AMERICAN ACADEMY OF OPHTHALMOLOGY®

EyeNet®
SUPPLEMENT

MIPS 2018: A Primer and Reference

Published June 2018

What's New for 2018 Reporting

Get an Overview, Then Take a Deeper Dive

61 Quality Measures—At a Glance

Small Practices Get a Break

Protecting Sight. Empowering Lives.®

EYLEA®
(aflibercept) Injection
For Intravitreal Injection

View long-term, 4-year clinical trial data in Wet AMD at EYLEA.us/data

POWER TO PREVAIL

As demonstrated in phase 3 clinical trials evaluating BCVA,* as measured by ETDRS letters, in patients with Wet AMD, Macular Edema following RVO, DME, and by ETDRS-DRSS† in DR in Patients with DME,[1] as well as your clinical experience

Start with EYLEA for proven efficacy outcomes[1]

AMD = Age-related Macular Degeneration; DME = Diabetic Macular Edema; DR = Diabetic Retinopathy; RVO = Retinal Vein Occlusion.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

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

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

- Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA.
- Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.
- 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. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

ADVERSE REACTIONS

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

Please see adjacent Brief Summary.

*Best-corrected visual acuity.
†Early Treatment Diabetic Retinopathy Study–Diabetic Retinopathy Severity Scale: an established grading scale for measuring the severity of DR.

Reference: 1. EYLEA® (aflibercept) Injection full U.S. Prescribing Information. Regeneron Pharmaceuticals, Inc. May 2017.

REGENERON

777 Old Saw Mill River Road, Tarrytown, NY 10591

10/2017
US-LEA-13946

EYLEA®
(aflibercept) Injection
For Intravitreal Injection

BRIEF SUMMARY—Please see the EYLEA package insert for full Prescribing 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) in Patients with DME

4 CONTRAINDICATIONS

4.1 Ocular or Periocular Infections

EYLEA is contraindicated in patients with ocular or periocular infections.

4.2 Active Intraocular Inflammation

EYLEA is contraindicated in patients with active intraocular inflammation.

4.3 Hypersensitivity

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

5 WARNINGS AND PRECAUTIONS

5.1 Endophthalmitis and Retinal Detachments. Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments [*see Adverse Reactions (6.1)*]. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately [*see Dosage and Administration (2.7) and Patient Counseling Information (17)*].

5.2 Increase in Intraocular Pressure. Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA [*see Adverse Reactions (6.1)*]. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with vascular endothelial growth factor (VEGF) inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately [*see Dosage and Administration (2.7)*].

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. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

6 ADVERSE REACTIONS

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

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

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

A total of 2711 patients treated with EYLEA constituted the safety population in seven phase 3 studies. Among those, 2110 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 floaters, intraocular pressure increased, and vitreous detachment.

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, active-controlled clinical studies (VIEW1 and VIEW2) for 12 months.

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

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

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

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

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

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

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

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

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

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

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

6.2 Immunogenicity. As with all therapeutic proteins, there is a potential for an immune response in patients treated with EYLEA. The immunogenicity of EYLEA was evaluated in serum samples. The immunogenicity data reflect the percentage of patients whose test results were considered positive for antibodies to EYLEA in immunoassays. The detection of an immune response is highly dependent on the sensitivity and specificity of the assays used, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to EYLEA with the incidence of antibodies to other products may be misleading.

In the wet AMD, RVO, and DME studies, the pre-treatment incidence of immunoreactivity to EYLEA was approximately 1% to 3% across treatment groups. After dosing with EYLEA for 24-100 weeks, antibodies to EYLEA were detected in a similar percentage range of patients. There were no differences in efficacy or safety between patients with or without immunoreactivity.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

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

Animal reproduction studies are not always predictive of human response, and it is not known whether EYLEA can cause fetal harm when administered to a pregnant woman. Based on the anti-VEGF mechanism of action for aflibercept [*see Clinical Pharmacology (12.1)*], treatment with EYLEA may pose a risk to human embryofetal development. EYLEA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

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

Data

Animal Data

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

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

8.2 Lactation

Risk Summary

There is no information regarding the presence of aflibercept in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production/excretion. Because many drugs are excreted in human milk, and because the potential for absorption and harm to infant growth and development exists, EYLEA is not recommended during breastfeeding.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for EYLEA and any potential adverse effects on the breastfed child from EYLEA.

8.3 Females and Males of Reproductive Potential

Contraception

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

Infertility

There are no data regarding the effects of EYLEA on human fertility. Aflibercept adversely affected female and male reproductive systems in cynomolgus monkeys when administered by intravenous injection at a dose approximately 1500 times higher than the systemic level observed humans with an intravitreal dose of 2 mg. A No Observed Adverse Effect Level (NOAEL) was not identified. These findings were reversible within 20 weeks after cessation of treatment [*see Nonclinical Toxicology (13.1)*].

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

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

17 PATIENT COUNSELING INFORMATION

In the days following EYLEA administration, patients are at risk of developing endophthalmitis or retinal detachment. If the eye becomes red, sensitive to light, painful, or develops a change in vision, advise patients to seek immediate care from an ophthalmologist [*see Warnings and Precautions (5.1)*].

Patients may experience temporary visual disturbances after an intravitreal injection with EYLEA and the associated eye examinations [*see Adverse Reactions (6)*]. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

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

Issue Date: June 2017
Initial U.S. Approval: 2011

Based on the May 2017 EYLEA® (aflibercept) Injection full Prescribing Information.

REGENERON

AMERICAN ACADEMY
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Programs

Saturday, Oct. 27

Sunday, Oct. 28

Monday, Oct. 29

Room E353c

McCormick Place

Check-in and Lunch Pickup

12:15-12:30 p.m. Lunches are provided on a first-come basis.

Program

12:30-1:30 p.m.

Check aao.org/eyenet/corporate-events for updated program information.

** These programs are non-CME and are developed independently by industry. They are not affiliated with the official program of AAO 2018 or Subspecialty Day. By attending a lunch, you may be subject to reporting under the Physician Payment Sunshine Act.*

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GOOD NEWS, BAD NEWS

MIPS—What's New for 2018 Reporting

The 2018 MIPS regulations included some welcome changes, such as increased relief for small practices, along with some undesirable developments. Here is a brief summary of what's new.

Your Final Score Got More Complicated

Your MIPS final score is a composite score. In 2017, it was based on your scores for 3 performance categories; this year, CMS will factor in 4 performance category scores and up to 2 new bonus scores.

Your MIPS final score (0-100 points) will mostly be based on 4 performance category scores. For each performance category, you get a score of 0%-100%, and its contribution to your final score is weighted (e.g., quality's weight is 50% of the final score, meaning it can contribute up to 50 points). The 4 scores would typically be weighted as follows:

- quality—50% (0-50 points), down from 60% in 2017
- advancing care information (ACI)—25% (0-25 points)
- improvement activities—15% (0-15 points)
- cost—10% (0-10 points), up from 0% in 2017

There are 2 new bonus scores:

- small practice bonus—0 or 5 points (see page 52)
- complex patient bonus score—0-5 points (see page 53)

Your MIPS final score is capped at 100 points.

In 2018, there are more opportunities to be excused from ACI. For example, you can apply for a significant hardship exception if you are in a small practice or if your electronic health record (EHR) system gets decertified (see page 37). Like last year, CMS is expected to start accepting applications in August; it will stop accepting applications after Dec. 31, 2018. If your application is approved, ACI's contribution to your final score is reduced to 0, and quality's weight is increased to compensate (see Table 1, page 9).

In extreme and uncontrollable circumstances, you can apply to have any performance category reweighted. Read "Quakes, Fires, and Other Disasters!" (see page 13).

