

# Eyelement Supplement

# MIPS 2020: A Primer and Reference

Published May 2020



Who Is Your MIPS Point Person, and Who Is Backup? Make Sure They Have This Ophthalmology-Specific Guide. FDA approved for several indications, including Diabetic Retinopathy (DR)

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

# RIGITIAN EYES YOUR EYES (aflibercept) 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.

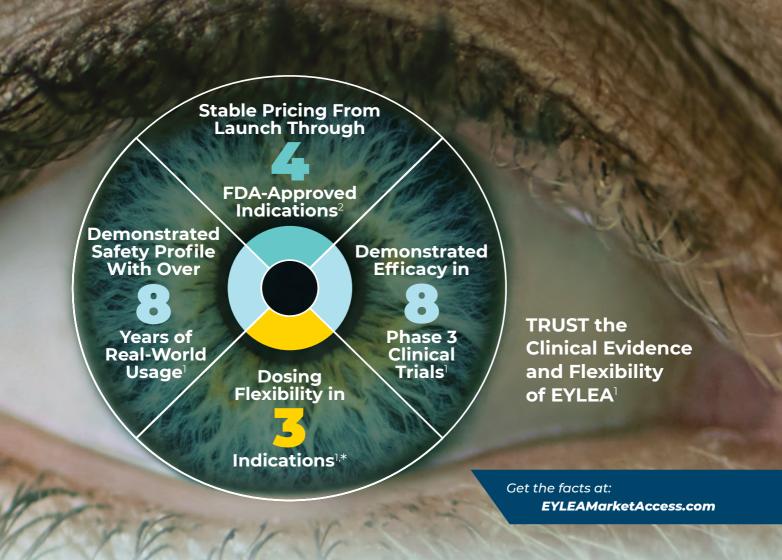
For Intravitreal Injection

#### 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.

EYLEA is a registered trademark of Regeneron Pharmaceuticals, Inc.

#### REGENERON



\*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.

#### 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.



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

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

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

#### 4 CONTRAINDICATIONS

**4.1 Ocular or Periocular Infections**EYLEA is contraindicated in patients with ocular or periocular infections.

4.2 Active Intraocular Inflammation EYLEA is contraindicated in patients with active intraocular inflammation.

4.3 Hypersensitivity
EVLEA 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

reactions may manifest as rash, pruntus, unucana, severe anapphylactic/anaphylactic

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 There is a potential risk of arterial thromboembolic events (ATES) following intravitreal use of YEGF inhibitors, including EYLEA. ATES are defined as nonfatal stroke, nonfatal mycarcial infarction, or vascular death (including deaths of unknown cause). The incidence of reported thromboembolic events in wet AMD studies during the first year was 18% (32 out of 1824) in the combined group of patients treated with teVEA compared with 15% (90 ut of 598) in patients treated with annibizumab through 96 weeks, the incidence was 3.3% (60 out of 1824) in the EYLEA group compared with 5.2% (19 out of 598) in the ranibizumab group. The incidence in the DME studies from baseline to week 20 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 4.28% (80 out of 578) 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% (10 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA compared with 4.2% (20 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA or patients.

#### **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 handled serious of 2 mg. Serious adverse reactions related to the injection procedure handled serious 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 monthly 2 mg dose in 218 patients following CRVO in 2 clinical studies (COPERNICUS and GALILEO) and 91 patients following one clinical study (VIBRANT).

#### REGENERON

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

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

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

EYL.19.07.0306

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

	CH	WO.	BRVU	
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

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 50.

The data described below the 10-masked below to the 10-masked below th

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

	Baseline t	o 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).

Collaminogenicity.

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 immunoasays. 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 mislanding.

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 LISE IN SPECIFIC POPUL ATIONS

#### 8.1 Pregnancy

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 affibercept) were approximately 6 times higher than AUC values observed in humans after a single intravitreal treatment at the

ere commended clinical dose [see Animal Dafa].

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 affibercept, treatment with EYLEA may pose a risk to human embryofetal development. EYLEA should be used during pregnancy only if the potential benefit justifies the protection of the foliar. notential risk to the fetus

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#### <u>a</u> nal Data

Thinking beta the properties of the 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

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, umblicial hemia, diaphragmatic hemia, gastroschisis, cleft palate, ectrodactly, interstinal aterias, spina blifda, enception plomeningocele, heart and major vessel defects, and skeletal malformations (fused vertebrae, sternebrae, and ribs; supernumerary vertebral archa and ribs; and incomplete ossification). The maternal No Observed Adverse Effect Level (NOAEL) in these studies was 5 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 (On mg per kg), systemic exposure (AUC) of free aflibercept was approximately 6 times higher than systemic exposure (AUC) of the aflibercept was approximately 6 times higher than systemic exposure (AUC) of the aflibercept was

#### 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 There is no mornimour regularing the presence or animotrepen mornimal mile, the retext on the order on the presence or animotrepen mornimal, the retext or the transport of 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 development 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

Contra

Infertility
There are no data regarding the effects of EYLEA on human fertility. Affibercept adversely affected female and male reproductive mere are in out a region morkey when a diministered by intravenous injection at a dose approximately 1500 times helpertously systems in cynomologis monkeys when a diministered by intravenous injection at a dose approximately 1500 times helpertously systems level observed humans with an intravitred of so 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.

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17 PATIENT COUNSELING INFORMATION
In the days following PYLEA 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.



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ACHIEVE YOUR MIPS GOAL FOR 2020

#### Succeed at MIPS

hat is your goal for tackling the Merit-Based Incentive Payment System (MIPS) in 2020? Whether it is to earn the exceptional performance bonus or simply to avoid a penalty, the Academy can provide you with the tools you need to succeed.

#### **Empower Your MIPS Team**

Your practice should have a MIPS point person and, in case of illness or staff turnover, at least one backup. These staff members should be responsible, detail-oriented, proactive, and patient. With the maximum penalty now increased to -9%, a physician should serve as the practice's MIPS champion and make sure your MIPS staff have what they need.

Give your MIPS team the tools they need. Do your MIPS specialists have access to all the Academy and AAOE MIPS resources (see page 62), especially the MIPS Roadmaps and the AAOE eTalk listserv? Do they have your practice's login credential for the IRIS Registry?

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 Lookup tool (see page 12). Also use the Lookup tool to learn about other important MIPS designations, such as practice size.

Is your 2020 MIPS performance on track? You should have already picked a quality reporting option (see pages 16-17) and know what quality measures you are reporting. You should also have reviewed the improvement activities (see pages 42-44) and, if applicable, the promoting interoperability measures. Have you decided whether your 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.

MIPS tip. The IRIS Registry will need to contact your MIPS point person. Makes sure staff members who answer the phones or email know to forward MIPS- or IRIS Registry -related inquiries to the right person.

#### 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).

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). 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.

#### Got a MIPS Conundrum?

If you can't find your answer among the Academy's extensive resources (see page 62), you can email the Academy with questions about MIPS (mips@aao.org) or about the IRIS Registry (irisregistry@aao.org). And the e-Talk listserv (aao. org/practice-mangement/listerv) provides AAOE members with a popular forum for exchanging MIPS tips (aao.org/ member-services/join).

#### What About COVID-19?

COVID-19 has been massively disruptive to all areas of life, and ophthalmology is no exception. Indeed, in mid-March, in an attempt to "flatten the curve" of the pandemic, many ophthalmology practices cancelled most patient encounters, only remaining available for urgent and emergent cases. No practice took the decision to close their doors lightly, and the costs of doing so have been high, with practices, for example, terminating staff members or putting them on furlough.

What will all this mean for MIPS? The regulations allow you to apply to be exempt from a performance category if you are hindered by "extreme and uncontrollable circumstances" (see page 13). At time of press, CMS hadn't said whether they would provide any additional accommodations to MIPS participants in light of the COVID-19 pandemic. Once CMS starts tackling this issue, the Academy will make sure that the agency takes ophthalmology's concerns into consideration. For the latest news, check your email for Washington Report Express (Thursdays) and—if you are an AAOE member—Practice Management Express (Sundays).

KNOW THE BASICS

# Your MIPS Final Score, Bonuses, and Penalties

nder MIPS, Medicare adjusts payments based on clinician performance, with your MIPS final score for the 2020 performance year determining whether your 2022 Medicare Part B payment adjustment will be positive (a bonus), neutral (no adjustment), or negative (a penalty).

#### **Your MIPS Final Score**

**Your 2020 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:

- quality score—45% (default weight)
- promoting interoperability score—25% (default weight)
- improvement activities score—15% (default weight)
- cost score—15% (default weight)

What the weights mean. If your quality score is weighted at 45%, it can contribute a maximum of 45 points to your MIPS final score; for example, a quality score of 50% would contribute 22.5 points (50% of 45 points).

In limited circumstances, CMS can reweight the performance categories. The reweighting scenarios that have most typically applied to ophthalmologists are as follows:

Promoting interoperability reweighted to zero. If you qualify for a promoting interoperability exception (see page 34), CMS can reduce the weight of that performance category to zero and increase quality's weight from 45% to 70%. A quality score of 50% would now contribute 35 points (50% of 70 points) to your MIPS final score.

Cost reweighted to zero. If you don't meet the case mini-

Table 1: How	the Performance	e Categories Are	e Weighted
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Default Weights		Quality	PI	Improvement Activities	Cost
Scored on all four performance	Weight	45%	25%	15%	15%
categories—no reweighting	Points	Up to 45	Up to 25	Up to 15	Up to 15

Most typical reweighting scenarios for ophthalmology practices. CMS can reweight performance categories if extreme and uncontrollable circumstances apply (see page 13), if a promoting interoperability exception applies (see page 34), or if you don't meet the case minimum for all cost measures (see pages 59 and 60).

Most Typical Reweighting Scenarios		Quality	PI	Improvement Activities	Cost
Promoting interoperability (PI) is reweighted to 0%	Weight	70%	0%	15%	15%
	Points	0-70	0	0-15	0-15
Cost is reweighted to 0%  Correction: An earlier PDF weighted quality at 60% and PI at 25%.	Weight	55%	30%	15%	0%
	Points	0-55	0-30	0-15	0
PI and cost are reweighted to 0%	Weight	85%	0%	15%	0%
	Points	0-85	0	0-15	0
Three performance categories are reweighted to 0%	If CMS can only score you on one performance category, you would be assigned a MIPS final score of 45 points.				

Other reweighting scenarios: If the improvement activities performance quality is reweighted to zero, its weight (15%) would be reallocated to quality. If quality is reweighted to zero, its weight (45%) would be reallocated to promoting interoperability (+20%) and improvement activities (+25%). Weights are never reallocated to cost.

mum for all cost measures, CMS will not factor cost into your MIPS final score. Instead, it will reduce cost's weight from 15% to zero and increase quality's weight from 45% to 60%. A quality score of 50% would now contribute 30 points (50% of 60 points) to your MIPS final score.

What if both cost and promoting interoperability are reweighted to zero? Quality would now have a weight of 85%, meaning that a quality score of 50% would contribute 42.5 points (50% of 85 points) to your MIPS final score.

Emergencies. CMS also can reweight performance categories if it determines that "extreme and uncontrollable circumstances" apply (see page 13).

