of an accredited safety or quality improvement program

Scoring: Medium weighted.
Notes: No EHR required.
Description: Completion of an accredited performance improvement continuing medical education (CME) program that addresses performance or quality improvement according to the following criteria:
• The activity must address a quality or safety gap that is supported by a needs assessment or problem analysis, or must support the completion of such a needs assessment as part of the activity;
• The activity must have specific, measurable aim(s) for improvement;
• The activity must include interventions intended to result in improvement;
• The activity must include data collection and analysis of performance data to assess the impact of the interventions; and
• The accredited program must define meaningful clinician participation in their activity, describe the mechanism for identifying clinicians who meet the requirements, and provide participant completion information.

An example of an activity that could satisfy this improvement activity is completion of an accredited continuing medical education program related to opioid analgesic risk and evaluation strategy (REMS) to address pain control (that is, acute and chronic pain).

Population Management

IA_PM_5: Engagement of community for health status improvement

Scoring: Medium weighted.
Notes: No EHR required.
Description: Take steps to improve health status of communities, such as collaborating with key partners and stakeholders to implement evidenced-based practices to improve a specific chronic condition. Refer to the local Quality Improvement Organization (QIO) for additional steps to take for improving health status of communities as there are many steps to select from for satisfying this activity. QIOs work under the direction of CMS to assist MIPS eligible clinicians and groups with quality improvement, and review quality concerns for the protection of beneficiaries and the Medicare Trust Fund.
Academy tip: To locate your local QIO, visit https://qioprogram.org/locate-your-qio.

IA_PM_6: Use of toolsets or other resources to close healthcare disparities across communities

Scoring: Medium weighted.
Notes: No EHR required.
Description: Take steps to improve healthcare disparities, such as Population Health Toolkit or other resources identified by CMS, the Learning and Action Network, Quality Innovation Network, or National Coordinating Center. Refer to the local Quality Improvement Organization (QIO) for additional steps to take for improving health status of communities as there are many steps to select from for satisfying this activity. QIOs work under the direction of CMS to assist eligible clinicians and groups with quality improvement, and review quality concerns for the protection of beneficiaries and the Medicare Trust Fund.
Academy tip: To locate your local QIO, visit https://qioprogram.org/locate-your-qio.

IA_PM_11: Regular review practices in place on targeted patient population needs

Scoring: Medium weighted.
Notes: No EHR required.
Description: Implementation of regular reviews of targeted patient population needs, such as structured clinical case reviews, which includes access to reports that show unique characteristics of eligible clinician's patient population, identification of vulnerable patients, and how clinical treatment needs are being tailored, if necessary, to address unique needs and what resources in the community have been identified as additional resources.
CMS note: This activity also can be fulfilled by participating in a prospective peer review of clinical cases.

IA_PM_17: Participation in population health research

Scoring: Medium weighted.
Notes: No EHR required.
Description: Participation in federally and/or privately funded research that identifies interventions, tools, or processes that can improve a targeted patient population.

NO REPORTING NEEDED FOR THIS PERFORMANCE CATEGORY

How CMS Evaluates Cost

Cost is the only one of the four performance categories where you don't report data or make attestations. Instead, CMS will use administrative claims data to evaluate performance. Cost's default weight in your MIPS final score is now 20%, meaning that it can contribute up to 20 points to that score.

Twenty Cost Measures in 2021

This year, cost measures include:

- the Total Per Capita Cost (TPCC) measure,
- the Medicare Spending Per Beneficiary measure, and
- 18 episode-based measures, including a measure for routine cataract surgery.

Only one cost measures is likely to apply to ophthalmologists. As an ophthalmologist, you may be scored on the cataract surgery measure. However, the other 17 episode-based cost measures don't apply to ophthalmology; the TPCC measure explicitly excludes ophthalmologists and optometrists; and the Medicare Spending Per Beneficiary measure focuses on inpatient hospitalization costs.

Performance period is the full calendar year. When CMS evaluates you on cost, they will include the cost of items and services that were provided from Jan. 1, 2021 to Dec. 31, 2021.

What if you don't get a cost score? If you don't meet the case minimum for the cataract surgery measure, and assuming you aren't scored on any of the other cost measures, cost's contribution to your final score will be reweighted to 0%, and quality's contribution will be reweighted upward (see "Table 1: How the Performance Categories Are Weighted," page 11).