Bonuses and Penalties Are Starting to Increase

Your MIPS final score in 2017 impacts your 2019 payments; your 2018 final score impacts your 2020 payments.

You need to score more points to avoid the penalty. In 2017, if your final score was below a 3-point performance threshold, your 2019 payments will be penalized; in 2018, the performance threshold to avoid a penalty has increased to 15 points (see Table 19, page 52).

The maximum penalty has increased. In 2017, a final score of 0 points would result in a –4% payment adjustment in 2019; in 2018, a final score of 3.75 points or less will result in a –5% payment adjustment in 2020.

2 Key Changes and an Interesting Addition

An increase in the low-volume threshold will exempt more clinicians. You can choose not to participate in MIPS if you provide a low volume of Medicare Part B services over a specific 12-month period (see top of page 11). How low? In 2018, the threshold is:

- no more than $90,000 of Medicare Part B allowed charges (up from $30,000 in 2017), or
- no more than 200 patients (up from 100 patients).

CMS will determine whether your practice is deemed small (15 or fewer eligible clinicians) or large (16 or more), and will do so based on historic data. This new approach (see page 12) is in contrast to last year, when practices attested to practice size based on the number of eligible clinicians during the performance year.

Virtual groups have become an option. Solo practices and group practice that have 10 or fewer eligible clinicians can combine their MIPS reporting, but they had to register as a virtual group by Dec. 31, 2017 (see page 11).

What's New in Quality

Here are some of the biggest changes to MIPS quality reporting.

Reduced contribution to final score. The quality performance category now contributes up to 50 points to your MIPS final score (down from 60 points in 2017).

Report 1 year of data. The performance period for quality is now the full calendar year (up from 90 days in 2017).

Report on more patients. The data completeness criteria (see page 24) is now 60% of applicable patients for each measure (up from 50% in 2017).

For large practices, quality measures now have a floor of 1 point. If you don't meet the data completeness criteria for a measure, and you are reporting as part of a large practice, you will score 1 point (down from 3 points in 2017); if reporting as part of a small practice, you will score 3 points (same as last year).

More measures available for automated reporting via IRIS Registry/EHR integration. You can now report 17 of the

ophthalmology-specific QCDR measures via IRIS Registry/EHR integration (see Table 12, page 31), but only if the IRIS Registry is able to extract the relevant data from your EHR system. However, these measures do not yet have benchmarks, so points may be limited unless CMS is able to establish a benchmark using 2018 reported data.

Six topped out measures now have a ceiling of 7 points. Most of these measures aren't relevant to ophthalmology, but 1 of them might be used by some ophthalmology practices—measure 224: Melanoma: Overutilization of Imaging Studies in Melanoma.

A new bonus for improved performance. If you reported the quality performance category in 2017, you may be able to score points for improved performance in 2018 (see page 26).

What's New in ACI

Unlike quality, the ACI performance category retains the same contribution to your MIPS final score (0-25 points) as it did in 2017, as well as the same performance period (at least 90 consecutive days). Here's what has changed.

New hardship exceptions for ACI. In certain circumstances, you can apply for an ACI exception. This year, CMS has added exceptions for small practices and for practices whose EHR system has been decertified (see page 37). If CMS approves your application for an ACI exception, you can opt out of ACI reporting. To ensure you aren't penalized for that, CMS reweights how your performance category scores contribute to your MIPS final score: ACI will contribute 0 points (instead of 0-25 points) and quality will contribute 0-75 points (instead of 0-50 points).

Exclusions continued for some base score measures. In November of last year, CMS introduced exclusions for some of the base score measures. These exclusions have been carried over to 2018 (see pages 38 and 40).

3 Ways to Stay Up to Date

Like many government regulations, the MIPS rules are constantly changing. Here's how to stay current:

First, go online. Bookmark the Academy's hub page for MIPS: aao.org/medicare.

Second, read *Washington Report Express.* Each Thursday, check your email for all the latest regulatory and advocacy news.

Third—and most important—report MIPS via the IRIS Registry. The IRIS Registry staff are focused on how each change in the MIPS regulations might impact ophthalmology practices, and they will update the IRIS Registry accordingly. Furthermore, IRIS Registry staff have a deep knowledge of MIPS quality measures—after all, they developed many of the ophthalmology-specific QCDR measures themselves—and, if you are reporting via IRIS Registry/EHR integration, they understand the nuances of obtaining the relevant ophthalmic data from your EHR system.

For more resources, see page 58.

A new bonus for using only 2015-edition CEHRT. You can earn a 10% bonus to your ACI score if you report the ACI measure set using only 2015-edition certified EHR technology for at least 90 consecutive days.

An alternative to the Immunization Registry Reporting measure. In 2017, if you reported the Immunization Registry Reporting measure, you could earn 10% toward your ACI performance score. That is still an option for 2018, but CMS has provided an alternate option. Instead of engaging with an immunization registry, you can earn that 10% toward your performance score by engaging with an alternate registry or agency and reporting an alternate measure (see page 36 to learn what measures are available). Furthermore, the measure can be reported a second time using a different registry or agency to earn a 5% registry/agency bonus score.

Suppose, for example, you integrate your EHR system with the IRIS Registry. Instead of reporting the Immunization Registry measure, you could report an alternate measure—e.g., the Specialized Registry Reporting measure (see page 39)—and earn 10% toward your performance score. But you couldn't use your active engagement with the IRIS Registry to also earn the 5% registry/agency bonus; instead, you would have to engage with a second registry.

What's New for Improvement Activities

This performance category is largely unchanged: Like last year, it contributes up to 15 points to your MIPS final score, and its performance period is a minimum of 90 consecutive days. However, there have been some limited changes, including the following.

You can now report 24 improvement activities—2 more than last year—via the IRIS Registry. The 2 new activities are:

- Transforming Clinical Practice Initiative (TCPI) participation (IA_CC_4)
- Annual Registration in the Prescription Drug Monitoring Program (IA_PSPA_5)

More ophthalmologists will take advantage of the MOC Part IV improvement activity. Last year, as part of a pilot project, the American Board of Ophthalmology (ABO) helped a number of ophthalmologists score improvement activity points while working on their Maintenance of Certification (MOC). See page 43 to learn how you can earn credit for MOC while performing a medium-weighted improvement activity.

What's New for Cost

Although CMS assigned you a cost score for 2017, your cost performance wasn't factored into your MIPS final score. In 2018, cost is slated to contribute up to 10 points to your final score.

Your 2018 cost score will be based on up to 2 measures—the Total Per Capita Cost measure and a Medicare Spending Per Beneficiary (MSPB) measure (see "How CMS Evaluates Cost," page 49).

Next year, CMS hopes to also include some episode-based measures that are currently under development, including one for routine cataract surgery.

GET UP TO SPEED, FAST!

Know the Nuts and Bolts of MIPS

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Now in its second year, the Quality Payment Program (QPP) is Medicare's system for adjusting payments based on clinician performance, with your 2018 performance impacting your 2020 payments.

The Quality Payment Program provides 2 pathways: MIPS and APMs. You can participate either in the Merit-Based Incentive Payment System (MIPS) or in an advanced alternative payment model (advanced APM). MIPS includes a hybrid option—the MIPS APM—for clinicians who are in certain types of accountable care organization (see "APMs in Brief," page 56). Most specialists only qualify for MIPS.

This *EyeNet* supplement focuses on MIPS. Advanced APMs are limited for ophthalmology, so most Academy members will be MIPS participants.

Scoring, Bonuses, and Penalties

Your 2018 MIPS final score (0-100 points) will be based on 4 performance scores. For each performance category, you'll get a score of 0%-100%, and its contribution to your final score will depend on how it is weighted.

Quality performance category is weighted at 50%, meaning it contributes up to 50 points to your final score. This performance category evolved out of the Physician Quality Reporting System (PQRS).