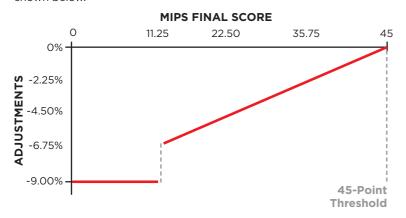
**Get up to 5 bonus points for patient complexity.** If you report MIPS data for at least one performance category, you may be eligible for a complex patient bonus. CMS determines this bonus based on two indicators: 1) the average Hierarchical Condition Category (HCC) risk score of your patients;

Table 2A: Bonuses and Penalties				
2020 MIPS Final Score	2020 Payment Adjustment			
0-11.25 points	Maximum penalty of -9%			
11.26-44.49 points	Penalty on a sliding scale (see Table 2B)			
45 points	Neutral (no penalty, no bonus)			
45.01-84.99 points	Initial bonus*			
85-100 points	Initial bonus* + exceptional performance bonus†			

<sup>\*</sup> The initial bonus is based on a linear sliding scale—those who score 45.01 points get the lowest bonus; those who score 100 points get the highest.

#### Table 2B: Payment Penalty

If your 2020 MIPS final score is less that the 45-point performance threshold, your 2022 Medicare Part B payments will be reduced as shown below.



and 2) a "dual eligible" score, which is based on the proportion of beneficiaries eligible for both Medicare and Medicaid.

**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 this 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 27 points (60% of 45 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 9 points (60% of 15 points)

If her complex patient score contributes 2 bonus points, her MIPS final score would be 73 points (the sum of 27 + 20 + 15 + 9 + 2).

Special scoring for clinicians who join a practice late in the year. If you join a practice in the last three months of 2020, 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, 2020) or if you join an established practice where the clinicians are reporting as individuals, CMS will award you a MIPS final score of 45 points, which is this year's performance threshold, meaning that you would get a neutral payment adjustment in 2022. But if you join an established practice that is reporting as a group and includes your National Provider Identifier (NPI; see page 13) in its reporting, you would get its group score; your data after you join should be included in its group reporting.

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

The performance period for each performance category must take place between Jan. 1, 2020, and Dec. 31, 2020, 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

<sup>&</sup>lt;sup>†</sup> 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.

period. For example, you could pick June-August for promoting interoperability and September-November for improvement activities—but you would need to perform all your scored promoting interoperability measures within that June-August time frame (the unscored Security Risk Analysis is the exception) and all your improvement activities within that September-November time frame, though they could also extend beyond that period. 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 90+-day date range.

#### **Bonuses and Penalties**

**CMS continues to raise the bar.** To avoid a payment penalty in 2022, you need a 2020 MIPS final score of at least 45 points (up from 30 points in performance year 2019); to earn an exceptional performance bonus, you need to score at least 85 points (up from 75 points in performance year 2019).

**Potential penalties are higher.** The maximum payment penalty has increased to –9% (up from –7% for the 2019 performance year/2021 payment year).

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 45 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, it won't know how far it has to stretch the \$500-millon bonus pool for exceptional performance.

Why is there a gap year between performance (2020) and payment adjustments (2022)? CMS needs time to process the MIPS data, determine final scores, perform targeted reviews, and calculate an adjustment factor that ensures budget neutrality.

#### **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 Tax 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 "What if you report as an individual and as part of a group?" on page 13).

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

Your 2020 MIPS final score will follow you to your next practice. Your 2020 final score will determine your 2022 payment adjustment, and this is the case even if you move to a new practice after the 2020 performance year is over.

The payment adjustments will be applied throughout the year. CMS will start applying the MIPS payment adjustments for 2020 MIPS performance in 2022. They will be applied to your Medicare Part B service remittances.

Table 3: How the	Table 3: How the Bonuses Are Funded							
2020 MIPS Final Score	2022 Payment Adjustment		Provenance of Bonus Dollars					
0-11.25 points	-9% penalty (negative payment adjustment)	$\rightarrow$	The negative payment adjustments reduce CMS					
11.26-44.99 points	Payment penalty on a linear sliding scale, as shown in Table 2B (negative payment adjustment)	$\rightarrow$	expenditure. These savings go into a bonus pool that funds the initial bonuses (which are therefore budget neutral).					
45 points	Neutral (no payment adjustment)							
45.01-84.99 points	Initial bonus (payment adjustment)	←	Funded by the penalties, this initial bonus is paid on a linear sliding scale. (Those who score 45.01					
	Initial bonus (payment adjustment)		points get the lowest bonus, those who score 100 points get the highest.)					
85-100 points	+ 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**

any 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 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—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 13) and 2) you fall within one of these clinician types:

- · physicians,
- · optometrists,
- · physician assistants,
- · nurse practitioners,

#### **MIPS Determination Period**

The MIPS determination period is a 24-month assessment period. It consists of two time segments; for the 2020 performance year, these are as follows:

- Oct. 1, 2018-Sept. 30, 2019 (with 30-day claims run out)
- Oct. 1, 2019-Sept. 30, 2020 (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 40).

- 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 2020, and you have not previously submitted claims under Medicare, you will be exempt from the MIPS rules for the 2020 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 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 comprised 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

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

# What's Your MIPS Participation Status?

**Check your status.** Use the QPP Participation Status Lookup 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 all the way down to check your status at each practice.

Preliminary eligibility information published in late 2019. CMS uses two 12-month time segments (see "MIPS Determination Period," previous page) to assess clinicians' MIPS status. Since late 2019, you could use the QPP Participation Status Lookup tool to see your preliminary eligibility information, based on data from the first time segment (Oct. 1, 2018-Sept. 30, 2019).

Final eligibility information published in November 2020. CMS will reconcile data from the second time segment (Oct. 1, 2019-Sept. 30, 2020) and will then update the Lookup 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.

Check your quarterly snapshots. During the determination period's second time segment (Oct. 1, 2019–Sept. 30, 2020), 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, 2020, these informational snapshots will give you a sense of what those final decisions are likely to be.

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 Lookup tool (see "What's Your MIPS Participation Status?").

How do you opt in to MIPS? At time of press, CMS hadn't announced the opt-in process for performance year 2020. If they repeat the process that was used for performance year 2019, you will be able to opt in for performance year 2020 by signing into your account at qpp.cms.gov; the window for opting in would open in January 2021 (when CMS opens the submission window for performance year 2020).

What are the consequences of opting in? If you opt in for the 2020 performance year, your 2022 payments will be subject to a MIPS payment adjustment based on your 2020 MIPS final score. You also will be eligible to have your data published on Physician 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 2020, 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 2022 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 Physician Compare; however, during the 30-day preview period, voluntary reporters can ask that their information not be publicly reported.

#### **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 Tax 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 avoid the MIPS payment penalty (see "Accommodations for Small Practices," page 14). 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 an undue hardship exception for promoting interoperability that is specifically for small practices.

**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 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. Typically, no registration is required to participate in MIPS as a group. The exception is if you are using the CMS Web Interface (see page 20), which is unlikely to be an option for ophthalmology practices.

#### 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 2020 MIPS final score and will receive the same payment adjustment in 2022. There are some advantages to reporting as a group: For example, if at least 50% of clinicians in a group satisfies 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 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 2022.

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.

By combining as a virtual group, clinicians could potentially enjoy some of the economies of scale that larger practices have.

There was a Dec. 31, 2019, deadline for forming a virtual group for the 2020 performance year.

#### "Extreme and Uncontrollable" Circumstances

What if circumstances beyond your control limit your ability to participate in MIPS?

You can apply for a reweighting due to "extreme and uncontrollable" circumstances. 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." In past years, CMS started reviewing applications in the fall. The application period will close on Dec. 31, 2020.

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 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.

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: How the Performance Categories Are Weighted," on page 8.

**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 a Break**

hile tackling MIPS is burdensome for all MIPS eligible clinicians, it is particularly challenging for solo practitioners and small group practices. With that in mind, CMS has provided small practices with several accommodations that can help them avoid the penalty and, perhaps, enable them to earn a small bonus.

#### 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 12), CMS reviews claims data from two 12-month time segments (see "MIPS Determination Period," page 11) 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 12).

#### **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 11).

**Virtual groups.** CMS developed the virtual group option for practices with 10 or fewer eligible clinicians. There was a Dec. 31, 2019, deadline for forming a virtual group for the 2020 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

#### MIPS and COVID-19

Will the pandemic prompt CMS to create new accommodations for practices? If it does, there may be a new route for avoiding the penalty, but nothing had been announced at time of press. Check aao.org/medicare for updates.

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 18.)

**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 of the downsides of claims-based reporting is that it must be done in real time, which means you probably had to start early in the year if you want to satisfy the 70%—data completeness criteria. Another problem is that many of the benchmarks for claims-based reporting are subject to scoring limitations, which can make it hard to get a high achievement points total (see the "Achievement Points" column in "Table 7: Reporting Quality Measures via Medicare Part B Claims," page 29). An upside is that, unlike manual reporting via the IRIS Registry, you don't have to track the data-completeness totals (see page 32), making claims-based reporting a reasonable option if you are just seeking to score 3 points for a quality measure with minimal reporting to help you avoid the penalty.

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 22.)

**Promoting interoperability (PI)—significant hardship exception.** If you are in a small practice, you can apply for a small practice significant hardship exception (see page 35); if approved, PI's weight in your MIPS final score would be reallocated to quality.

Improvement activities—score double. Clinicians with a special status, such as being in a small practice, receive double points for each improvement activity that they perform. This means that they don't have to jump through as many hoops to get a 100% score for the improvement activities performance category. For example, a clinician with a special status can score 100% by performing one high-weighted activity while a practice without such a status would have to perform two of them (see "How You Will Be Scored," page 40).

#### **How Small Practices Can Avoid the Penalty**

Practices need 45 points to avoid a penalty. To avoid a MIPS payment penalty in 2022, you need a 2020 MIPS final score of at least 45 points (see "Table 2A: Bonuses and Penalties," page 9).

Your route to 45 points will depend on which performance categories you are scored on. Your MIPS final score (0-100 points) is a composite of up to four performance category scores. What you need to do to attain 45 points will depend, in part, on which of those performance categories apply to you, since that determines how each performance category is weighted in your MIPS final score:

- The default weighting: Quality: 45%; PI: 25%; improvement activities: 15%; and cost:15%.
- Weighting if you are excluded from PI: Quality: 70%; PI: 0%; improvement activities: 15%; and cost 15%.
- Weighting if you are excluded from cost: Quality: 60%; PI: 25%; improvement activities: 15%; and cost 0%.
- Weighting if you are excluded from PI and cost: Quality: 85%; PI: 0%; improvement activities: 15%; and cost 0.

What do the weights mean? If quality is weighted at 85% of your MIPS final score, it contributes up to 85 points to that score. For example, a quality score of 60% would contribute 51 points (60% of 85 points = 51 points).

Which performance categories will you be scored on? You should expect to be scored on the quality and improvement activities performance categories, but it is possible that you might be excluded from the cost performance category (see pages 59 and 60) and/or the PI performance category (see "Some Clinicians May Be Excused From PI," page 34).

**Example #1:** A *small* practice that is only scored on quality and improvement activities. Dr. Argus reports as an individual. He doesn't perform cataract surgery, so he doesn't expect to be scored on cost. CMS accepts his applications for a small practice hardship exception from PI, so he is excused from that performance category. Consequently, his MIPS final score will be based on his improvement activities score and his quality score, which would be weighted at 15% and 85%, respectively. (Note: CMS has said that it would start processing PI exception applications in early summer, but in the past it hasn't done so until August.)

Dr. Argus performs and attests to one high-weighted improvement activity, and he scores 100% for that performance category. This contributes 15 points to his MIPS final score.

Because it takes 45 points to avoid the MIPS penalty, Dr. Argus needs his quality score to contribute at least 30 points to his MIPS final score. Quality is weighted at 85% of his

#### Avoid the Maximum -9% Penalty

Score more than 11.25 points to avoid the maximum -9% penalty. Even if you don't get a MIPS final score of 45 points, which is what you need to avoid a future payment penalty, you can minimize the penalty by getting as close to 45 points as possible.