Telehealth in 2021. To address increased use of telehealth during the pandemic, CMS has included additional telehealth codes in the cost measure specifications.

Routine Cataract Surgery Measure

The Routine Cataract Removal With IOL Implantation measure doesn't involve any additional reporting on your part. Instead, CMS will use Medicare claims data to 1) attribute routine cataract surgeries to you and 2) track costs that are clinically associated with those surgeries.

Which surgeries are attributed to you? An episode of routine cataract surgery will be attributed to the MIPS eligible clinician who performed the procedure that "triggers" the episode. That procedure is known as the "trigger service" and the date it took place is the "trigger day." If you bill CPT code 66984—which is the code for routine cataract surgery—an episode of cataract surgery will be attributed to you unless an exclusion applies. Exclusions include significant ocular conditions, such as a retinal detachment, that might impact the outcome of the surgery. CMS reviews the patient's Medicare claims history to see if there were any ICD-10 diagnosis codes that would flag such an exclusion. (Note: Under this measure, billing CPT code 66982 for complex cataract surgery would not trigger an episode.)

A 10-episode case minimum. The cataract measure will only contribute to your cost score if at least 10 episodes of routine cataract surgery are attributed to you in 2021.

What costs are included? The measure takes into account only the cost of services that are clinically related to the cataract surgery. CMS identifies those costs by reviewing the patient's Medicare claims over a five-month period. This review period starts 60 days before the day of surgery (the trigger day) and ends 90 days after surgery (mirroring the familiar 90-day postoperative period).

CMS tries to level the playing field. Your costs for the measure will undergo payment standardization and risk adjustment. This is intended to account for cost variations that are beyond your control, such as patient characteristics that may lead to increased spending and geographic variations in wage levels.

Furthermore, CMS recognizes that costs might vary depending on whether surgery was done in an ambulatory surgery center (ASC) or a hospital outpatient department

Cost 101

Default weight in MIPS final score: 20%.

Performance period: Full calendar year.

Won't apply to all ophthalmologists: You are only likely to be scored on cost if you perform cataract surgery and/or are in a multispecialty practice that reports as a group. If you are not scored on cost, its weight is reallocated to quality.

No reporting requirements: CMS evaluates clinicians' cost score based on Medicare claims data for patients that it attributes to them.

(HOPD), and that costs also can vary depending on whether the cataract surgery is unilateral or bilateral (which it defines as the second surgery being done within 30 days of the first). Consequently, CMS divides episodes of routine cataract surgery into four subgroups and will only compare an episode's costs against the cost of episodes within the same subgroup. The four subgroups for routine cataract surgery are:

- unilateral surgery in an ASC,
- bilateral surgery in an ASC,
- unilateral surgery in a HOPD, and
- bilateral surgery in a HOPD.

(Note: The 10-episode case minimum requirement applies to the cataract measure as a whole, not to the individual subgroups.)

You score 1-10 points. You can get a score from each of the four cost subgroups, and a weighted average will be used to calculate your score for the cataract measure. Each subgroup score will be based on how your performance compares with that of other MIPS participants in that subgroup during the current performance year.

Learn more about the cataract measure. To learn how the measure was developed, read an overview by David Glasser, MD, (*Ophthalmology* 2019;126(2):189-191) at aao.org/journals. You also can download a detailed measure information form at aao.org/medicare/cost (scroll down to "What You Can Do").

Total Per Capita Cost Measure

This measure tries to allocate all of a patient's Medicare Part A and Part B costs to a primary care clinician; but if the patient doesn't see such a clinician, he or she could be attributed to a non–primary care clinician.

Academy advocacy pays off. The Academy and other specialty societies have long urged CMS to rethink the unfair way this measure has attributed Medicare costs to specialists. In past years, ophthalmologists have been held responsible for the cost of hernia repair and hospice stays, to give just two examples. Fortunately, the advocacy has paid off, with eye care specialists now being excluded from this measure.

Ophthalmologists and optometrists are excluded from the TPCC measure. In years gone by, some ophthalmologists were scored on the TPCC measure, and some eye care practices decided to bill Eye visit codes rather than Evaluation and Management (E/M) codes in order to avoid meeting the 20-patient case minimum for this measure. Since 2020, ophthalmologists and optometrists are excluded from this measure based on their two-digit specialty identifier in the Provider Enrollment, Chain, and Ownership System, better known as PECOS.