Advancing care information (ACI) performance category is weighted at 25%, meaning it contributes up to 25 points. However, if an ACI exception applies, this contribution is reduced to zero, with quality's contribution being reweighted upward (see "Some Clinicians May Be Excused From ACI," page 37). The ACI category replaced the meaningful use (MU) program for electronic health records (EHRs).

Improvement activities performance category is weighted at 15%, meaning it contributes up to 15 points. In 2018, the requirements and scoring for this performance category are largely the same as they were in 2017. You may also see this category referred to as clinical practice improvement activities (CPIAs), the term used in the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, which is the statute that underpins the QPP.

Cost performance category is weighted at 10%, meaning it contributes up to 10 points. You don't report any additional data for cost; CMS will determine your cost score based on Medicare administrative claims data. You will sometimes see this category referred to as resource use, which is the term used in the 2015 statute.

Note: In addition to the ACI exceptions mentioned above, there are very limited circumstances where you may apply to have 1 or more of these 4 performance categories reweighted (see "Quakes, Fires, and Other Disasters!," page 13).

Your 2018 MIPS final score (0-100 points) will impact your 2020 payments. If your 2018 final score is:

- 0-3.75 points, your 2020 Medicare payments will suffer a 5% penalty;
- more than 3.75 points and less than 15 points, your 2020 Medicare payments will suffer a payment penalty, based on a linear sliding scale;
- 15 points, you will get no penalty and no bonus;
- more than 15 points, you will get a small bonus, based on a linear sliding scale;
- 70-100 points, you will also get an exceptional performance bonus,

Table 1: 2018 MIPS Final Score

Your MIPS final score is a composite score. It is typically based on your scores in 4 performance categories but would be based on 3 scores if you are excused from ACI (see page 35). Less commonly, you may be excused from other performance categories (see Table 3, page 12).

Performance Category	Final Score's Default Composition	Final Score's Composition if an ACI Exception Applies
Quality	0-50 points	0-75 points
+ ACI	0 or 12.5-25 points	
+ Improvement activities	0-15 points	0-15 points
+ Cost	0-10 points	0-10 points
= MIPS final score	0-100 points	0-100 points

based on a linear sliding scale.

For a more detailed look at payment adjustments, see "How CMS Will Calculate Bonuses and Penalties" on page 52.

Why is there a gap year between performance (2018) and payment adjustments (2020)? CMS needs time to process the MIPS data, determine final scores, calculate an adjustment factor that ensures budget neutrality (see page 53), and perform a targeted review.

Performance Period

Your score for a measure or an improvement activity will depend on how you perform over a performance period. The performance period must take place between Jan. 1, 2018 and Dec. 31, 2018, and its length depends on the performance category:

- Quality: 12 months (full calendar year)
- ACI: 90 consecutive days or longer (up to 12 months)
- Improvement activities: 90 consecutive days or longer (up to 12 months)
- Cost: 12 months (full calendar year)

You don't have to tackle ACI and improvement activities at the same time. For example, you could pick a June-August performance period for ACI and a September-November performance period for improvement activities—but you would need to perform all your ACI measures within that June-August time frame and all your improvement activities within that September-November time frame, though they could also extend beyond that period (see "You must perform improvement activities for at least 90 days," page 43).

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

Eligible clinicians *may* participate in MIPS. The term eligible clinician—meaning a clinician who is eligible to take part in MIPS—includes physicians, optometrists, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists.

MIPS eligible clinicians *must* participate in MIPS. Not all eligible clinicians have to participate in MIPS (see the 3 exclusions, described below), but those that do are known as MIPS eligible clinicians. (Note: When the MIPS regulations use the term MIPS eligible clinician, it doesn't just refer to *individuals* who are taking part in MIPS, it can also refer to a *group* that includes such an individual.)

Some eligible clinicians may be exempt from MIPS. You may be exempt from MIPS if at least 1 of the following 3 exclusions applies.

Exclusion 1—Eligible clinicians who are new to Medicare. If you enroll in Medicare for the first time in 2018, and you have not previously submitted claims under Medicare, you will be exempt from the MIPS rules for the 2018 performance year. Furthermore, eligible clinicians who enroll in Medicare toward the end of 2018 may also fall within the low-volume exclusion for the 2019 performance year (see below).

Exclusion 2—Eligible clinicians who are below the low-volume threshold. You will be exempt from MIPS if, over a 12-month period (see next paragraph), you:

- have Medicare Part B allowed charges of no more than $90,000, or
- care for no more than 200 Medicare Part B beneficiaries.

Table 2: Select Your Reporting Mechanism(s)

Reporting Mechanism	Performance Category			Used By	It Involves
	Quality	ACI	Improvement Activities		
Medicare claims	●			Individuals	Real-time reporting
CMS web portal	●	●*	●	Individuals or groups	Manual data entry
IRIS Registry web portal	●	●*	●	Individuals or groups	Manual data entry
IRIS Registry/EHR integration	●			Individuals or groups	Automated data extraction
EHR vendors	●†	●†	●†	Individuals or groups	A possible fee

Four factors to consider when selecting your reporting mechanism(s):

- For each performance category, select 1 reporting mechanism.
- You don't have to use the same reporting mechanism for all performance categories.
- Group-level reporting: For a given performance category (e.g., improvement activities), everyone within the group must use the same reporting mechanism (e.g., the IRIS Registry web portal).
- Whether or not you have an EHR system, the IRIS Registry offers the least burdensome and most ophthalmology-focused reporting options.

Note: For the cost performance category, your score will be based on Medicare administrative claims data.

*Although you can report ACI via the IRIS Registry web portal or the CMS web attestation portal, you also need a certified EHR technology to perform the ACI measures. †Contact your EHR vendor to confirm which performance categories, as well as which measures and activities, you can report through them; also ask the vendor for its reporting deadlines.

You have 2 chances to qualify for the low-volume exclusion. To see if you are exempt for the 2018 performance year, CMS will review your data for 2 time periods:

- Sept. 1, 2016, to Aug. 31, 2017, with a 30-day claims run out.
- Sept. 1, 2017, to Aug. 31, 2018, with a 30-day claims run out.

If you are below the low-volume threshold during either of these time periods, you will be exempt—even if you surpass the threshold in the other time period. Why does CMS check data for 2 time periods? The intent of the earlier time period was to enable CMS to inform MIPS eligible clinicians that they are exempt before the performance year started. The review of more current data will identify practices that have had a drop in volume.

Low-volume threshold determinations are made at the individual level *and* at the group level. An eligible clinician could fall below the low-volume threshold at the individual reporting level, but he or she would not be exempt from MIPS if reporting as part of a group that exceeds that threshold. Note: Low-volume threshold determinations are not made at the virtual group level.

Exclusion 3—Eligible clinicians in advanced APMs. If you are participating in an advanced APM (see "APMs in Brief," page 56), you may be exempt from the MIPS rule if you satisfy the APM track's reporting thresholds.

Does an exclusion apply to you? You should receive a letter from CMS indicating whether you are a MIPS eligible clinician and whether any of the 3 exclusions apply to you. Later this year, CMS will perform a second review of clinicians—reviewing services provided from Sept. 1, 2017, to Aug. 31, 2018 (see "Exclusion 2," above)—to see if any providers should be added to the low-volume exclusion list.

You also will be able to check online whether a new clinician exclusion or a low-volume exclusion applies to you (https://qpp.cms.gov/learn/eligibility); you can use a second lookup tool to check whether you are an APM participant (https://data.cms.gov/qplookup). Tip: When you use these lookup tools to check for exclusions, make sure you are checking for the 2018 (not 2017) performance year.