If you score less than 45 points but more than 11.25 points, your penalty will be based on a sliding scale (see "Table 2B: Payment Penalty," page 9). If you score 11.25 points or less, that sliding scale becomes a precipice and your payments will be subject to the maximum –9% penalty.

MIPS final score, so he will need a quality score of at least 35.3% (35.3% of 85 points = 30 points).

What does he need to do to get a quality score of 35.3%? Small practices can earn 3 achievement points for a quality measure with minimal reporting—which could be as little as reporting on one qualifying patient just one time. If he does that for six quality measures (including at least one outcome measure) his quality score would be calculated as follows:

- Numerator: achievement points total (18 points) + measure bonus points (0 points) + small practice bonus (6 points) = 24 points
- Denominator: available achievement points (60 points) = 60 points
- Quality score = numerator  $(24) \div denominator (60) = 0.4$ , or 40%.

His MIPS final score would be 49 points, with his quality score of 40% contributing 34 points (40% of 85 points) and his improvement activities score of 100% contributing 15 points. This would be enough to avoid the penalty, but with not much margin for error.

**Example #2:** A *small* practice that is scored on quality, improvement activities, and cost. To tweak the previous example, suppose Dr. Argus is a cataract surgeon. He is now also scored on cost, which would be weighted at 15% when CMS calculates his MIPS final score, with quality and improvement activities weighted at 70% and 15%, respectively.

If he performs one high-weighted improvement activity, he scores 100% for that performance category, which contributes 15 points to his MIPS final score.

He still needs to score 30 points to reach the 45-point threshold for avoiding the penalty. Because he doesn't know what his cost score will be, he should try to score at least 30 points for quality. He can do that as follows:

- report six quality measures, with at least one being an outcome measure;
- meet the two data submission thresholds (see page 18) for two of those measures and earn a total of 8 points for them; and
- for the remaining four measures, report on at least one qualifying patient per measure, earning 3 achievement points for each measure for a total of 12 points.

His quality score would be calculated as follows:

- Numerator: achievement points total (20 points) + measure bonus points (may earn bonus points for the two fully reported measures; see page 20) + small practice bonus (6 points) = at least 26 points.
- Denominator: available achievement points (60 points) = 60 points
- Quality score = numerator (26) ÷ denominator (60) = 0.43, or 43%.

His MIPS final score would be 45 points, with his quality score of 43% contributing 30 points (43% of 70 points) and his improvement activities score of 100% contributing 15 points. This would be barely enough to avoid the penalty.

What about other small practice scenarios. For further information on avoiding the penalty, see the Small Practice Roadmap at aao.org/medicare/resources/small-practice.

DECIDE HOW YOU WILL REPORT YOUR QUALITY DATA

# Pick Your Quality Collection Type(s)

our 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.

Which reporting option(s) should you pick? After reading about the options below, review Tables 5, 6, and 7 (on pages 23, 26, and 29) to see which quality measures are available for each reporting option, and to see whether those measures are subject to significant scoring limitations. CMS may score a measure differently depending on which collection type was used, with many quality measures subject to significant scoring limitations when reported via claims. However, there may be a role for claims-based reporting of quality measures, especially for small practices that simply want to avoid the MIPS payment penalty even if they don't earn a bonus (see page 15).

#### Meet These IRIS Registry Deadlines

# If you want to start reporting MIPS quality measures via IRIS Registry-EHR integration:

- Sign up for integration 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.
- E-sign a data release consent form by Jan. 31, 2021.
- Press the "Submit" button to send data to CMS by Jan. 31, 2021.
   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, 2021.
- E-sign a data release consent form by Jan. 31, 2021.
- Press the "Submit" button to send data to CMS by Jan. 31, 2021.
   Got questions? If the IRIS Registry User Guide doesn't answer

your questions, contact Academy customer service staff at customer\_service@aao.org or 415-561-8599. If you have more technical questions—relating, for example, to quality data mapping issues, obtaining your IRIS Registry log in credentials, or changing your IRIS Registry practice information—contact irisregistry@aao.org.

#### 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 5, page 23), 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 which EHR system you are using. Furthermore, you only can use integrated reporting if your EHR system has been certified as

a 2015-edition certified EHR technology (CEHRT). To find out which 2015-editon CEHRTs have been integrated with the IRIS Registry, visit aao.org/iris-registry/ehr-systems.

Automated reporting. After the performance year is over, an IRIS Registry algorithm will select the quality measures that will maximize your score. (Note: This automated process is only applied to quality measures; you must manually report promoting interoperability measures and improvement activities.)

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

Start checking your quality data. You should make sure that data from your EHRs are being transferred over to the IRIS Registry correctly. If you suspect a problem, you can work with IRIS Registry staff 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.

**Not yet integrated?** If you want to start integrating your EHR system with the IRIS Registry for 2020 reporting, you need to meet both the June 1 and Aug. 1 deadlines.

# Option 2: Report Quality Measures Manually via the IRIS Registry

Each year, hundreds of ophthalmology practices avoid a future MIPS penalty by entering quality measure data into the IRIS Registry. Some of them have no EHR system; others have one but haven't integrated it with the IRIS Registry.

**Choose from 56 quality measures.** These 56 measures (see Table 6, page 26) include 30 ophthalmology-specific ones 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.

Enter quality data at the individual-clinician level.

Throughout the year, enter quality data at the individualclinician level. In January 2021, when you are getting ready to hit the "submit" button that sends your data to CMS, you can opt to report as an individual or as part of a group.

**Start entering quality data ASAP.** The Academy urges you to enter data for quality measures as promptly as possible after each relevant patient encounter. This will help you to identify areas of underperformance while you still have time to do something about it, and will also avert the stress of the last-minute rush.

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 "Data Completeness Totals," page 32). 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., IRIS2).

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 six QCDR measures. There are already benchmarks for IRIS1, IRIS2, IRIS13, IRIS17, IRIS23, and IRIS26. After the 2020 performance year is over, CMS will see if there is enough 2020 performance data to retroactively create reliable benchmarks for the other 24 IRIS measures.

# Option 3: Report Quality Measures via Medicare Part B Claims

Table 7 (page 29) lists the 15 claims-based measures that are most relevant to ophthalmology. Scoring for many claims-based measures "stalls" at a low decile. (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 12).

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 were reported via the IRIS Registry and one measure 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 13).

#### **Other Reporting Options**

Via EHR. Some EHR vendors may offer a reporting option.

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 will 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 2022.

**Facility-based scoring isn't an option for most ophthal-mologists.** 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, 2018, and Sept. 30, 2019.

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**

f the four MIPS performance categories, quality can contribute the most to your MIPS final score. Its default weight is 45% of that score, meaning that it would contribute up to 45 points to it, but that weight can be increased in certain cases (see "Table 1," page 8).

#### **Reporting Quality Measures**

Here's how you can maximize your quality score.

**Report at least one outcome measure.** A measure that is listed as an intermediate outcome measure or a patient-reported outcome measure would suffice.

If no outcome measure is available, you must report another high-priority measure instead. Alternative highpriority 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 20), and your quality improvement percent score (see page 22).

Table 5 (page 23) and Table 6 (page 26) 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 7 (page 29) shows the 15 claims-based measures that are most relevant to ophthalmology, but there are many more. (Explore them all at https://qpp.cms.

#### **Quality 101**

Default weight in MIPS final score: 45%. 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.

gov/mips/explore-measures/quality-measures; make sure you select "2020" 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.

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 19) and, for a high priority measure, earn bonus points (see page 20).

The case minimum requirement is **20** patients. The exception is the all-cause hospital readmission (ACR) measure (see page 20), 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 2020 calendar year.

Who are the denominator-eligible patients? That de-

pends 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 are reporting via the Medicare Part B claims collection type, you would just include Medicare patients; if you are using any other reporting mechanism, you would include both Medicare and non-Medicare patients. Your reporting will indicate what percentage of those patients had an eye screening for diabetic retinal disease. (To see the denominator criteria for quality measures, go to the detailed listings at aao.org/medicare/quality-reporting-measures.)

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

What if you don't satisfy the data completeness criteria for a reported measure? Provided that you report at least one patient, you will score 3 achievement points if you are in a small practice; 0 achievement points (down from 1 point in 2019) if you are in a large practice.

#### **Do Not Cherry-Pick Your Patients**

If you report on fewer than 100% of patients, do not cherrypick. When you submit your MIPS quality data to CMS, you must certify that, to the best of your knowledge, your data are "true, accurate, and complete." Last August, CMS clarified that 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 for 2020 underscore that, stating 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

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 2018 performance data to try to establish 2020 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., IRIS2: Intraocular Pressure Reduction) 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

# ICD-10 Turbulence and Changes in Clinical Guidelines

During the course of the performance year, quality measures may be impacted by changes in diagnosis codes or in clinical best practices.

On Oct. 1, CMS updates the ICD-10 code set—and this could have repercussions for quality measures. The quality performance category relies on ICD-10 codes (the diagnosis codes) to determine which patients are eligible for each quality measure. However, CMS updates the ICD-10 code set annually on Oct. 1, which is 75% of the way through the MIPS performance year. In some cases, these changes to the ICD-10 code set may mean that it would no longer be fair to compare your performance on a measure to its historical benchmark—you would be comparing apples to oranges.

**Quality measures that are significantly impacted by ICD-10 changes will be subject to a nine-month assessment.** After CMS has determined its changes to the ICD-10 code set, it will assess whether any quality measures are significantly impacted by those changes. It will publish a list of those measures on the CMS website at some point between Oct. 1, 2020, and Jan. 2, 2021. For the measures on that list, CMS would evaluate your performance based only on the first nine months of 2020, before the ICD-10 codes were changed.

In rare cases, a quality measure may be "suppressed." During the course of the year, changes in clinical guidelines may mean that continued adherence to a measure could result in patient harm and/or provide misleading results as to good quality care. In the unlikely event that this happens with one of ophthalmology's measures, CMS could suppress that measure. This means that if you submitted data on the measure before it was suppressed—because, for example, you were reporting 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).

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.

# Warning—Some Benchmarks Are Subject to Scoring Limitations

**Scoring "stalls" for some benchmarks.** 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 sixth decile (see Table 4A, 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 wasn't enough performance data from 2018 to establish a reliable benchmark for a measure, or if the measure didn't exist in 2018, CMS will try to establish a benchmark retroactively using 2020 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"

**New for 2020: CMS introduced "flat" benchmarks.** CMS has applied flat benchmarks to the following two measures:

 Measure 1: Diabetes: Hemoglobin A1c (HBA1c) Poor Control (>9%)

#### The ACR Measure for Large Practices

It is very unlikely that the All-Cause Hospital Readmission (ACR) measure applies to you. You would need to have a high volume of unplanned readmissions to a hospital within 30 days of an initial discharge. This measure only applies to large groups (16 or more eligible clinicians) that meet the case minimum requirement of 200 cases. Such practices don't need to report this measure; they will be evaluated based on Medicare administrative claims data.

#### What Is the CMS Web Interface?

The CMS Web Interface is used by some big practices that provide primary care services. It is a reporting option for the quality performance category. It has its own reporting requirements, its own set of quality measures (mostly primary care-based), and a 12-month performance period. It replaced the PQRS program's Group Practice Reporting Option (GPRO) web interface and is only available to practices that have at least 25 eligible clinicians reporting quality data. To utilize this option for 2020, you must register for it between April 1, 2020, and June 30, 2020.

· Measure 236: Controlling High Blood Pressure

Measure 1 has a flat benchmark when reported by claims or manually via the IRIS Registry, but not when reported via IRIS Registry-EHR integration. Measure 236 has a flat benchmark for all three collection types.