Caveat. Suppose you are in a multispecialty practice and you have colleagues who aren't excluded from the TPCC measure; if the practice reports as a group, the group may be scored on this measure.

What if you aren't excluded? If the above caveat doesn't apply to you but you are still scored on this measure, please contact the Academy at healthpolicy@aao.org.

What You Can Do

Do you perform cataract surgery? If you—or, if reporting as a group, a colleague in your practice—performs cataract surgery, familiarize yourself with the Routine Cataract Removal With IOL Implantation measure (see "Learn more about the cataract measure," above).

Review your past performance. If you were scored on any cost measures during the 2019 performance year, CMS should have sent you some detailed feedback last summer.

Medicare Spending Per Beneficiary Measure

The Medicare Spending Per Beneficiary (MSPB) measure focuses on costs associated with hospital admission.

The MSPB measure is unlikely to factor into your MIPS score. Episodes of care are attributed to the MIPS eligible clinician who provided the most Medicare Part B covered services during the hospitalization. You only will receive a score for the MSPB measure in the unlikely event that at least 35 hospitalization episodes are attributed to you.

What if you are scored on the MSPB measure? If you are scored on this measure, please contact the Academy at healthpolicy@aao.org.

How CMS Calculates Your Cost Score

This can be described as a three-step process.

1. Your achievement point total is your numerator. For each cost measure you are scored on, you will receive 1 to 10 achievement points based on how your performance compares to the measure's benchmark.

2. The number of points available to you is your denominator. If you are only scored on the cataract surgery measure, then your denominator would be 10.

3. CMS does the math. After dividing the numerator by the denominator, CMS turns the result into a percentage, which is your cost performance category percent score. This contributes up to 20 points to your MIPS final score.

Example. After the performance year is over, CMS determines that a clinician only met the case minimum for the cataract surgery cost measure. Suppose the clinician scores 6.0 achievement points for that measure. Her numerator is 6.0 and, because she was only scored on one cost measure, her denominator is 10. So her cost score is $6.0 \div 10 = 0.60$, which is reported as a percentage: 60%. Since cost is weighted at 20% of your MIPS final score (0-100 points), a cost score of 60% would contribute 12 points (60% of 20 points) to that score.

Cost's Shifting Role in Your MIPS Final Score

During the first five years of MIPS, cost's weight in your MIPS final score increased from 0% in 2017 to 10% in 2018, 15% in 2019 and 2020, and now 20% in 2021.

Starting with the 2022 performance year, CMS is slated to weight cost at 30% of your MIPS final score.