Use of TINs and NPIs as Identifiers

Tax identifier 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). If you are participating in MIPS at the individual level, CMS will use both your TIN and your NPI to distinguish you as a unique MIPS eligible clinician. You must use the same TIN/NPI combination for all performance categories. If you have more than 1 TIN/NPI combination—because, for instance, you moved to a new practice—you will be assessed separately for each TIN. Physicians in such situations should meet the reporting requirements at all the TIN/NPI combinations where they practice during the performance year.

MIPS groups (TIN alone). If you and your colleagues choose to participate jointly as a group, the group's TIN alone will—for reporting purposes—be your identifier for all 4 categories. CMS defines a group as "a single TIN with 2 or more eligible clinicians (including at least 1 MIPS eligible clinician), as identified by their individual NPI, who have reassigned their billing rights to the TIN." Typically, no registration is required to participate in MIPS as a group; the exception is if you are using the CMS web interface (see "CMS Web Portal Versus CMS Web Interface," page 13). Note: Although groups report at the TIN level, payment adjustments will be applied at the individual TIN/NPI level.

Advanced APM entity group. If you and your colleagues participate jointly as an APM entity group (see "APMs in Brief," page 56), each MIPS eligible clinician within that group would be identified by a unique APM participant identifier.

Bonuses and penalties applied at the TIN/NPI level. Whether you participate in MIPS as an individual, as part of a MIPS group, or as part of an APM entity group, payment adjustments will be applied at the TIN/NPI level.

Your payment adjustment will follow you to your next practice. Your final score for the 2018 performance year will impact your payment adjustment during the 2020 payment year, and—unlike PQRS—this is the case even if you move to a new practice after the 2018 performance year finishes. In that scenario, when CMS determines your 2020 payment adjustment, it will look at the 2018 final score that was associated with the TIN you were using in 2018, not the 2018 final score that is associated with your new practice's TIN.

Virtual Groups

This year, you can participate in MIPS as part of a virtual group; however, you must have formed that group by Dec. 31, 2017.

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 1 of whom must be a MIPS eligible clinician). The virtual group must include 2 or more TINs, with each TIN belonging to a solo practitioner or a group of 10 or fewer eligible clinicians.

Why form a virtual group? Small practices that combine together as a virtual group could potentially enjoy some of the economies of scale and expanded options that larger practices have.

Few virtual groups in 2018. Clinicians have found it challenging to think through the complexities of MIPS within their own practice, never mind the repercussions of combining with other practices for MIPS reporting. Consequently, few—if any—ophthalmology practices met the deadline for forming virtual groups for this performance year. However, any practices that did form a virtual group cannot leave the virtual group during the 2018 performance year.

Report as an Individual or as Part of a Group

You can choose to take part in MIPS as an individual or as part of a group. There is a third option, virtual groups, but few practices were able to meet the Dec. 31, 2017, deadline for forming a virtual group (see "Virtual Groups," page 11).

What is a group? For MIPS, a group consists of 2 or more eligible clinicians (each with their own NPI) who have each reassigned their billing rights to the same TIN. At least 1 of them must be a MIPS eligible clinician.

What is group-level reporting? In group reporting, clinicians pool their MIPS data and are scored at the TIN level; they'll all get the same 2018 MIPS final score and will receive the same payment adjustment in 2020. A practice that opts to report as a group will be scored as a group for all 4 performance categories.

Small or Large Practice?

The impact of some MIPS regulations depends on the size of your practice, with small practices sometimes getting a break (see page 19). For the 2017 performance year, you could attest to your practice size, but this year CMS will make that determination—and will do so based on historic data.

How CMS determines practice size. CMS determines how many eligible clinicians are in a practice by reviewing claims data and looking at the number of NPIs associated with the practice's TIN. This would include NPIs of eligible clinicians (NPIs) who were excluded from MIPS—see "Who Does (and Doesn't) Take Part in MIPS," page 10—and consequently weren't taking part in the MIPS program.

Next, it designates practice size as follows:

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

What data does CMS look at? In determining practice size for the 2018 performance year, CMS looks at 12 months of claims data, from Sept. 1, 2016, to Aug. 31, 2017, and will include a 30-day claims run out. Unfortunately, this means practices that have fewer than 16 eligible clinicians in 2018 could be designated as large based on historic data.

Table 3: Reweighting the Performance Categories

CMS can reweight the way performance categories contribute to your MIPS final score as shown below. It would do this in the following situations:

- It approves your application for an exclusion due to extreme and uncontrollable circumstances (see page 13).
- One of the ACI hardship exclusions applies (see "Some Clinicians May Be Excused From ACI," page 37).
- CMS determines that you don't have enough applicable measures for the quality, ACI, or cost performance categories (this is very unlikely).

Reweighting Scenario	Maximum Point Contribution to Final Score (0-100 Points)			
	Quality	ACI	Improvement Activities	Cost
No Reweighting Needed				
Scores for all 4 performance categories	50	25	15	10
Reweight 1 Performance Category to a Zero Weight				
No cost	60	25	15	0
No ACI	75	0	15	10
No quality	0	45	45	10
No improvement activities	65	25	0	10
Reweight 2 Performance Categories to a Zero Weight				
No cost and no ACI	85	0	15	0
No cost and no quality	0	50	50	0
No cost and no improvement activities	75	25	0	0
No ACI and no quality	0	0	90	10
No ACI and no improvement activities	90	0	0	10
No quality and no improvement activities	0	90	0	10
No Score for 3 Performance Categories				
If CMS can only score you on 1 performance category, you would be assigned a MIPS final score of 15 points, which is just enough to avoid the payment penalty.				

Size determined by spring. If your practice is deemed small, CMS has said that it will notify you of that by spring 2018. You also will be able to look up the result of this size determination at https://qpp.cms.gov/participation-lookup.

Quakes, Fires, and Other Disasters!

If you have difficulty reporting 1 or more performance categories due to the impact of "extreme and uncontrollable circumstances"—for example, a fire destroyed your EHR system—you can apply to have your performance categories reweighted. You would need to submit your application no later than Dec. 31, 2018.

What is considered extreme and uncontrollable? It must be a rare event that is entirely outside of the control of the physician and of the facility where he or she works. 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 pertinent details that might impact your ability to report each individual performance category.

How performance categories are reweighted. If CMS approves your application to reweight 1 or 2 performance categories to a zero weighting, the other categories would be reweighted as shown in Table 3 (page 12). However, if CMS only scores you on 1 performance category, CMS would assign you a MIPS final score of 15 points, which is the 2018 performance threshold, which would be enough to avoid a payment penalty.

Use the IRIS Registry for MIPS Reporting

CMS has designated the IRIS Registry (aao.org/iris-registry) both a qualified registry and a qualified clinical data registry (QCDR). Either of these designations would allow the IRIS Registry to be used to report MIPS quality measures, but the QCDR designation also empowers the Academy to develop specialty-specific QCDR measures that can be reported via the IRIS Registry (see Table 12, page 31).

The Academy IRIS Registry provides 2 platforms to help you tackle MIPS. One platform requires EHRs (integrating your EHR system with the clinical data registry) and the other doesn't (manual data entry via a web portal).

In ophthalmology, the IRIS Registry is the MIPS tool of choice. It allows you to do the following:

- **Access a one-stop shop for MIPS reporting.** You can use the IRIS Registry to manually attest to ACI measures and improvement activities, and—either manually or via automated data extraction—report data on quality measures. Using 1 reporting mechanism for all 3 of these performance categories will make MIPS reporting more manageable, and you'll only have to sign 1 data consent release form.
- **Gain access to additional QCDR quality measures.** The Academy developed the QCDR quality measures specifically for ophthalmology (see Table 12, page 31).
- **Use the dashboard to monitor performance.** The IRIS Registry dashboard can act as an early warning system, alerting you to problems with your quality reporting while you still have time to address them.
- **Reduce your reporting burden.** Compared with other reporting options, the IRIS Registry involves less labor and—thanks to its dashboard—less uncertainty.
- **Use a reporting mechanism that is focused exclusively on ophthalmology.** The Academy developed the IRIS Registry as part of its mission to support ophthalmologists and their patients.