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

For measure 1, 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. (Measure 1 is an inverse measure, meaning that a lower performance rate represents a superior performance.)

For measure 236, 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.

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, you must meet both the case minimum requirement (at least 20 patients) and the data completeness criteria (at least 70% of denominator-eligible patients) and you also need a perfor-

#### Table 4A: Scoring "Stalls" for Some Benchmarks

**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 2018 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 EHI	R Reporting	Manual Reporting (No EHR Needed)					
	Performance Rate (%)	Points	Performance Rate (%)	Points				
d3	0.23-2.62	3.0-3.9	1.13-5.89	3.0-3.9				
d4	2.63-10.46	4.0-4.9	5.9-51.75	4.0-4.9				
d5	10.47-37.69	5.0-5.9	51.76-96.19	5.0-5.9				
d6	37.7-68.19	6.0-6.9	96.2-99.99	6.0-6.9				
d7	68.2-90.18	7.0-7.9	Scoring stalls at d6					
d8	90.19-97.42	8.0-8.9						
d9	97.43-99.99	9.0-9.9						
d10	100	10	100	10				
Summary	3-10 points		3-6.9 points or, with 100% performance rate, 10 points					
Notes			Topped out					

#### Table 4B: Examples of 7-Point Cap and Score Stalling

**Measure 117: Diabetes Eye Exam.** The three benchmarks for measure 117 demonstrate two types of scoring limitations for achievement points—a 7-point cap is imposed on two of them and scoring "stalls" for two of them.

Decile		IRIS R		Medicare Part B			
	Integrated E	EHR Reporting		Manual Reporting (No EHR Needed)		sed Reporting	
	Performance Rate (%)	Points	Performance Rate (%)	Points	Performance Rate (%)	Points	
d3	0.6-6.83	3.0-3.9	0.61-23.29	3.0-3.9	3.32-25.79	3.0-3.9	
d4	6.84-21.2	4.0-4.9	23.3-80.68	4.0-4.9	25.8-91.04	4.0-4.9	
d5	21.21-49.99	5.0-5.9	80.69-97.83	5.0-5.9	91.05-99.99	5.0-5.9	
d6	50-97-97.37	6.0-6.9	97.84-99.99	6.0-6.9	Scoring	stalls at d5	
d7	97.38-99.84	7.0-7.9	100	7	100	7	
d8	99.85-99.99	8.0-8.9					
d9	Scoring stalls at d8						
d10	100	10					
Summary	3-8.9 points or, formance rate, 1	with a 100% per- 0 points	3-7 points		3-5.9 points or, with a 100% performance rate, 7 points		
Notes			Topped out, 7-p	Topped out, 7-point cap		Topped out, 7-point cap	

mance rate 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, your data submission must be done using a 2015-edition CEHRT, 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 ACR measure (see page 20)—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 2020 than you did in 2019, you may be able to earn a quality improvement percent score.

CMS checks whether your score for measure performance has improved. CMS compares your 2020 performance with your 2019 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 2019 quality performance.)

How CMS determines your improvement percent score. Your improvement percent score = ([your increase in quality performance category achievement percent score from 2019 to 2020]  $\div$  your 2019 quality performance category achievement percent score)  $\times$  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 achievement score for the ACR measure (see "The ACR Measure for Large Practices," page 20).
- **2. Measure bonus points:** CMS determines your total measure bonus points (see "Scoring—Bonuses for High-Priority Measures and CEHRT," page 20).
- **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 ACR measure 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 8) it contributes up to 45 points to your final score. For example, if your quality score is 60%, it would contribute 27 points (60% of 45 points) to your MIPS final score.

#### Which Quality Measures Should You Report?

If you are using the IRIS Registry to report quality measures manually and/or if you are reporting via Medicare Part B claims: Skim Tables 6 and/or 7 on pages 26 and 29, 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.

If you are reporting quality measures via IRIS Registry-EHR integration: You don't have to actively select which quality measures you want to report; after the performance year is over, an IRIS Registry algorithm will select the quality measures that will maximize your score. However, you should still 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.

**Understand the quality measures.** Detailed measure specifications, plus the Academy's Quality Measure Reading Guide, are available at aao.org/medicare/quality-reporting-measures.

#### Tables 5-7: Quality Measures at-a-Glance

Column 1—ID: Measure Name. For each measure, the Academy has created a detailed web page that explains which patients are denominator eligible, lists relevant CPT and ICD-10 codes, describes how to report the measure, and provides detailed benchmark information. You can use the Web versions of Tables 5, 6, and 7—available at aao.org/eyenet/mips-manual-2020—and click on the measure title in column 1 for links to those detailed pages. You also can access those detailed web pages at aao.org/medicare/quality-reporting-measures, where the measures are listed by ID number.

**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 meeting the two data submission thresholds for additional high-priority measures (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 4B, page 21), especially if it stalls at a low decile. Also be mindful of measures that don't yet have a benchmark for your collection type (see page 20).

**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).
- Inverse measures are ones 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 20).

#### Table 5: Reporting Quality Measures via IRIS Registry-EHR Integration

For tips on using this chart, see above.

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.** For detailed measure descriptions, visit aao.org/medicare/quality-reporting-measures, where you also can download the Quality Measure Reading Guide.

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

ID: Measure Name	High-Priority Measure (Bonus Points)	Achievement Points	Notes
Pr	eventive Health Measures		
<b>110:</b> Preventive Care and Screening: Influenza Immunization		3-10 points	
111: Pneumonia Vaccination Status for Older Adults		3-10 points	
117: Diabetes: Eye Exam		3-8.9 points or, with a 100% performance rate, 10 points	See Table 4B (page 21) for benchmark data
<b>128:</b> Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up Plan		3-10 points	
<b>130:</b> Documentation of Current Medications in the Medical Record	Patient safety (+1 point)	3-7 points	Topped out, 7-point cap
<b>226:</b> Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention		3-8.9 points, or, with a 100% performance rate, 10 points	
236: Controlling High Blood Pressure	Intermediate outcome (+2 points)	3-10 points	Flat benchmark
238: Use of High-Risk Medications in the Elderly	Patient safety (+1 point)	3-7 points	Inverse measure, topped out, 7-point cap

<b>318:</b> Falls: Screening for Future Fall Risk	Patient safety (+1 point)	3-10 points	
<b>374:</b> Closing the Referral Loop	Care coordination (+1 point)	3-10 points	See page 21 for benchmark data.
Resour	ce Use and Opioid Manage	ement	
IRIS26: Avoidance of Routine Antibiotic Use Before or After Intravitreal Injections	Efficiency (+1 point)	3-6.9 points or, with a 0% performance rate, 10 points	Reintroduced measure, inverse measure
IRIS52: Postoperative Opioid Management Following Ocular Surgery	Opioid-related (+1 points)	No benchmark yet	Change of ID # (previously IRIS37)
C	ataract/Anterior Segment		
<b>191:</b> 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	
IRIS54: Complications After Cataract Surgery	Outcome (+2 points)	No benchmark yet	Inverse measure, change of ID # (previously IRIS27)
IRIS59: Regaining Vision After Cataract Surgery	Outcome (+2 points)	No benchmark yet	Change of ID # (previously IRIS40)
Also see IRIS55 and IRIS60, under "Glaucoma."	u		
	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 yet	Inverse measure
Also see IRIS52 under "Resource Use and Opio	oid Management."		
	Glaucoma		
<b>12:</b> Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation		3-8.9 points or, with a 100% performance rate, 10 points	
IRIS2: Intraocular Pressure (IOP) Reduction	Intermediate outcome (+2 points)	3-10 points	
<b>IRIS39:</b> IOP Reduction Following Trabeculectomy or an Aqueous Shunt Procedure	Outcome (+2 points)	No benchmark yet	
IRIS43: IOP Reduction Following Laser Tra- beculoplasty	Outcome (+2 points)	No benchmark yet	
IRIS44: Visual Field Progression in Glaucoma	Outcome (+2 points)	No benchmark yet	Inverse measure
IRIS55: Visual Acuity Improvement Following Cataract Surgery and Minimally Invasive Glau- coma Surgery	Outcome (+2 points)	No benchmark yet	New measure
IRIS60: Visual Acuity Improvement Following Cataract Surgery Combined With a Trabe- culectomy or an Aqueous Shunt Procedure	Outcome (+2 points)	No benchmark yet	Change of ID # (previously IRIS36)
	Neuro-Ophthalmology		
IRIS56: Adult Diplopia: Improvement of Ocular Deviation or Absence of Diplopia or Functional Improvement	Outcome (+2 points)	No benchmark yet	New measure
IRIS57: Idiopathic Intracranial Hypertension: Improvement of Mean Deviation or Stability	Outcome (+2 points)	No benchmark yet	Reintroduced measure

Oculofacial Plastics/Reconstructive				
IRIS5: Surgery for Acquired Involutional Ptosis: Patients With an Improvement of Marginal Reflex Distance (MRD)	Outcome (+2 points)	No benchmark yet		
IRIS6: Acquired Involutional Entropion: Normalized Lid Position After Surgical Repair	Outcome (+2 points)	No benchmark yet		
Also see IRIS52 under "Resource Use and Opio	id Management."			
Pediatric	Ophthalmology and Stra	bismus		
IRIS48: Adult Surgical Esotropia: Post- operative Alignment	Outcome (+2 points)	No benchmark yet		
IRIS49: Surgical Pediatric Esotropia: Post- operative Alignment	Outcome (+2 points)	No benchmark yet		
IRIS50: Amblyopia: Interocular Visual Acuity	Outcome (+2 points)	No benchmark yet		
	Refractive Surgery			
IRIS23: Refractive Surgery: Patients With a Postoperative Uncorrected Visual Acuity (UCVA) of 20/20 or Better Within 30 Days IRIS24: Refractive Surgery: Patients With a	Outcome (+2 points)  Outcome (+2 points)	3-7.9 points or, with a 100% performance rate, 10 points No benchmark yet		
Postoperative Correction Within ± 0.5 Diopter (D) of the Intended Correction	, and a second ( = p and )			
	Retina/Vitreous			
Retina: Age-I	Related Macular Degenera	ation (AMD)		
IRIS45: Exudative AMD: Loss of Visual Acuity	Outcome (+2 points)	No benchmark yet		
Also see IRIS 26, under "Resource Use and Opi	ioid Management."			
Retina: Diabetic Retino	pathy (DR) and Diabetic I	Macular Edema (DME)		
<b>19:</b> Diabetic Retinopathy: Communication With the Physician Managing On-going Diabetes Care	Care coordination (+1 point)	3-8.9 points or, with a 100% performance rate, 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 yet	New measure	
Re	etina: Epiretinal Membrane	9		
IRIS41: Improved Visual Acuity After ERM Treatment Within 120 Days	Outcome (+2 points)	No benchmark yet		
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 yet		
Uveitis/Immunology				
IRIS17: Acute Anterior Uveitis: Post-treatment Grade O anterior chamber cells	Outcome (+2 points)	3-10 points	Reintroduced measure	
IRIS35: Improvement of Macular Edema in Patients with Uveitis	Outcome (+2 points)	No benchmark yet		
<b>IRIS51:</b> Acute Anterior Uveitis: Post-Treatment Visual Acuity	Outcome (+2 points)	No benchmark yet		
IRIS53: Chronic Anterior Uveitis: Post-Treatment Visual Acuity	Outcome (+2 points)	No benchmark yet	Change of ID # (previously IRIS18)	

#### Table 6: Reporting Manually via the IRIS Registry (No EHR Needed)

For tips on using this chart, see page 23.

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.** For detailed measure descriptions, visit aao.org/medicare/quality-reporting-measures, where you also can download the Quality Measure Reading Guide.