Key Dates for Performance Year 2021

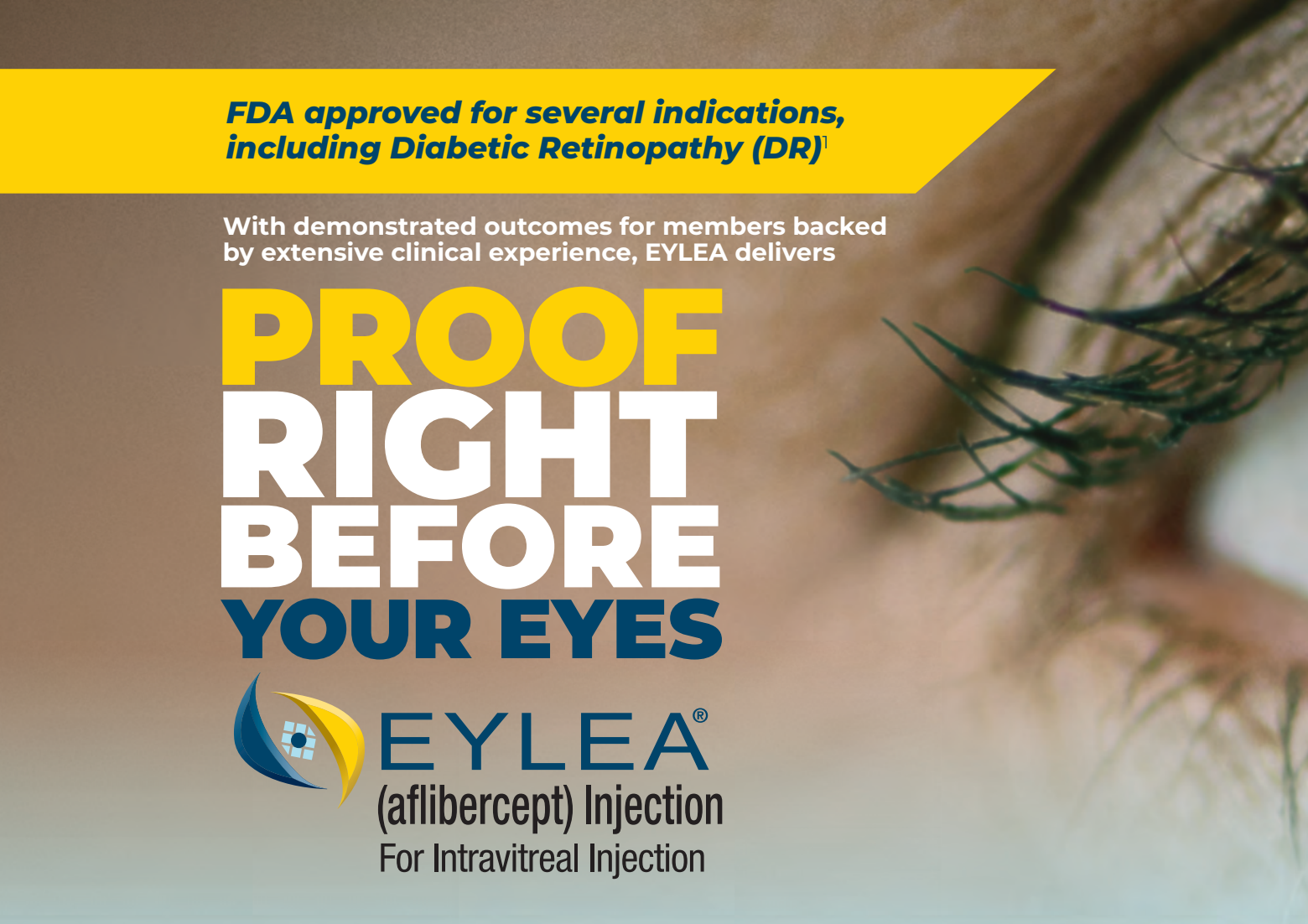
2020	Dec. 1	CMS publishes the 2021 MIPS rules.
	Dec. 31	Deadline to form a virtual group for the 2020 performance year.
2021	Jan. 1	Start of 2021 MIPS performance year.
	June 1	Deadline to sign agreements for IRIS Registry–EHR integration (if not already integrated), and to select quality measures for data mapping.
	June 15	Deadline for IRIS Registry–EHR integrated users to report changes to their EHR system, such as an upgrade, a change to EHR network server, a change to a cloud-based service, or a change to a new EHR system.
	Aug. 1	Deadline to complete integration of your EHR system with the IRIS Registry for automated transmission of 2021 quality data.
	Aug. 31	Deadline for submitting your improvement plan to the American Board of Ophthalmology for the MOC improvement activity (see https://abop.org/IRIS).
	Sept. 1	Deadline to add new clinicians for practices reporting via IRIS Registry–EHR integration.
	Late Summer	CMS starts accepting applications for 1) extreme and uncontrollable circumstances exceptions (see page 16) and 2) hardship exception to PI performance category (see page 46).
	Sept. 30	Last day to request IRIS Registry mapping refinements for selected quality measures.
	Oct. 3	Last day to start performance period for PI measures and improvement activities.
	Oct. 31	Deadline for new IRIS Registry users to sign agreements to use the IRIS Registry for manual reporting of improvement activities, PI measures, and quality measures.
	Dec. 31	Application deadline for 1) extreme and uncontrollable circumstances exceptions (see page 16) and 2) hardship exception to PI performance category (see page 46).
		End of 2021 MIPS performance year.
2022	Jan. 31	Deadline to submit your 2021 IRIS Registry data release consent form.
		Deadline for IRIS Registry users to enter 2021 quality measure data, attest to PI measures, and attest to improvement activities.
		Last day to submit 2021 MIPS data and attestations to CMS via the IRIS Registry.
	March 31	Last day to submit 2021 MIPS data if reporting directly to the CMS QPP attestation portal.
	July	CMS will provide you with feedback based on your 2021 performance year data.
		Targeted review starts after release of feedback data.
	Aug. 31	Targeted review ends.
	Dec. 1	CMS must notify MIPS participants of their 2023 payment adjustment factor at least 30 days before the 2023 payment year.
2023	Jan. 1	Your Medicare Part B reimbursements will start being adjusted up or down based on your 2021 MIPS performance.
	January	For a limited time, you can check that your 2021 measure data are accurate before CMS posts them at Care Compare. Find out more at www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Compare-DAC.