You'll find the IRIS Registry increasingly important for MIPS. A founding maxim of MIPS is that CMS should encourage the use of QCDRs, which are expected to play an increasingly prominent role in the payment program over the coming years.

CMS Web Portal Versus CMS Web Interface

You may see 2 similar terms used for 2 very distinct reporting options—CMS web portal and CMS web interface.

The CMS web portal can be used to submit MIPS data. Rather than using the CMS web portal (https://qpp.cms.gov/login), you should consider using the IRIS Registry web portal (aao.org/iris-registry), which is easier to use and is geared exclusively toward ophthalmology.

The CMS web interface is used by some large 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 reporting period. It replaces the PQRS program's GPRO web interface and is only available to practices that have at least 25 eligible clinicians reporting quality data. To utilize this option for 2018, you must register by June 30, 2018.

Next Steps

Decide what reporting mechanism to use. You don't have to use the same reporting mechanism across all performance categories. For instance, you can report quality and improvement activities using the IRIS Registry and report ACI via the CMS web portal. However, within each performance category, you must use just 1 reporting mechanism—the exception is the "Consumer Assessment of Health Providers and Systems (CAHPS) for MIPS" survey, which can be used as a second data submission mechanism for quality but is not applicable for most ophthalmologists.

Use the Academy and AAOE resources. For a sampling of what's available, see page 58.

Physician leadership is crucial. The reporting requirements—and the payment penalties—are expected to ramp up rapidly over the next few years. Because so much money will ultimately be at stake, a physician ought to oversee your practice's MIPS planning and processes, which should be implemented by experienced staff who are keeping track of MIPS' evolving regulations.

Overview 1: The Quality Performance Category

FIRST STEPS

Pick your reporting mechanism for quality measures: If you don't have a certified EHR system, you can choose to report via:

- claims or
- the IRIS Registry web portal.

If you do have a certified EHR system, you also can report via:

- IRIS Registry/EHR integration or
- your EHR vendor.

Which quality measures should you report? If you report via IRIS Registry/EHR integration, you can let an automated process select which quality measures would give you the highest score. If you are using another reporting mechanism, see Tables 11 (page 29) and 12 (page 31) for lists of suitable measures. Measures that don't yet have a benchmark or are topped out may limit your ability to get a high score (see page 25).

REPORTING AT A GLANCE

For all 4 of the reporting mechanisms listed above, your reporting requirements are as follows.

To maximize your quality score, you should do the following:

- Report at least 6 quality measures. Up to 6 quality measures contribute achievement points to your quality score; if you report more than 6, the extra measures can contribute bonus points, but not achievement points, to your quality score.
- Include at least 1 outcome quality measure (if no outcome measure is available, report another high-priority measure).

Editor's note: Other reporting options—such as CMS Web Interface and MIPS APMs—involve different reporting requirements.

Submission thresholds: For each quality measure that you report, you should do both of the following:

1) Meet the case minimum requirement: Report at least 20 cases.

2) Meet the data completion criteria: Submit data for at least 60% of …

- Medicare patients (if submitting by claims) or
- Medicare and non-Medicare patients (if submitting data via the IRIS Registry or your EHR vendor)

… who were seen during the 2018 calendar year and to whom the measure applies.

What if you report more than 6 quality measures? CMS will select the 6 measures that give you the most achievement points based on your performance rates; the remaining measures can still contribute bonus points (see below).

SCORING SUMMARY

How you are scored: If you submit data for a quality measure, CMS determines whether you met both of the submission thresholds:

- If so, you get 3-10 achievement points, based on how you compare against a benchmark for that measure.
- If you meet the data completeness criteria, but not the case minimum requirement, you get 3 achievement points.
- If you don't meet the data completeness criteria, you score 1 point if you are part of a large practice and 3 points if you are part of a small practice, provided you report the measure for at least 1 patient.

High-priority bonus points: You get no bonus points for your first outcome measure (or alternate high-priority measure), but after that you get:

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

CEHRT bonus points: You may get 1 bonus point for each quality measure submitted using EHR or IRIS Registry/EHR integration.

Up to 12 (or 14) bonus points: The high-priority and CEHRT bonuses are each capped at 6 or—if you are scored on the All-Cause Hospital Readmission measure—7 points.

All-Cause Hospital Readmission (ACR) measure: Larger groups (≥ 16 eligible clinicians) with at least 200 ACR cases will also be scored on the ACR measure (up to 10 points). You don't need to report anything; assessment is based on administrative claims. Most ophthalmologists will not be evaluated on this measure.

New: Score extra points for quality improvement. If you scored more achievement points in 2018 than you did in 2017, then you may get an improvement percent score, which is capped at 10 points (see page 26).

Calculating your quality performance score (0%-100%): CMS determines your numerator. This is your total number of achievement points earned on as many as 6 measures plus, if applicable, your ACR points, plus your total bonus points; next, CMS divides that numerator by your denominator, which is 60 (or 70 if the ACR measure applies). Finally, CMS turns the resulting fraction into a percentage (capped at 100%).

This percentage is added to your improvement percent score (see page 26) to determine your score for the quality performance category.

Example: A small group practice reports 6 quality measures and scores 37.5 points, based on its performance rate for those measures. It also scores a 3-point bonus for reporting high-priority measures and a 6-point CEHRT bonus. It adds those together (37.5 + 3 + 6) to determine its numerator (46.5). Because this is a small practice, the ACR measure does not apply, so the denominator is 60. To determine its quality score, it divides the numerator by the denominator (46.5/60), turns the resulting fraction into a percentage (77.5%), and then adds the improvement percent score. Suppose, for example, the improvement percent score is 2.5%, the quality score would be 80%.

Your quality score (0%-100%) contributes up to 50 points to your MIPS final score. Example: If a physician's quality score is 80%, it would contribute 40 points (80% of 50) to her final score.

For a deeper dive, *see pages 21-32.*

Overview 2: The Advancing Care Information (ACI) Performance Category

FIRST STEPS

Your EHR system must be a certified EHR technology (CEHRT). There are 2 types of certification: the 2014 edition and the 2015 edition.

Exceptions: If an ACI exception applies to you (see page 37), the composition of your MIPS final score will be reweighted (see Table 1, page 9).

REPORTING AT A GLANCE AND SCORING SUMMARY

The minimum performance period is 90 consecutive days. (See page 35.)

There are 2 measure sets. If you have a 2014-edition CEHRT, you can use the 2018 ACI transition measure set; if you have a 2015-edition CEHRT, you can choose to use either the ACI measure set or the 2018 ACI transition measure set.

Five scores contribute to your ACI score: Base score, performance score, and 3 bonus scores. Note: While CMS uses percentage points to express ACI scores (e.g., base score of 50%), you will frequently see them expressed as points (e.g., base score of 50 points).

1 Base Score

Base score (0% or 50%) is mandatory. If your base score is 0%, your entire ACI score is 0%.

Base score is all or nothing. To get the full 50%, you must report (or claim an exclusion for) *all* 4 base score measures from the 2018 ACI transition measure set or *all* 5 from the ACI measure set; if you fall short, you get 0%. To learn about the 2 2018 ACI transition measures that have exclusions, see page 38; for the 3 ACI measures with exclusions, see page 40.

The reporting threshold for the base score is fairly low. For the Security Risk Analysis measure, you must report that you performed the analysis; for the other base score measures, report a numerator of at least 1.