Ligh Driggity Massage				
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		3-8.9 points or, with a 100% performance rate, 10 points		
111: Pneumonia Vaccination Status for Older Adults		3-10 points		
117: Diabetes: Eye Exam		3-7 points	Topped out, 7-point cap; see page 21 for benchmark data	
<b>128:</b> Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan		3-7.9 points or, with a 100% performance rate, 10 points		
<b>130:</b> Documentation of Current Medications in the Medical Record	Patient safety (+1 point)	3-7 points	Topped out, 7-point cap	
<b>154:</b> Falls: Risk Assessment	Patient safety (+1 point)	3-7 points	Topped out, 7-point cap	
<b>226:</b> Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention		3-7.9 points or, with a 100% performance rate, 10 points		
236: Controlling High Blood Pressure	Intermediate outcome (+2 points)	3-10 points	Flat benchmark	
<b>238:</b> Use of High-Risk Medications in the Elderly	Patient safety (+1 point)	3-7 points	Inverse measure, topped out, 7-point cap	
<b>317:</b> Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented		3-7.9 points or, with a 100% performance rate, 10 points		
<b>374:</b> Closing the Referral Loop	Care coordination (+1 point)	3-6.9 points or, with a 100% performance rate, 10 points	Topped out; see page 21 for bench- mark data	
<b>402:</b> 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)	3-6.9 points or, with a 0% performance rate, 10 points	Reintroduced measure, inverse measure	
IRIS52: Postoperative Opioid Management Following Ocular Surgery	Opioid-related (+1 points)	No benchmark yet	Change of ID # (previously IRIS37)	

Cataract/Anterior Segment				
	_		Topped out	
<b>191:</b> Cataracts: 20/40 or Better Visual Acuity Within 90 Days Following Cataract Surgery	Outcome (+2 points)	3-7 points	Topped out, 7-point cap	
<b>389:</b> Cataract Surgery: Difference Between Planned and Final Refraction	Outcome (+2 points)	3-8.9 points or, with a 100% performance rate, 10 points		
IRIS54: Complications After Cataract Surgery	Outcome (+2 points)	No benchmark yet	Inverse measure, change of ID # (previously IRIS27)	
IRIS59: Regaining Vision After Cataract Surgery	Outcome (+2 points)	No benchmark yet	Change of ID # (used to be IRIS40)	
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 yet	Inverse	
Also see IRIS52, under "Resource Use and Opio	oid Management."			
	Glaucoma			
<b>12:</b> Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation		3-5.9 points or, with a 100% performance rate, 7 points	Topped out, 7-point cap	
<b>141:</b> Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% or Documentation of a Plan of Care	Outcome (+2 points)	3-8.9 points or, with a 100% performance rate, 10 points		
IRIS2: Intraocular Pressure (IOP) Reduction	Intermediate outcome (+2 points)	3-10 points		
<b>IRIS39:</b> IOP Reduction Following Trabeculectomy or an Aqueous Shunt Procedure	Outcome (+2 points)	No benchmark yet		
IRIS43: IOP Reduction Following Laser Trabeculoplasty	Outcome (+2 points)	No benchmark yet		
IRIS44: Visual Field Progression in Glaucoma	Outcome (+2 points)	No benchmark yet	Inverse measure	
IRIS55: Visual Acuity Improvement Following Cataract Surgery and Minimally Invasive Glaucoma Surgery	Outcome (+2 points)	No benchmark yet	New measure	
IRIS60: Visual Acuity Improvement Following Cataract Surgery Combined With a Trabe- culectomy or an Aqueous Shunt Procedure	Outcome (+2 points)	No benchmark yet	Change of ID # (previously IRIS36)	
Neuro-Ophthalmology				
<b>419:</b> Overuse of Imaging for the Evaluation of Primary Headache	Efficiency (+1 point)	No benchmark yet	Inverse measure	
IRIS56: Adult Diplopia: Improvement of Ocular Deviation or Absence of Diplopia or Functional Improvement	Outcome (+2 points)	No benchmark yet	New measure	
IRIS57: Idiopathic Intracranial Hypertension: Improvement of Mean Deviation or Stability of Mean Deviation	Outcome (+2 points)	No benchmark yet	Reintroduced measure	

Oculofacial Plastics/Reconstructive				
<b>137:</b> Melanoma: Continuity of Care—Recall System	Care coordination (+1 point)	3-5.9 points or, with a 100% performance rate, 10 points		
138: Melanoma: Coordination of Care	Care coordination (+1 point)	3-5.9 points or, with a 100% performance rate, 10 points	Topped out	
265: Biopsy Follow-Up	Care coordination (+1 point)	3-7 points	Topped out, 7-point cap	
<b>397:</b> Melanoma Reporting	Care coordination (+1 point)	3-4.9 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 Marginal Reflex Distance (MRD)	Outcome (+2 points)	No benchmark yet		
IRIS6: Acquired Involutional Entropion: Normalized Lid Position After Surgical Repair	Outcome (+2 points)	No benchmark yet		
Also see IRIS52, under "Resource Use and Opio	oid Management."			
Pediatric	Ophthalmology and Stra	bismus		
IRIS48: Adult Surgical Esotropia: Postoperative Alignment	Outcome (+2 points)	No benchmark yet		
IRIS49: Surgical Pediatric Esotropia: Post- operative Alignment	Outcome (+2 points)	No benchmark yet		
IRIS50: Amblyopia: Interocular Visual Acuity	Outcome (+2 points)	No benchmark yet		
	Refractive Surgery			
IRIS23: Refractive Surgery: Patients With a Postoperative Uncorrected Visual Acuity (UCVA) of 20/20 or Better Within 30 Days	Outcome (+2 points)	3-7.9 points or, with a 100% performance rate, 10 points		
IRIS24: Refractive Surgery: Patients With a Postoperative Correction Within ± 0.5 Diopter (D) of the Intended Correction	Outcome (+2 points)	No benchmark yet		
Retina/Vitreous				
Retina: Age-I	Related Macular Degenera	tion (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 yet		
Also see IRIS 26, under "Resource Use and Opi	oid Management."			
Retina: Diabetic Retinopathy (DR) and Diabetic Macular Edema (DME)				
<b>19:</b> 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 yet	New measure	
Re	etina: Epiretinal Membrane	,		
IRIS41: Improved Visual Acuity After ERM Treatment Within 120 Days	Outcome (+2)	No benchmark yet		

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 yet	
R	etina: Retinal Detachment		
<b>384:</b> Adult Primary Rhegmatogenous Retinal Detachment: No Return to the Operating Room Within 90 Days of Surgery	Outcome (+2 points)	3-4.9 points or, with a 100% performance rate, 10 points	Topped out
<b>385:</b> Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery	Outcome (+2 points)	No benchmark yet	
	Uveitis/Immunology		
IRIS17: Acute Anterior Uveitis: Post-treatment Grade O anterior chamber cells	Outcome (+2 points)	3-10 points	Reintroduced measure
IRIS35: Improvement of Macular Edema in Patients with Uveitis	Outcome (+2 points)	No benchmark yet	
IRIS51: Acute Anterior Uveitis: Post-Treatment Visual Acuity	Outcome (+2 points)	No benchmark yet	
IRIS53: Chronic Anterior Uveitis: Post-Treatment Visual Acuity	Outcome (+2 points)	No benchmark yet	Change of ID # (previously IRIS18)

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#### Table 7: Reporting Quality Measures via Medicare Part B Claims

For tips on using this chart, see page 23.

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.** For detailed measure descriptions, visit aao.org/medicare/quality-reporting-measures, where you also can download the Quality Measure Reading Guide.

ID: Measure Name	High-Priority Measure (Bonus Points)	Achievement Points	Notes
Pr	eventive 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		3-7.9 points or, with a 100% performance rate, 10 points	
111: Pneumonia Vaccination Status for Older Adults		3-7.9 points or, with a 100% performance rate, 10 points	
117: Diabetes: Eye Exam		3-5.9 points or, with a 100% performance rate, 7 points	Topped out, 7-point cap; see page 21 for benchmark data

128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up Plan		3-7 points	Topped out, 7-point cap	
<b>130:</b> Documentation of Current Medications in the Medical Record	Patient safety (+1 point)	3-5.9 points or, with a 100% performance rate, 7 points	Topped out, 7-point cap	
<b>154:</b> Falls: Risk Assessment	Patient safety (+1 point)	3-4.9 points or, with a 100% performance rate, 7 points	Topped out, 7-point cap	
<b>226:</b> Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention		3-5.9 points or, with a 100% performance rate, 10 points	Topped out	
236: Controlling High Blood Pressure	Intermediate outcome (+2 points)	3-10 points	Flat benchmark	
<b>317:</b> Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented		3-6.9 points or, with a 100% performance rate, 10 points	Topped out	
	Glaucoma			
<b>12:</b> Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation		3-4.9 points or, with a 100% performance rate, 7 points	Topped out, 7-point cap	
<b>141:</b> Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% or Documentation of a Plan of Care	Outcome (+2 points)	3-4.9 points or, with a 100% performance rate, 10 points		
Neuro-Ophthalmology				
	Neuro-Ophthalmology			
<b>419:</b> Overuse of Imaging for the Evaluation of Primary Headache	Neuro-Ophthalmology Efficiency (+1 point)	No benchmark yet	Inverse measure	
Primary Headache		No benchmark yet	Inverse measure	
Primary Headache	Efficiency (+1 point)	No benchmark yet	Inverse measure  Topped out, 7-point cap	
Primary Headache Oculo	Efficiency (+1 point)  facial Plastics/Reconstruct  Care coordination	No benchmark yet  tive  3-3.9 points or, with a 100% performance	Topped out,	
Primary Headache  Oculo 397: Melanoma Reporting	Efficiency (+1 point)  facial Plastics/Reconstruct  Care coordination (+1 point)	No benchmark yet  tive  3-3.9 points or, with a 100% performance rate, 7 points	Topped out,	

TRY THESE PROVEN STRATEGIES FOR MIPS SUCCESS

# **Tips for Reporting Quality Measures Manually** Via the IRIS Registry

or ophthalmology, the IRIS Registry has proved to be the tool of choice for MIPS reporting. Indeed, it has helped ophthalmology practices avoid several hundred million dollars in penalties based on their performance during the first three years of MIPS.

If you haven't already started with this year's MIPS, you need to get busy. "The sooner you start, the better," said Karen Turkish, RN, administrator for Lance Turkish, MD, and Associates in New Orleans. Her practice is on paper charts, and they report manually using the IRIS Registry MIPS portal. "When you wait to the end of the year, you are in panic mode," added Belinda Brodoski, CPC, practice administrator for Eye Clinic of Livonia in Livonia, Michigan.

First step: Review your Academy MIPS Roadmap. Visit aao.org/medicare to see your Academy MIPS Roadmap. There is one for small practices and one for large practices.

The tips below are for manual reporting (no EHR needed.) Hundreds of ophthalmology practices successfully avoid MIPS penalties by manually entering data in the IRIS registry web portal. Some of these have no EHR system; others have EHR but haven't yet integrated it with the IRIS Registry. Here are some tips for such practices.

#### **Which Quality Measures Should You Report?**

As discussed in "Reporting Quality Measures" (page 18), you ought to report on six quality measures, and at least one of these must be an outcome measure or, if no outcome measure is available, you can report on another type of highpriority measure.

Don't automatically pick the same measures as last year. Each year, Ms. Turkish reviews the quality measures as soon as the Academy posts them online at aao.org/medicare. She looks for any changes to measure specifications (which are flagged by red font) before making her selections.