Quarterly to-do list for EHR users: If reporting via IRIS Registry–EHR integration, do the following at least quarterly:

For promoting interoperability (PI): Run your EHR system's PI reports (if available). Identify any deficient measures and address them, so you'll be ready for your PI performance period.

For quality: Review your IRIS Registry dashboard and verify that your practice's data for quality measures were pulled in correctly. Problems can arise if data aren't being properly recorded within the EHR or aren't mapped properly to the IRIS Registry. If you have a mapping problem, submit a help desk ticket immediately (aao.org/iris-registry/user-guide/submit-help-desk-ticket).

You also should regularly give each care provider their IRIS Registry report so they can see their performance across the quality measures.



FDA approved for several indications, including Diabetic Retinopathy (DR)[1]

With demonstrated outcomes for members backed by extensive clinical experience, EYLEA delivers

PROOF RIGHT BEFORE YOUR EYES

EYLEA®
(aflibercept) Injection
For Intravitreal Injection

IMPORTANT SAFETY INFORMATION AND INDICATIONS

CONTRAINDICATIONS

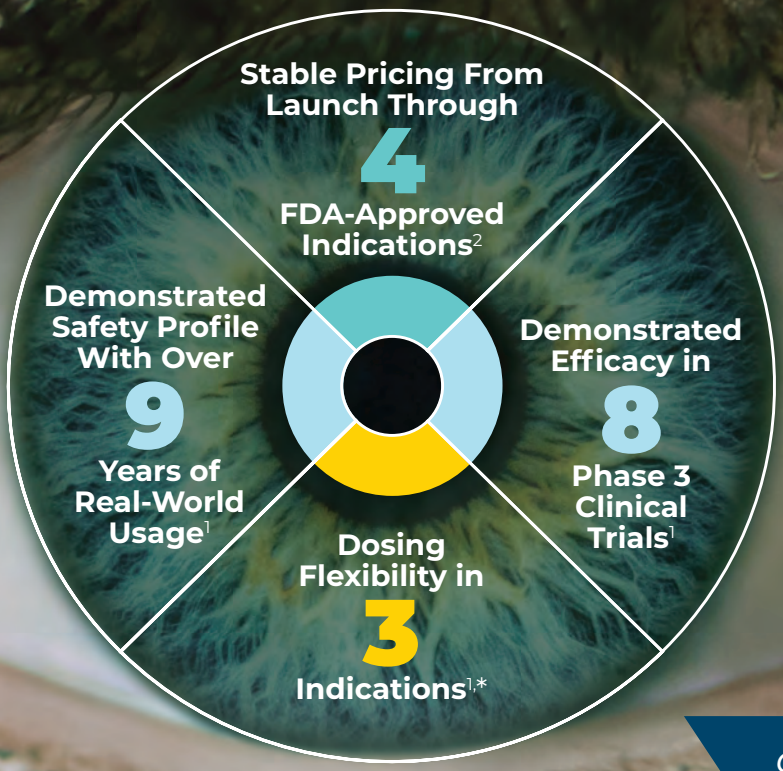
- EYLEA is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in EYLEA.

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.
- 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.

REGENERON

777 Old Saw Mill River Road, Tarrytown, NY 10591



TRUST the Clinical Evidence and Flexibility of EYLEA[1]

Get the facts at:
EYLEAMarketAccess.com

***Wet Age-related Macular Degeneration (AMD):** The recommended dose of EYLEA is 2 mg administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months, followed by 2 mg via intravitreal injection once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (approximately every 25 days, monthly), additional efficacy was not demonstrated in most patients when EYLEA was dosed every 4 weeks compared to every 8 weeks. Some patients may need every-4-week (monthly) dosing after the first 12 weeks (3 months). Although not as effective as the recommended every-8-week dosing regimen, patients may also be treated with one dose every 12 weeks after one year of effective therapy. Patients should be assessed regularly. **Diabetic Macular Edema (DME) and DR:** The recommended dose of EYLEA is 2 mg administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections, followed by 2 mg via intravitreal injection once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (approximately every 25 days, monthly), additional efficacy was not demonstrated in most patients when EYLEA was dosed every 4 weeks compared to every 8 weeks. Some patients may need every-4-week (monthly) dosing after the first 20 weeks (5 months).