2 Performance Score

Performance score (0%-90%) is based on your performance rate for the measures that you report. For instance, the Patient-Specific Education measure can contribute 0%-10% to your ACI performance score. If you meet that measure's requirements for 33% of applicable patients, you would score 4% for that measure.

Mandatory or optional? Most performance score measures are optional, but some of them are also base score measures and are therefore required. However, CMS has added exclusions for some "required" measures. For example, if you seldom refer or transfer patients, you may be excluded from the Health Information Exchange measure (see page 38).

New: Instead of reporting the Immunization Registry Reporting performance score measure, you can engage with a public health agency or clinical data registry (see page 36).

3 4 5 Three Bonus Scores

Registry bonus score (0% or 5%). You can get a 5% bonus if you report to a registry or public health agency.

CEHRT for improvement activities bonus score (0% or 10%). Earn this bonus if you use CEHRT functionality for an improvement activity.

2015-edition CEHRT bonus (0% or 10%). Earn this bonus if you report the ACI measure set using only the 2015-edition CEHRT.

For a deeper dive, see pages 34-41.

Calculating the ACI Score

	Add 5 Scores Together	Contribution to ACI Score
1	Base score	0% or 50%
2 +	performance score	0%-90%
3 +	registry/agency bonus	0% or 5%
4 +	CEHRT for improvement activities bonus	0% or 10%
5 +	2015-edition CEHRT bonus	0% or 10%
=	ACI score	0%-100%

Your ACI score (0%-100%) contributes up to 25 points to your MIPS final score. For example, an ACI score of 80% contributes 20 points.

	2018 ACI Transition Measure Set	ACI Measure Set
Number of measures:	11 measures (see Table 15, page 38)	15 measures (see Table 16, page 40)
Strictly mandatory:	2 base score measures (1 of these also is a performance score measure)	2 base score measures (1 of these also is a performance score measure)
Mandatory, possible exclusion:	2 base score measures (1 of which is also a performance score measure)	3 base score measures (2 are also performance score measures)
Optional:	5 performance score measures, 2 registry/agency bonus measures	6 performance score measures, 4 registry/agency bonus measures
Can be reported using:	2014- or 2015-edition CEHRT or a mixture of 2014- and 2015-edition modules	2015-edition CEHRT or a mixture of 2014- and 2015-edition CEHRT modules

Overview 3: The Improvement Activities Performance Category

REPORTING AT A GLANCE

The *minimum* performance period is 90 consecutive days. Like ACI, this performance category has a minimum performance period of 90 days—but you don't have to use the same 90-day period for both performance categories.

To get the maximum score, you must perform and report 1 to 4 improvement activities. The number of activities depends on how they're weighted, and on the size and location of your practice (see "Scoring Summary," below).

If you use EHR, go for the ACI bonus for using CEHRT for improvement activities. Certain activities not only contribute to your improvement activities score but also can boost your ACI score if performed using certified EHR technology (CEHRT) functionalities.

A yes/no approach to reporting improvement activities. To score points for an activity, affirm (yes) that you successfully performed that activity for at least 90 consecutive days.

Consider the Maintenance of Certification (MOC) Part IV improvement activity. If you have integrated your EHR system with the IRIS Registry, you can work with the American Board of Ophthalmology (ABO) to earn credit for both MIPS and MOC (see page 43).

In case of a future audit, document performance of your improvement activities. For documentation suggestions, visit aao.org/medicare/improvement-activities.

SCORING SUMMARY

How many points do you get for an activity? It depends on how the activity is weighted (and whether you're able to double the score). If the activity weight is:

- Medium—10 points (double score: 20 points)
- High—20 points (double score: 40 points)

Who scores double? Those who are:

- in small practices (≤ 15 eligible clinicians, based on historic data)
- in rural practices (as defined by CMS)
- in practices in geographic health professional shortage areas (HPSAs)
- non–patient-facing MIPS clinicians

Maximum score is 40 points. A small practice could max out by successfully performing and reporting 1 high-weighted activity.

Calculating your improvement activities score (0%-100%). CMS divides your total number of points by 40 and turns the resulting fraction into a percentage. For example, if you get 30 points, your improvement activities score would be 75%.

Your improvement activities score (0%-100%) contributes up to 15 points to your MIPS final score. For example, if your improvement activities score is 75%, it would contribute 11.25 points.

For a deeper dive, *see pages 42-48.*

Overview 4: The Cost Performance Category

NO REPORTING NECESSARY

CMS will review administrative claims data and attempt to score you on 2 measures. The performance period is the full calendar year.

The Total Per Capita Cost measure. If a patient is seen for any office visit during 2018, CMS will attempt to determine if they were seen for primary care services and assign all that patient's Medicare Part A and Part B costs to the primary care clinician.

A 2-step attribution process. First CMS attempts to assign a patient's costs to the primary care physician or supporting clinician (e.g., a nurse practitioner) who provided the patient with the most primary care services during 2018. If it can't do that, CMS assigns the patient's costs to the physician who provided the most office visits for the patient.

The Medicare Spending Per Beneficiary (MSPB) measure. The MSPB measure focuses on hospital admissions. It defines an episode of care as starting 3 days before the admission and ending 30 days after the patient is discharged.

Attribution. All Medicare Part A and Part B costs that were incurred during a patient's episode of care are assigned to the clinician who provided the most Medicare part B costs. Very few ophthalmologists will fall under this measure.

SCORING

You will only be scored on a measure if you meet the case minimum. The Total Per Capita Cost and MSPB measure have case minimums of 20 patients and 35 episodes of care, respectively. If you don't meet the case minimum for both measures, cost's contribution to your MIPS final score will be reweighted to zero and quality's contribution reweighted upward (see Table 3, page 12).

CMS attempts to level the playing field. CMS will, for example, exclude extreme outliers and make risk adjustments. However, the Academy believes that these adjustments are inadequate and the measures are substantively flawed.

Score 1-10 points for each measure. Your score will depend on how your performance compares against the national average for 2018.

CMS calculates your cost score (1%-100%). Your points total is divided by either 10 or 20 (depending on whether you met the case minimum for 1 or 2 measures) and the resulting fraction is turned into a percentage. This is your cost score.

Cost score contributes up to 10 points to your MIPS final score. For example, if your cost score is 50%, it contributes 5 points.

For a deeper dive, *see pages 49-50.*

Table 4: MIPS Timeline 2018—Key Dates for CMS and the IRIS Registry

	Date	CMS	IRIS Registry
2017	Nov. 16	CMS published the 2018 MIPS rules.	
	Dec. 31	Deadline to form a virtual group for the 2018 MIPS performance year.	
2018	Jan. 1	2018 MIPS performance year starts.	
	Spring	CMS notifies clinicians if they are exempt from MIPS.	
		CMS notifies practices whether they have been designated a small practice (see page 12).	
	June 1		Deadline for new users to sign agreements for IRIS Registry/EHR integration, which enables automated reporting of quality data.
	August	ACI hardship application opens in late August: https://qpp.cms.gov/mips/advancing-care-information/hardship-exception.	Aug. 1 deadline for integrating your EHR system with the IRIS Registry for automated reporting of 2018 quality data.
		Aug. 31 deadline for submitting your improvement plan to the American Board of Ophthalmology for the MOC Part IV improvement activity (see page 43).	
	Oct. 1	ACI and improvement activities have a minimum performance period of 90 days. Start by Oct. 1. (The Academy strongly urges you to start much earlier in the year.)	
	Oct. 31		Deadline for new users to sign agreements to use the IRIS Registry web portal for improvement activities attestation, ACI attestation, and manual reporting of quality measures.*
	Dec. 31	Application deadline for (1) ACI hardship and (2) reweighting due to extreme circumstances.	
		End of 2018 performance year.	
2019	Jan. 15		Deadline to submit your 2018 IRIS Registry data release consent form.
			Deadline to enter 2018 quality measure data, attest to ACI, and attest to improvement activities through the IRIS Registry web portal.
	March 1	Last day for CMS to process claims from 2018 for claims-based reporting.	
	March 31	Last day to submit 2018 MIPS data if reporting directly to the CMS attestation portal.	
	Dec. 1	CMS must notify MIPS participants of their 2020 payment adjustment factor at least 30 days before the 2020 payment year.	
2020	Jan. 1	Your Medicare Part B reimbursements will be adjusted up or down based on your 2018 MIPS performance.	