The measures that you picked last year may have new **scoring restrictions.** Ms. Turkish also watches out for measures that have onerous scoring limitations, as this could prevent you from getting a high achievement points total. Review the "Achievement Points" column in Table 6 (page 26) to see which quality measures are subject to scoring limitations when reported manually via the IRIS Registry. Some measures may be subject to a 7-point cap on achievement points, scoring for some measures may "stall" before the 10th decile, and some measures may lack a benchmark

(see "Warning—Some Benchmarks Are Subject to Scoring Limitations," page 20).

Take a look at the QCDR measures. Notably, this year, six of the IRIS Registry's QCDR measures have historical benchmarks: IRSI1, IRIS2, IRIS13, IRIS17, IRIS23, and IRIS26 (see "Table 6," page 26).

#### Which Patients to Report On?

**Don't just report Medicare patients.** Practices that report quality measures via a registry must do so on patients across all payers, not just Medicare.

Meet the data submission thresholds. If you report on fewer than 70% of a quality measure's eligible patients, you will score 3 achievement points if you are in a small practice and 0 achievement points if you are in a large practice. To score more than 3 achievement points for a measure you must satisfy the 70%-data completeness criteria and meet the 20-patient case minimum.

If you report on fewer than 100% of patients, do not cherry-pick. When you submit your MIPS quality data to CMS, you must certify that, to the best of your knowledge, your data are "true, accurate, and complete." In 2019, CMS clarified that if you report on a measure for fewer than 100% of applicable patients, you should not select patients with the goal of boosting your performance rate; the agency states that such "cherry-picking" would result in data that are not "true, accurate, and complete."

#### **Keeping Track of Quality Data**

How do you make sure that you are reporting on at least 70% of eligible patients for each measure? You may need to establish a process to keep track of the quality data.

Using a paper-based approach. Ms. Turkish creates a quality measure worksheet each year that asks for all information needed for each of the six measures that her practice reports. That worksheet is placed inside every patient chart. The technicians in her practice are trained to fill out the worksheet for each patient visit, and the worksheets are collected for a staff person to enter the data.

Using billing software. Joyce Hogue, CPC, OCS, Quality Analyst at Wheaton Eye Clinic in Wheaton, Illinois, said that her practice uses its billing software to help them gather the data they need for quality reporting. For a cataract surgery measure, for example, Ms. Hogue can run a report to get a

list of patients who are eligible for that measure. She then enters data using those patient records. This process includes reviewing to see if there is any comorbid condition that would exclude the patient, and gathering the final visual acuity or complications information needed for reporting the measure.

**Start data entry ASAP.** Ms. Brodoski said it is key for her practice to not save data entry for the end of the year. Instead, they input data for the quality measures as promptly as possible, patient by patient.

**Keep staff focused on MIPS.** Ms. Brodoski recommends ensuring that all staff keep on top of documentation throughout the year. She noted that this can be a challenge, so in her practice, they discuss the importance of maintaining documentation for the quality measures with staff throughout the year. "Try to get everyone on board," she said.

#### **Data-Completeness Totals**

What is the data-completeness requirement? Since 2018, CMS has required practices that report quality measures manually through registries to submit data-completeness totals for each quality measure reported. Even if an eligible clinician or practice reports a measure for just one patient, CMS wants to know how many patients the measure could have been reported on over the calendar year. Consequently, for each quality measure that you report manually via the IRIS Registry, you must do the following:

- · Report the total number of patients eligible for the measure
- If the measure includes an exception, report the total number of patients excepted from the measure

You won't be able to submit a measure's quality data to CMS without including the eligible patients total and, if applicable, the excepted patients total.

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.

**Get the total number of eligible patients for quality measures.** First view the detailed specifications for each quality measure you report. They are posted at aao.org/medicare/ quality-reporting-measures.

The detailed measure descriptions include the denominator criteria that indicate which patients qualify for each measure. 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 "1/1/20-12/31/20." Apply a filter for the following:

- Diagnosis of primary open-angle glaucoma (using ICD-10 codes outlined in the measure specification)
- Eligible CPT codes billed during the 2020 calendar year

(using CPT codes outlined in the measure specification)

• Date of birth, so that only patients age 18 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.

**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. Note: If you have manually entered 100% of eligible patients into the IRIS Registry, the patient exceptions would already be captured, and you would already have the total number of patients excepted from the measure.

**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.).

Gathering data manually. 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 will need a manual approach for gathering this information. Because Ms. Turkish's practice includes the quality measure worksheets in every patient chart, she is able to review the charts to calculate the eligible patients and exceptions.

#### **Entering Quality Data Into the IRIS Registry**

Some practices, such as Ms. Brodoski's, have a designated staff person responsible for entering data into the IRIS Registry. Others take an all-hands-on-deck approach.

**Get step-by-step instructions on how to enter data.** See the IRIS Registry User Guide at aao.org/iris-registry/user-guide/getting-started. If you have questions, contact irisregistry@aao.org.

Enter quality data at the individual-clinician level. Regardless of whether clinicians participate in the MIPS quality performance category as a group or as individuals, the data for their quality measures will be entered at the individual-clinician level. Later, when they get ready to submit their data to CMS, they would stipulate whether they are reporting quality at the group or individual level.

Ms. Brodoski is with the Eye Clinic of Livonia in Livonia, Mich.; Ms. Hogue is with the Wheaton Eye Clinic in Wheaton, Ill.; and Ms. Turkish is with Lance Turkish, MD, and Associates, in New Orleans. *Financial disclosures: None* 

NOTE: The interviews in this article were excerpted from "Avoid the MIPS Penalty Without EHR: Tips for Reporting Via the IRIS Registry" (October 2019, *EyeNet*).

THE EHR-BASED PERFORMANCE CATEGORY IS BROADLY THE SAME AS LAST YEAR

# **How to Report Promoting Interoperability**

romoting interoperability (PI) is the MIPS electronic health record (EHR)—based performance category, and it can have a significant impact on your MIPS final score. Its default weight is 25% of that score, meaning that it can contribute up to 25 points to it. However, if you are excused from PI (see page 34), that weight would be reallocated to the quality performance category.

#### You Must Use 2015-Edition CEHRT

You will need an EHR system that is a 2015-edition certified EHR technology (CEHRT). To check whether your EHR system is a 2015-edition CEHRT, visit https://chpl.healthit.gov/#/search. (Note your system's CHPL ID#; you will need this when you report your PI performance to CMS.)

What if your 2015-edition certification is still pending? CMS recognizes that some vendors may be providing upgraded EHR systems to practices while 2015-edition certification is still pending. If this is the case with your EHR system, you may still be able to satisfy the 2015-edition CEHRT requirement provided:

- your EHR system has 2015-edition functionality for all 90+ days of your PI performance period, and
- CMS grants 2015-edition 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:** You will need 2015-edition CEHRT. Perform the Security Risk Analysis. Make three attestations. Perform—or claim an exclusion for—all mandatory PI measures. Document your performance in case of 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).

**Not everybody has to take part in PI.** In some cases, you may be excused from performing the PI measures (see page 34).

#### **Understand How PI Is Structured**

PI is now arranged around four objectives: 1) e-Prescribing; 2) Health Information Exchange; 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 8, page 35).

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 9, page 37). For example, there is an exclusion available for the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure. If you qualify for and claim this exclusion, the 20 points available for that measure 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, which CMS has described as "the crux" of the PI performance category. And the e-Prescribing objective's opioid-related bonus measure is optional in

2020, and therefore doesn't need an exclusion.

#### **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 2020 calendar year. However, it must be an analysis of the same 2015-edition 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. Check for changes to the measures (these are flagged in the measure descriptions 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—is data being entered into the right field? Do you need to make change 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 2020 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 with ONC 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.)

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 Guery 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."

#### 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 NPIs and TINs as Identifiers," page 13). 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 next page). 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 70%, meaning quality would contribute up to 70 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 8).

Warning: If you do any PI reporting for the 2020 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% when calculating 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 that might qualify for the significant hardship exception:

- insufficient internet connectivity and insurmountable barriers prevented you from obtaining sufficient access;
- extreme and uncontrollable circumstances that caused

#### Table 8: Promoting Interoperability (PI)—at a Glance

To get a PI score of more than 0%, you must perform all nine of these steps:

- 1 have 2015-edition CEHRT;
- 2 submit a "Yes" for the Security Risk Analysis attestation;
- 3 submit a "Yes" for the Prevention of Information Blocking attestation;
- 4 submit a "Yes" for the ONC Direct Review attestation; and satisfy the reporting requirements
- 5 through 9, 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	S 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 5 (bonus)
Health Information	6 Report a numerator of at least 1 or claim an exclusion for this measure:	Support Electronic Referral Loops by <i>Sending</i> Health Infor- mation	Report performance rate (numerator/ denominator)	Up to 20
Exchange	Report a numerator of at least 1 or claim an exclusion for this measure:	Support Electronic Referral Loops by <i>Receiving and Incor-</i> <i>porating</i> Health Information	Report performance rate (numerator/denominator)	Up to 20
Provider to Patient Exchange	3 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
	Do one of the following:     Depart two massures or	Immunization Registry Reporting	Attest "yes" or "no"	
	<ul><li>(a) Report two measures, or</li><li>(b) report one measure for</li></ul>	Electronic Case Reporting	Attest "yes" or "no"	
Public Health and Clinical Data Exchange  registries agencies, (c) repo claim one	two different clinical data registries or public health	Public Health Registry Reporting	Attest "yes" or "no"	0 10
	agencies, or  (c) report one measure and claim one exclusion, or  (d) claim two exclusions.	Clinical Data Registry Reporting	Attest "yes" or "no"	0 or 10
		Syndromic Surveillance Reporting	Attest "yes" or "no"	

2020 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).

your CEHRT to become unavailable (see page 13), 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 2019 or 2020 (though you must be able to show a good faith effort to replace it with a CEHRT and if you have qualified for this exception multiple years, check whether you have maxed out); and
- 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 being scored on the PI performance category.

**Submit your application by Dec. 31, 2020.** When can you start submitting applications for the PI hardship exception? In past years, CMS opened the application process in August. The submission link is usually posted at https://qpp.cms.gov/mips/exception-applications.

Want tips on submitting this application? The Academy

has posted some guidance at aao.org/medicare/promoting-interoperability/exceptions.

The exception is only good for one year at a time. If you applied for this exception in 2019 and it was approved, the approval doesn't roll over to 2020—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 13), 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.



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### Table 9: 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	2020 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 would be distributed to each of the HIE measures.
	Query of Prescription Drug Monitoring Program (PDMP)	Up to 5 (bonus)	No exclusion is needed for this optional bonus measure.	
Health Information Exchange	Support Electronic Referral Loops by Sending Health Infor- mation	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 Incorporating 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 Infor- mation measure.
Provider to Patient Exchange	Provide Patients Elec- tronic Access to Their Health Information	Up to 40	No exclusion available.	
Public Health and Clinical Data Exchange	Immunization Registry Reporting Electronic Case Reporting Public Health Registry Reporting Clinical Data Registry Reporting Syndromic Surveillance 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.

Continued on page 38.

Table 9: PI Measure Exclusions—at a Glance (continued)					
Objective	2019 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 10: Pl'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	2019 Pl 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)	Up to 5 (bonus)	Didn't report this optional measure.		
Health Information Exchange	Support Electronic Referral Loops by <i>Sending</i> Health Information	Up to 20	135/185	73%	73% of 20 = 15
	Support Electronic Referral Loops by <i>Receiving and</i> <i>Incorporating</i> Health Information	Up to 20	145/175	83%	83% of 20 = 17
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	Immunization Registry Reporting	0 or 10	Claimed exclusion	N/A	10
Data Exchange	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 avail	able:	110	Total points scored:		80
2020 PI score is s	2020 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).