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.
- Patients may experience temporary visual disturbances after an intravitreal injection with EYLEA and the associated eye examinations. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

INDICATIONS

EYLEA® (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).

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

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

01/2021
EYL.21.01.0071

EYLEA® (aflibercept) Injection
For Intravitreal Injection

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

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

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

4 CONTRAINDICATIONS

4.1 Ocular or 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

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

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

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

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

	CRVO		BRVO	
Adverse Reactions	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

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

Less common adverse reactions reported in <1% of the patients treated with EYLEA were hypersensitivity, retinal detachment, retinal tear, corneal edema, and injection site hemorrhage.
Safety data observed in 269 patients with nonproliferative diabetic retinopathy (NPDR) through week 52 in the PANORAMA trial were consistent with those seen in the phase 3 VIVID and VISTA trials (see Table 3 above).

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy
Risk Summary
Adequate and well-controlled studies with EYLEA have not been conducted in pregnant women. Aflibercept produced adverse embryofetal effects in rabbits, including external, visceral, and skeletal malformations. A fetal No Observed Adverse Effect Level (NOAEL) was not identified. At the lowest dose shown to produce adverse embryofetal effects, systemic exposures (based on AUC for free aflibercept) were approximately 6 times higher than AUC values observed in humans after a single intravitreal treatment at the recommended clinical dose [*see Animal Data*].
Animal reproduction studies are not always predictive of human response, and it is not known whether EYLEA can cause fetal harm when administered to a pregnant woman. Based on the anti-VEGF mechanism of action for aflibercept, treatment with EYLEA may pose a risk to human embryofetal development. EYLEA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

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

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

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

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

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

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

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

REGENERON

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

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

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

EYL.20.09.0052

KEEP THIS REFERENCE HANDY

Your Guide to MIPS Acronyms

When the Medicare Access and CHIP Reauthorization (MACRA) Bill of 2015 launched MIPS, it equipped the new pay-for-performance program with dozens of acronyms—some were co-opted from existing regulatory programs; others were brand-new.

Keep this guide to those acronyms handy; it will prove helpful whenever you are trying to refresh your memory on the MIPS regulations.

AAPM	Advanced alternative payment model
ACI	Advancing care information[1]
ACO	Accountable care organization
ACR measure	All-Cause Readmission measure
APM	Alternative payment model
APP	APM performance pathway
ASC	Ambulatory surgical center
CAHPS	Consumer Assessment of Healthcare Providers and Systems
CCDS	Common Clinical Data Set[2]
CEHRT	Certified electronic health record technology
CHPL	Certified Health IT Product List
CMS	Centers for Medicare & Medicaid Services
CPIA	Clinical practice improvement activities[1]
CQM	Clinical quality measure
CTBS	Communications technology-based services
dQM	Digital quality measure
EC	Eligible clinician
eCQM	Electronic clinical quality measure
EHR	Electronic health record
FFS	Fee for service
HARP	HCQIS Access Roles and Profile[3]
HCC	Hierarchical Condition Category
HCQIS	Health Care Quality Information Systems
HHS	Health and Human Services
HPSA	Health professional shortage area
HWR measure	Hospital-Wide Readmission measure
IRIS Registry	Intelligent Research in Sight Registry
MACRA	Medicare Access and CHIP [Children's Health Insurance Program] Reauthorization Bill of 2015
MIPS	Merit-Based Incentive Payment System
MIPS APM	MIPS alternative payment model
MIPS CQM	MIPS clinical quality measure
MIPS EC	MIPS eligible clinician
MVP	MIPS Value Pathway
MSPB measure	Medicare Spending Per Beneficiary measure
MU	Meaningful use[1]
NPI	National Provider Identifier
ONC	Office of the National Coordinator for Health Information Technology
P4P	Pay for performance
PECOS	Provider Enrollment, Chain, and Ownership System
PHE	Public Health Emergency
PI	Promoting interoperability
PQRS	Physician Quality Reporting System[1]
PROM	Patient-reported outcome measure
QCDR	Qualified Clinical Data Registry
QP	Qualifying APM participant
QPP	Quality Payment Program
TIN	Taxpayer Identification Number
TPCC measure	Total Per Capita Cost measure
USCDI	US Core Data for Interoperability[2]

1 Term no longer in use for MIPS: CMS replaced "advancing care information" with "promoting interoperability;" "clinical practice improvement activities" are now generally known as "improvement activiites;" the EHR "meaningful use" program evolved into the "promoting interoperability" performance category; and the "Physician Quality Reporting System" evolved into the quality performance category.