* If you already signed up for IRIS Registry/EHR integration, you don't have to sign up separately to use the web portal for attestation.

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THE RULES AREN'T ONE SIZE FITS ALL

Small Practices Get a Break

BY REBECCA HANCOCK, FLORA LUM, MD, CHRIS MCDONAGH, CHERIE MCNETT, JESSICA PETERSON, MD, MPH, AND SUE VICCHRILLI, COT, OCS, OCSR.

While the transition to MIPS is burdensome for all clinicians, it is particularly challenging for solo practices and small group practices. With that in mind, CMS has provided small practices with several concessions (see Table 5, below) that should help them to avoid the penalty and may enable them to earn a bonus.

What Is a Small Practice?

A practice is small if it has 15 or fewer eligible clinicians. Simple, right? Not quite. For the 2017 performance year, you could attest to your practice's size based on real-time staffing levels. But for the 2018 performance year, CMS makes that determination—and does so based on historic claims data.

CMS determines practice size based on claims data from 2016 and 2017. CMS has said that, for operational reasons, it needs to know early in the performance year whether you are in a small practice, and this is why it now determines practice size based on historic claims data. To learn more, see "Small or Large Practice?" on page 12.

CMS counts clinicians who aren't participating in MIPS. When determining practice size, CMS counts eligible clinicians even if they aren't taking part in MIPS because one of the program exclusions (see page 10) applies to them.

CMS is making its practice size–determinations available via the MIPS Participation Status lookup tool at https://qpp.cms.gov/participation-lookup.

How to Avoid the MIPS Penalty

All small practices should be able to get a 2018 MIPS final score of 15 points, which would be enough to avoid a payment penalty in 2020. They can do this by:

- Performing and reporting 1 high-weight improvement activity; or
- doing minimal reporting (report on at least 1 patient at least 1 time) for 6 quality measures.

Although either option would earn a small practice a MIPS final score of 15 points, it would be safer to pursue both options, and to report quality more extensively. (Note: Larger practices must do more to attain 15 points.)

CMS Is Offering Help for Small Practices

CMS provides customized assistance to clinicians in small practices. To find out what help is available, visit https://qpp.cms.gov/about/small-underserved-rural-practices.

Table 5: How CMS Accommodates Small Practices

General	**Small practice bonus for MIPS final score.** If you report at least 1 MIPS performance category, you may be awarded a 5-point bonus if you are in a small practice (see "Small practices get a 5-point bonus," page 52).
	Low volume exclusion. You may be exempt from MIPS if, over a specific 12-month period, you have Medicare Part B allowables of no more than $90,000 or care for no more than 200 Medicare Part B beneficiaries (see "Exclusion 2—Eligible clinicians who are below the low-volume threshold," page 11). Given ophthalmology's patient mix, this exclusion will apply to a limited number of ophthalmology practices.
	Virtual groups. CMS developed this option with small practices in mind, but few practices are likely to go this route in 2018 (see "Virtual Groups," page 11).
Quality	**Small practices enjoy a 3-point floor for quality measures.** Like last year, small practices can still earn 3 points for a measure with minimal reporting (see "Meet Quality's Data Submission Thresholds," page 24).
Advancing Care Information (ACI)	**Significant hardship exception.** If you are in a small practice, you can apply to be excused from ACI (see "Some Clinicians May Be Excused From ACI," page 37).
Improvement Activities	**Score double.** If you're in a small practice, your point score for an improvement activity is automatically doubled (see "How You'll Be Scored," page 42).

E VERY DOSE COUNTS

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anti-VEGF = anti–vascular endothelial growth factor; AMD = Age-related Macular Degeneration; DME = Diabetic Macular Edema.

References: 1. Heier JS et al. *Ophthalmology.* 2016;123(11):2376-2385. **2.** Rosenfeld PJ et al. *N Engl J Med.* 2006;355(14):1419-1431. **3.** Ho AC et al. *Ophthalmology.* 2014;121(11):2181-2192. **4.** Nguyen QD et al. *Ophthalmology.* 2012;119(4):789-801. **5.** Kaiser PK et al. *Ophthalmol Retina.* 2017;1(4):304-313. **6.** Peden MC et al. *Ophthalmology.* 2015;122(4):803-808.

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STREAMLINE REPORTING WITH IRIS REGISTRY/EHR INTEGRATION

How to Report Quality Performance

BY REBECCA HANCOCK, FLORA LUM, MD, CHRIS MCDONAGH, CHERIE MCNETT, JESSICA PETERSON, MD, MPH, AND SUE VICCHRILLI, COT, OCS, OCSR.

MIPS' quality performance category contributes up to 50 points to your 2018 MIPS final score. It is 1 of 4 performance categories that contribute to that score. Start by selecting a reporting mechanism and then decide which quality measures to report.

Select a Reporting Mechanism

There are several ways to report quality measures. Your options will depend, in part, on whether you have an electronic health record (EHR) system that has been designated a 2014- or 2015-edition certified EHR technology (CEHRT).

If your practice does not have CEHRT, you can report quality via:

- Medicare Part B claims, which involves real-time reporting, or
- the IRIS Registry web portal, which, unlike claims-based reporting, doesn't involve real-time reporting and doesn't involve entering patients multiple times.

If your practice has CEHRT, you have 2 additional options. You can report quality via:

- IRIS Registry/EHR integration, in which case an automated process will extract the relevant data from your records, or
- your EHR vendor (check that your vendor offers this option).

Which quality measures can you report? Your choice of reporting mechanism will determine which quality measures you can report:

- If you report via IRIS Registry/EHR integration, you can choose from 15 of the standard MIPS quality measures (see Table 11, page 29). You can also select from 17 of the Qual-

Table 6: Quality—Summary of 4 Reporting Options

Your choice of reporting mechanism will determine the pool of quality measures that you can choose from.

	IRIS Registry/ EHR Integration	IRIS Registry Web Portal	EHR Vendor	Medicare Claims
Need EHR?	Yes	No	Yes	No
Used by:	Individuals or groups	Individuals or groups	Individuals or groups	Individuals
It involves:	Automated data extraction	Manual data entry into web portal	A possible fee	Real-time reporting and a lower success rate
Of the 30 MIPS measures in Table 11, you can choose from:	14 MIPS measures (dependent on mapping)*	27 MIPS measures	Up to 16 MIPS measures (dependent on EHR vendor)†	16 MIPS measures
Of the 30 QCDR measures in Table 12, you can choose from:	17 QCDR measures (dependent on mapping)*	29 QCDR measures		
Which MIPS quality measures are available?	To review quality measures that are available for each reporting mechanism—and to see which are topped out or have no benchmark—see Table 11 (page 29) for the MIPS measures that are most relevant to ophthalmology and Table 12 (page 31) for QCDR measures.			

* The IRIS Registry uses a mapping process to determine where your EHR system keeps the data that are needed for a particular measure; you will only be able to report a quality measure if mapping is successful for that measure.

† Ask your EHR vendor which, if any, of these MIPS measures they offer.