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MAX OUT YOUR SCORE FOR THIS PERFORMANCE CATEGORY

# **How to Succeed With Improvement Activities**

mprovement 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.

Aside from an important change for practices that report as a group (see "Improvement Activities 101," below) and some changes to your choice of improvement activities, this performance category is largely the same as last year.

### **How You Will Be Scored**

Scoring for this performance category is the same as in 2019. 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)
   Who scores double? MIPS participants can score double

### **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.

**New for group reporting in 2020:** For group reporting, each improvement activity must be performed by at least 50% of the group's clinicians (up from just one clinician last year).

for an improvement activity if they have one of these special statuses:

- small practice (fewer than 16 eligible clinicians during the MIPS determination period; see page 12),
- 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 in the past),
- 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 Lookup tool. (See "What's Your MIPS Participation Status?" on page 12.)

**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  $(2 \times 20 \text{ points})$
- two medium-weighted activities (2  $\times$  10 points) and one high-weighted activity (1  $\times$  20 points), or
- four medium-weighted activities ( $4 \times 10$  points). If you are eligible to score double, you can accrue 40 points by performing:
- one high-weighted activity ( $1 \times 40$  points) or
- two medium-weighted activities (2  $\times$  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 2020.

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.

### 2020 Versus 2019

What's new with improvement activities for 2020?

More reporting needed for groups. In 2020, 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). 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. (In 2019, only one of the group's clinicians needed to perform the activity.)

**CMS** has removed some improvement activities. CMS has removed 15 activities, including five that you could report via the IRIS Registry in 2019:

- IA\_AHE\_4: Leveraging a QCDR for use of standard questionnaires
- IA\_CC\_4: TCPI Participation
- IA\_CC\_6: Use of QCDR to promote standard practices, tools, and processes in practice for improvement in care coordination
- IA\_PM\_10: Use of QCDR data for quality improvement such as comparative analysis reports across patient populations
- IA\_PSPA\_5: Annual registration in the Prescription Drug Monitoring Program

CMS makes substantive changes to IA\_PSPA\_7: Use of QCDR data for ongoing practice assessment and improvements. CMS removed several activities (see above) and incorporated them into IA\_PSPA\_7.

### **Select, Perform, and Document Your Activities**

The MIPS regulations include 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 61 improvement activities that are most meaningful for ophthalmology practices (see Table 11, page 42).

**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 activity 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 2020 calendar year.

pocument 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. Last summer, Guidehouse, a CMS contractor, started contacting practices to conduct the first ever MIPS audits. If you receive such a request, please contact the Academy at mips@aao.org.

### Table 11: Improvement Activities—at a Glance

Which improvement activities should you perform? The IRIS Registry supports reporting of the 61 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 12 (page 45), as well as the detailed specifications and documentation suggestions at aao.org/medicare/improvement-activities.

	HIGH-WEIGHTED ACTIVITIES					
	ID#	Improvement Activity	Notes			
	Achieving Health Equity					
45	IA_AHE_1	Engagement of new Medicaid patients and follow-up	No EHR required			
page	IA_AHE_3	Promote use of patient-reported outcome tools	No EHR required, new*			
ed	IIA_AHE_6	Provide education opportunities for new clinicians	No EHR required			
		Beneficiary Engagement				
page 45	IA_BE_6	Collection and follow-up on patient experience and satisfaction data on beneficiary engagement	No EHR required			
pag	IA_BE_14	Engage patients and families to guide improvement in the system of care	No EHR required, new*			
		Emergency Response and Preparedness				
46	IA_ERP_2	Participation in a 60-day or greater effort to support domestic or international humanitarian needs.	No EHR required			
		Expanded Practice Access				
46	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				
	IA_PSPA_6	Consultation of the Prescription Drug Monitoring Program	No EHR required, new*			
46	IA_PSPA_11	Participation in CAHPS or other supplemental questionnaire	No EHR required			
page	IA_PSPA_22	CDC Training on CDC's guideline for prescribing opioids for chronic pain <sup>†</sup>	No EHR required, new*			
	IA_PSPA_23	Completion of CDC training on antibiotic stewardship <sup>†</sup>	No EHR required, new*			
	IA_PSPA_31	Patient medication risk education	No EHR required, new*			
47	IA_PSPA_32	Use of CDC guideline for clinical decision support to prescribe opioids for chronic pain via clinical decision support	New*			
		Population Management				
page 47	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, new*			
O.	IA_PM_7	Use of QCDR for feedback reports that incorporate population health	Facilitated by IRIS Registry-EHR integration			

<sup>\* &</sup>quot;New" means that this is the first year that the improvement activity can be reported via the IRIS Registry. It doesn't necessarily mean that the improvement activity didn't exist in 2019.

<sup>&</sup>lt;sup>†</sup> 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					
47	IA_AHE_5	MIPS eligible clinician leadership in clinical trials or CBPR [community-based participatory research]	No EHR required, new*			
48	IA_AHE_7	Comprehensive eye exams	No EHR required			
	Beneficiary Engagement					
	IA_BE_1	Use of certified EHR to capture patient reported outcomes	New*			
	IA_BE_3	Engagement with QIN-QIO to implement self-management training programs [Quality Innovation Network-Quality Improvement Organization]	No EHR required, new*			
page 48	IA_BE_4	Engagement of patients through implementation of improvements in patient portal				
ă	IA_BE_5	Enhancements/regular updates to practice websites/tools that also include considerations for patients with cognitive disabilities	No EHR required, new*			
	IA_BE_12	Use evidence-based decision aids to support shared decision-making.	No EHR required, new*			
	IA_BE_13	Regularly assess the patient experience of care through surveys, advisory councils and/or other mechanisms	No EHR required			
page 49	IA_BE_15	Engagement of patients, family, and caregivers in developing a plan of care				
pa	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					
	IA_CC_1	Implementation of use of specialist reports back to referring clinician or group to close referral loop	No EHR required			
ge 49	IA_CC_2	Implementation of improvements that contribute to more timely communication of test results	No EHR required			
ba	IA_CC_7	Regular training in care coordination	No EHR required, new*			
	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, new*			
20	IA_CC_12	Care coordination agreements that promote improvements in patient tracking across settings	No EHR required, new*			
page 50	IA_CC_13	Practice improvements for bilateral exchange of patient information				
	IA_CC_14	Practice improvements that engage community resources to support patient health goals	No EHR required, new*			
	IA_CC_18	Relationship-centered communication	No EHR required, new*			
		Emergency Response and Preparedness				
20	IA_ERP_1	Participation on Disaster Medical Assistance Team, registered for 6 months.	No EHR required, new*			

		Expanded Practice Access	
	IA_EPA_2	Use of telehealth services that expand practice access	No EHR required
51	IA_EPA_3	Collection and use of patient experience and satisfaction data on access	No EHR required
See page	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, new*
	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	
<u> </u>	IA_PSPA_1	Participation in an AHRQ-listed patient safety organization.	New*
page 51	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, new*
	IA_PSPA_7	Use of QCDR data for ongoing practice assessment and improvements	Facilitated by IRIS Registry-EHR integration
52	IA_PSPA_8	Use of patient safety tools	No EHR required, new*
page	IA_PSPA_9	Completion of the AMA STEPS Forward program	No EHR required, new*
ď	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, new*
	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, new*
2	IA_PSPA_18	Measurement and improvement [of quality] at the practice and panel level	No EHR required
page 53	IA_PSPA_19	Implementation of formal quality improvement methods, practice changes, or other practice improvement processes	No EHR required, new*
Ω	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, new*
	IA_PSPA_25	Cost display for laboratory and radiographic orders	No EHR required, new*
page 54	IA_PSPA_26	Communication of unscheduled visit for adverse drug event and nature of event	No EHR required, new*
ed ed	IA_PSPA_28	Completion of an accredited safety or quality improvement program	No EHR required, new*
		Population Management	
54	IA_PM_5	Engagement of community for health status improvement	No EHR required, new*
page	IA_PM_6	Use of toolsets or other resources to close healthcare disparities across communities	No EHR required, new*
page 55	IA_PM_11	Regular review practices in place on targeted patient population needs	No EHR required, new*
pai	IA_PM_17	Participation in population health research	No EHR required, new*

<sup>\* &</sup>quot;New" means that this is the first year that the improvement activity can be reported via the IRIS Registry. It doesn't necessarily mean that the improvement activity didn't exist in 2019.

### Table 12: Improvement Activity Descriptions

The IRIS Registry supports reporting of the 61 improvement activities that are most relevant to ophthalmology—15 of those are high-weighted (see below) and 46 are medium-weighted (see page 47).

**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.

**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 of 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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**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 experi-

ence 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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**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 nearreal time to clinical care teams, active devices and platforms 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.

### **Expanded Practice Access**

# 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. New: This will be the first time you can use the IRIS Registry to attest to this activity. **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 3 days. Clinicians must attest to 75 percent 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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**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:** New: This will be the first time you can use the IRIS Registry to attest to this improvement activity. 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 Clinic (FQHC) quality improvement activities

**Scoring:** High weighted.

**Notes:** No EHR required. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity

**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 benchmark-

ing 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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

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 **EHR Required:** No EHR required.

**Description:** In order to receive credit for this activity, MIPS eligible clinicians must promote the importance of a comprehensive eye exam, which may be accomplished by providing literature and/or facilitating a conversation about this topic using resources such as the "Think About Your Eyes" campaign and/or 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.

This activity is intended for:

(1) non-ophthalmologists/optometrist 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.

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.

**Notes:** New: This will be the first time you can use the IRIS Registry to attest to this improvement activity. **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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**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 patients through implementation of improvements in patient portal

Scoring: Medium weighted.

**Description:** Access to an enhanced patient portal that provides up-to-date information related to relevant chronic disease health or blood pressure control, and

includes interactive features allowing patients to enter health information and/or enables bidirectional communication about medication changes and adherence.

# 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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**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=/InfoTech GenInfo/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. New: This will be the first time you can use the IRIS Registry to attest to this improve-

ment activity.

**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

### IA\_BE\_15: Engagement of patients, family, and caregivers in developing a plan of care

Scoring: Medium weighted.

Notes: New: This will be the first time you can use the IRIS Registry to attest to this improvement activity. 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 the 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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**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 highquality, 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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**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 each 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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**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 clinicians 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.

Notes: New: This will be the first time you can use the IRIS Registry to attest to this improvement activity. **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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**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/patientsafety/culture/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 improve-

ments 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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**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 meaning-

ful 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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**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. New: This will be the first time you can use the IRIS Registry to attest to this improve-

ment activity.

**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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**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:

- Train appropriate staff on interpretation of cost and utilization information;
- 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 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

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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**Description:** Implementation of fall screening and assess-

ment 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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**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 percent 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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

**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 Organi-

zation (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. New: This will be the first time you can use the IRIS Registry to attest to this improvement activity.

Description: Implementation of regular reviews of targeted patient population needs, such as structured clinical case reviews, which includes access to reports that

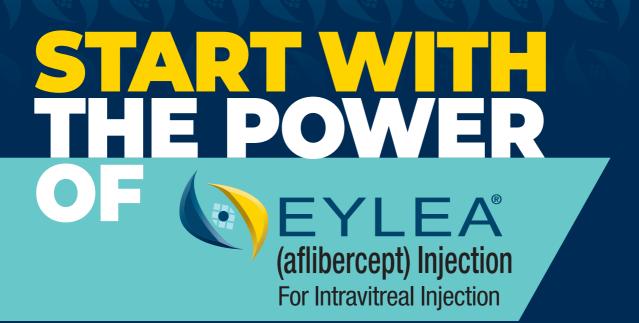
show unique characteristics of eligible clinician's patient population, identification of vulnerable patients, and how clinical treatment needs are being tailored, if necessary, to address unique needs and what resources in the community have been identified as additional resources. CMS note: This activity 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.