2 The Common Clinical Data Set is used in 2015-edition CEHRT; the US Core Data for Interoperability is used in 2015-edition Cures Update CEHRT.

3 The HARP system involves a CMS secure identity management portal that provides you with a user ID and password for several CMS applications.

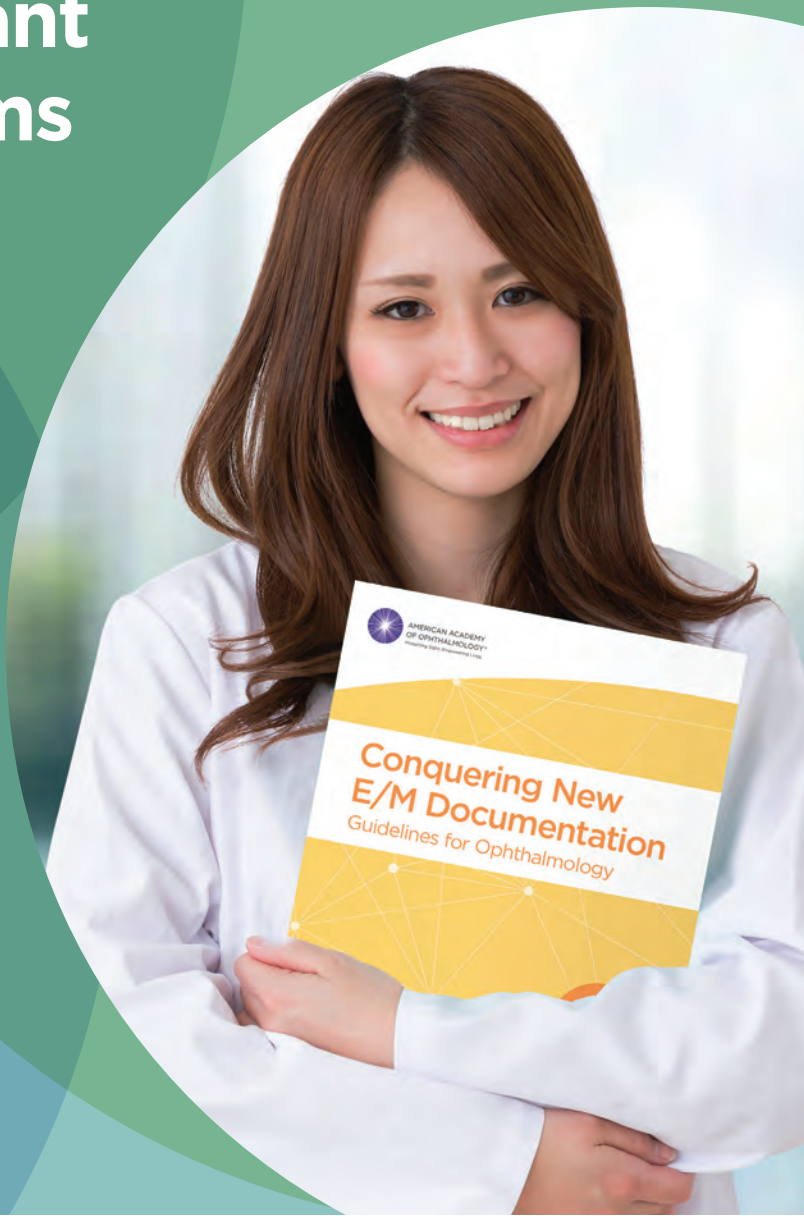
AMERICAN ACADEMY
OF OPHTHALMOLOGY®

2021

American Academy of Ophthalmic Executives®

It's Never Been More Important to Code Claims Correctly

Make every claim count with the Academy's professional coding tools and expert support at your fingertips.



Order Now
aao.org/codingtools
866.561.8558

Protecting Sight. Empowering Lives.®