As Demonstrated in Phase 3 Clinical Trials<sup>1</sup>

# 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

# TRUST ≈8 YEARS of Extensive Clinical Experience and the Integrity of Data From Large, Well-Controlled Trials¹

**EYLEA IS THE** 

PRESCRIBED
anti-VEGF
FDA approved for
Wet AMD, DME,
and MEfRVO\*

\*IBM Truven MarketScan data: Number of injections administered from Q4 2017 through Q3 2018; data on file. **AN ESTIMATED** 

MILLION
doses
administered
to ≈790,000
eyes since
launch
(and counting)²

ACROSS ALL APPROVED INDICATIONS



### **START WITH EYLEA**

Visit HCP.EYLEA.us to see our data.

### **ADVERSE REACTIONS**

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

### **INDICATIONS**

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

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

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

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



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

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

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

### 4 CONTRAINDICATIONS

4.1 Ocular or Periocular Infections
EYLEA is contraindicated in patients with ocular or periocular infections.

**4.2 Active Intraocular Inflammation** EYLEA is contraindicated in patients with active intraocular inflammation

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

reactions may manifest as rash, pruntus, unclana, severe anaphylactic/

See Patient Consistent in Intraocular Pressure.

Acute increases 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 Thromboemholic Events

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 1.3% (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 mibizumab; through 96 weeks, the incidence was 3.3% (60 out of 1824) in the EYLEA group compared with 5.2% (19 out of 578) in the rombined 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% (10 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA compared with 4.2% (10 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA or compared with 4.2% (10 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA or compared with 4.2% (10 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA out of 5.8% (10 out of 5.8%) in the Control group.

### 6 ADVERSE REACTIONS

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. Amount of 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 1225 patients treated with the 2-mg dose, in 2 double-masked, controlled clinical studies (VIEWI and VIEW2) for 24 months (with active control in year I).

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

### REGENERON

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

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Initial U.S. Approval: 2011 Based on the August 2019 EYLEA" (aflibercept) Injection full Prescribing Information. EYL.19.07.0306

Issue Date: 08/2019

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

	CF	RVO	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%
Evelid 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 102.

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

	Baseline t	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

Less common devices reactions reported in 1978 of the potential treated with ELEA week hypersensitivity, retain detactioning, retain detactioning, retain detactioning the account of the properties of the proper

### 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 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 affiliercept) 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 affilbercept, treatment with EYLEA may pose a risk to human embryofetal development. EYLEA should be used during pregnancy only if the potential benti usifies 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.

### <u>Data</u> Animal Data

Thinking both the control of the co

In two embryofteal development studies, affilbercept produced adverse embryofteal effects when administered every three day during organogenesis to pregnant rabbits at intravenous doses ≥3 mg per kg, or every six days during organogenesis at subcutant doses a.0.1 mg per kg.
Adverse embryofteal effects included increased incidences of postimplantation loss and fetal malformations, including anasarca, umbilical hernia, diaphragmatic hernia, gastroschisis, cleft palate, ectrodactyly, intestinal atresia, spina bifida, encephalomeningoc heart and major vesad defects, and skeletal malformations (fused vertebrae, sternebrae, and ribs, supernumerary vertebral arternal No Observed Adverse Effect Level (NOAE) in these studies was 3 mg per kg. Affibercept produced fetal malformations at all doses assessed in rabbits and the fetal NOAEL was not dentified. At the lowest dose shown to produce adverse embryofteal effects in rabbits (O.1 mg per kg), systemic exposure (AUC) of free afficerept was approximately 6 times higher than systemic exposure (AUC) observed in humans after a single intravitreal dose of 2 mg.

### 8.2 Lactation

RES 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 cynonolgus 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

If 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.

NO REPORTING NEEDED FOR THIS PERFORMANCE CATEGORY

## **How CMS Evaluates Cost**

ost 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 15%, meaning that it can contribute up to 15 points to that score.

# Twenty Cost Measures in 2020, But Only One Is Likely to Apply to Ophthalmologists

This year, cost measures include:

- the Total Per Capita Cost (TPCC) measure,
- · the Medicare Spending Per Beneficiary measure, and
- 18 episode-based measures, including the Routine Cataract Surgery With Intraocular Lens (IOL) Implantation measure.

Only one cost measures is likely to apply to ophthalmologists. As an ophthalmologist, you may be scored on the cataract surgery measure, but the other 17 episode-based cost measures and the Medicare Spending Per Beneficiary measure should not apply to you, and—new for 2020—ophthalmologists and optometrists are explicitly excluded from the TPCC measure.

**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, 2020 to Dec. 31, 2020.

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

### **Cost 101**

Default weight in MIPS final score: 15%.

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.

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 8).

### **Routine Cataract Surgery Measure**

The Routine Cataract Surgery 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 2020.

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 (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 new 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.

New for 2020: Ophthalmologists and optometrists are excluded from the TPCC measure. In past years, 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

### What You Can Do

**Do you perform cataract surgery?** If you—or, if reporting as a group, anybody in your practice—performs cataract surgery, familiarize yourself with the Routine Cataract Surgery 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 will send you some detailed feedback this summer and has said that it aims to get this to you by July.

meeting the 20-patient case minimum for this measure. In 2020, ophthalmologists and optometrists will be 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.

### **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 15 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 15% of your MIPS final score (0-100 points), a cost score of 60% would contribute 9 points (60% of 15 points) to that score.

### **Cost's Shifting Role in Your MIPS Final Score**

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

**Future weight?** At time of press, CMS had not yet announced cost's weight for 2021. By 2022, CMS is required by statute to weight cost at 30% of your MIPS final score.

### Key Dates for Performance Year 2020

2019	Nov. 1	CMS publishes the 2020 MIPS rules.
20	Dec. 31	Deadline to form a virtual group for the 2020 performance year.
	Jan. 1	Start of 2020 MIPS performance year.
	June 1	Deadline to sign agreements for IRIS Registry-EHR integration (if not already integrated).
	Aug. 1	Deadline to complete integration of your EHR system with the IRIS Registry for automated transmission of 2020 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).
2020	Late Summer	CMS starts accepting applications for 1) extreme and uncontrollable circumstances exceptions (see page 13) and 2) hardship exception to PI performance category (see page 35).
	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 13) and 2) hardship exception to PI performance category (see page 35).
		End of 2020 MIPS performance year.
		Deadline to submit your 2020 IRIS Registry data release consent form.
	Jan. 31	Deadline for IRIS Registry users to enter 2020 quality measure data, attest to PI measures, and attest to improvement activities.
_	March 31	Last day to submit 2020 MIPS data if reporting directly to the CMS QPP attestation portal.
2021	July	CMS will provide you with feedback based on your 2020 performance year data.
	July	Targeted review starts after release of feedback data.
	Aug. 31	Targeted review ends.
	Dec. 1	CMS must notify MIPS participants of their 2022 payment adjustment factor at least 30 days before the 2022 payment year.
2022	Jan. 1	Your Medicare Part B reimbursements will start being adjusted up or down based on your 2020 MIPS performance.

**Quarterly to-do list for EHR users:** If you have integrated your electronic health record (EHR) system with the IRIS Registry, you should do the following at least quarterly.

For promoting interoperability (PI): Run your EHR systems 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.

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

### CMS Status Determination Dates for Performance Year 2020

MIPS Pathway	
MIPS Determination Period: Segment 1	Oct. 1, 2018-Sept. 30, 2019 (plus a 30-day claims run out)
MIPS Determination Period: Segment 2	Oct. 1, 2019-Sept. 30, 2020 (no claims run out)

THE ACADEMY CAN HELP YOU SUCCEED

# Your Nine-Step To-Do List for MIPS Resources

se this to-do list to make sure that you are using all the key MIPS resources from the Academy, the American Academy of Ophthalmic Executives (AAOE), and CMS.

### **Start Today**

- **1. Bookmark aao.org/medicare.** From this hub page, you can navigate to a rich range of ophthalmic-specific resources, including:
- The 2020 MIPS Small Practice Roadmap
- A survival guide to help solo practitioners and small practices
- The 2020 MIPS Large Practice Roadmap
- Guidance on the four performance categories: quality, promoting interoperability, improvement activities, and cost
- Subspecialty-specific lists of quality measures
- A dedicated web page for each of the quality measures most relevant to ophthalmology. These web pages feature:
  - -reporting options
  - -instructions
- -lists of relevant ICD-10, CPT Category I, HCPCS, and CPT Category II codes
  - -benchmarks
- A web page for each of the most relevant improvement activities and the promoting interoperability measures
- A MIPS-specific news feed
- 2. Make the IRIS Registry your one-stop shop for MIPS reporting. The IRIS Registry is a unique MIPS reporting mechanism: It is free for Academy members, it focuses exclusively on ophthalmology, and it offers subspecialty-specific QCDR quality measures (see the IRIS measures listed in Table 5, page 23, and Table 6, page 26).

IRIS Registry–EHR integration minimizes the reporting burden. If you integrate your electronic health record (EHR) system with the IRIS Registry, you can use an automated process to extract the data that are needed for reporting the quality performance category. After the performance year is over, an IRIS Registry algorithm will select the quality measures that will maximize your score. Promoting interoperability measures and improvement activities can only be reported manually.

No EHR? If you don't have an EHR system, you can report MIPS quality measures and the subspecialty-specific QCDR quality measures manually via the IRIS Registry.

IRIS Registry staff monitor changes to the MIPS regulations. Physician payment regulations are constantly in flux. When there are changes to MIPS, IRIS Registry staff—working closely with the AAOE's coding specialists and with regulatory experts at the Academy's D.C. office—determine how those changes specifically impact ophthalmology, and they update the IRIS Registry accordingly.

Make sure you are signed up for the IRIS Registry at aao. org/iris-registry. There is a June 1 deadline for signing up for IRIS Registry—EHR integration; if you are only interested in manual reporting via the IRIS Registry and haven't previously registered with it, you have until Oct. 31 to register. (Note: If you signed up for IRIS Registry—EHR integration, you don't sign up separately for the manual reporting.)

- **3.** Check your email. To learn about the latest MIPS developments, watch for *Washington Report Express* (Thursdays), *Medicare Physician Payment Update* (first Saturday of the month), and—if you are in the AAOE—*Practice Management Express* (Sundays).
- **4. Use the email hotlines.** Send MIPS questions to mips@ aao.org; IRIS Registry questions to irisregistry@aao.org.
- **5.** Share tips and crowdsource solutions via the AAOE's e-Talk. If you are a member of the AAOE, use the e-Talk listserv to find out how other practices are tackling MIPS: Go to aao.org/practice-management and click "Listservs." Not an AAOE member? Join at aao.org/member-services/join.
- **6.** Schedule yourself some MIPS time at AAO 2020 (aao. org/2020). At AAO2020 in Las Vegas (Nov. 14-17), sit in on this year's MIPS sessions. You can bring your MIPS and IRIS Registry questions to the Academy Resource Center, where IRIS Registry users also can report their improvement activities and learn how to report quality measures.
- **7. Find out when Codequest is presenting for your state.** Codequest 2020 features tips and guidance on MIPS. See the schedule at aao.org/codequest.
- **8.** Bookmark aao.org/eyenet/mips-manual-2020. The online version of Tables 5, 6, 7, 8, and 11 include links to dedicated web pages for all the quality measures, promoting interoperability measures, and improvement activities that are listed in those at-a-glance charts.
- **9. See how CMS can help.** If you are in a small practice, you can request some free assistance from CMS; to learn more, visit https://qpp.cms.gov/about/small-underserved-rural-practices.





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