Note: The CMS web interface has its own reporting requirements, its own set of measures (which are mostly primary care–based), and a 1-year performance period. The Consumer Assessment of Health Providers and Systems (CAHPS) for MIPS survey and MIPS APMs also have different reporting requirements.

ified Clinical Data Registry (QCDR) quality measures (see Table 12, page 31), which are subspecialty-specific measures designed for use with the IRIS Registry (see "You Can Report 2 Types of Quality Measure," next page). Ideally, you would pick 6 quality measures that have benchmarks and that aren't topped out (see Table 11, page 29). In addition to your first 6 measures, you also should report QCDR measures because (1) they would earn you high-priority bonus points and (2) CMS can only establish benchmarks for these measures if enough clinicians report them.

- If you report via the IRIS Registry web portal, you can choose from 27 of the standard MIPS quality measures (see Table 11, page 29). You also can select from 29 of the QCDR measures (see Table 12, page 31), with the caveat that they don't yet have benchmarks (see page 25).
- If you report via claims, you can choose from the standard MIPS quality measures. Table 11 (page 29) shows the 16 measures available for claims reporting that are most relevant to ophthalmology, though 9 of them are topped out at a low decile, which will make it hard to get a high score.
- If you report via your EHR vendor, you can choose from the MIPS quality measures offered by your vendor. Table 11 (page 29) shows the 17 measures available for EHR-based reporting that are most relevant to ophthalmology; check with your vendor to see which of those measures they support.

Note: If you are reporting via IRIS Registry/EHR integration, you should keep in mind that there are some EHR systems where the IRIS Registry hasn't been able to extract the data that is needed for certain measures—so the MIPS and QCDR measures that are available to you may depend on which EHR system you are using.

Large practices can report via the CMS web interface. This option is available to practices with 25 or more eligible clinicians. It differs from the other reporting mechanisms in several ways. It has its own set of measures, which are primary care–based. Few ophthalmologists are likely to use this reporting mechanism.

Select just 1 reporting mechanism for quality. When reporting quality, you can use only 1 reporting mechanism. The exception is the Consumer Assessment of Health Providers and Systems (CAHPS) for MIPS survey, which can be used as a second data-submission mechanism. However, the burden of conducting this survey makes CAHPS measures an unappealing option.

What happens if you use more than 1 reporting mechanism in 2018? Suppose, for instance, you use both claims and the IRIS Registry web portal to report quality measures. CMS will (1) assess your score for the claims-based submissions, (2) assess your score for the IRIS Registry–based submissions, and (3) assign you the higher of those 2 scores.

You do not have to use the same reporting mechanism for quality, ACI, and improvement activities—but maybe you should! The MIPS regulations don't require you to use just 1 reporting mechanism for the entire program. For example, you can report quality via IRIS Registry/EHR integration while reporting ACI and improvement activities via the CMS web portal. However, the IRIS Registry provides you with a one-stop shop. You can use it to attest to ACI measures, attest to improvement activities, and—if reporting quality manually—enter your quality data.

Consider reporting as a group. There are some advantages to reporting as a group. Suppose, for example, a practice

IRIS REGISTRY IN ACTION: Improving Care, Facilitating Research

Supporting quality improvement in Brighton, Michigan. "Like many physicians, our practice was frustrated with electronic health records as being tools that merely 'check the boxes' rather than improve patient care," said Ayad. A Farjo, MD, who is founder and president of Brighton Vision Center. "In the IRIS Registry, we have found a means of extracting value from our time and effort in entering these data. My practice manager and I meet monthly and part of our standard agenda is reviewing our performance in the IRIS Registry. The registry has become a very useful tool in our outlier analysis, allowing us to identify both isolated and systematic problems in our documentation and coding."


Ayad A. Farjo, MD

Improving care in Batesville, Indiana. "I have participated in the IRIS Registry since its inception, and my practice has achieved important gains as a result," said Gerald J. Roper, MD, in Batesville, Indiana.

"Through report-reviewing activities, my entire care team realizes our ongoing focus on patient care improvement, which they take seriously, in line with our practice goals.

"And in the rural setting of my practice, I can more carefully evaluate and improve our care delivery systems through reports comparing our performance to the performance of other similar practices within the IRIS Registry and to national averages among all registry participants," he said.

Provide real-world data for research. "Also, the IRIS Registry represents a collaborative system that can advance our scientific knowledge, especially as it pertains to real patients across various clinical care settings," said Dr. Roper.

"I am truly excited about the pooling of our data with those of other physicians," added Dr. Farjo. "Although 'big data' is becoming cliché, interesting results will come from the accumulation of so much real world data. I am confident that positive and negative practice patterns will be identified, which will help us to improve the care of our patients."


Gerald J. Roper, MD

consists of 4 cataract subspecialists and a pediatric ophthalmologist. The latter might find it a challenge to report on 6 quality measures, but doing so wouldn't be a problem for the group as a whole. Group-based reporting is the default for practices that sign up for IRIS Registry/EHR integration, though they can opt to switch to reporting as individuals. If you report quality as part of a group, you must also report the ACI and improvement activities performance categories as a group.

If you're in an accountable care organization (ACO), you should still report MIPS quality measures in case your ACO's reporting is unsuccessful. Under PQRS, a number of ACO-affiliated ophthalmologists were penalized because their ACO failed to successfully meet the PQRS requirements. CMS has addressed this under MIPS. You should report quality measures independently of the ACO and can do so using the IRIS Registry. 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 5% payment penalty in 2020.

You Can Report 2 Types of Quality Measure

The Academy has developed *QCDR quality measures* to augment the *standard MIPS quality measures.*

What are the "standard" MIPS quality measures? These are the quality measures that are published in the MIPS regulations—there are hundreds of them, but most won't be applicable to ophthalmologists. See Table 11 (page 29) for the 30 that are most relevant to ophthalmology.

What are the QCDR measures? The IRIS Registry has been designated as both a qualified registry and a QCDR. Each of these designations would allow it to be used for MIPS reporting, and the QCDR designation empowers the Academy to develop quality measures for MIPS that capture the genuine value of medical and surgical eye care. These are known as QCDR quality measures. Since launching the IRIS Registry in 2014, the Academy, working in conjunction with subspecialty societies, has developed dozens of QCDR measures (see Table 12, page 31).

Use the IRIS Registry to report QCDR measures. Of the 30 QCDR measures that are available for MIPS quality reporting, 29 can be reported manually via the IRIS Registry web portal. CMS also has approved 17 of them for reporting via IRIS Registry/EHR integration, but which—if any—of those you'll be able to use will depend on your EHR.

Reporting Quality Measures

If you are reporting individual quality measures by claims, the IRIS Registry (via EHR integration or manually via the web portal), or your EHR vendor, here's how you can maximize your score for the quality performance category.

Report *at least* 6 quality measures. Your score for the quality performance category will be based on your performance rates for up to 6 quality measures, plus high-priority and CEHRT bonus points, and—new this year—your quality category improvement percent score (see page 26).

The All-Cause Hospital Readmission Measure for Larger Practices

In addition to the 6 quality measures that you should actively report, the quality performance category includes 1 population measure—the All-Cause Hospital Readmission (ACR) Measure.

It is very unlikely that this measure applies to you. You would need to have a high volume of unplanned readmissions to hospital within 30 days of an initial discharge. This measure only applies to larger groups (16 or more eligible clinicians) that meet the case minimum requirement of 200 cases (10 times larger than the case minimum requirement for the reportable quality measures).

The performance period for the ACR measure is the calendar year. Practices don't need to report this measure; they will be evaluated based on Medicare administrative claims data.

Select your quality measures. The measures available to you will depend on your choice of reporting mechanism. Tables 11 (page 29) and 12 (page 31) indicate which measures are available for each reporting mechanism. Use these tables to check whether measures lack benchmarks or are topped out; either of those situations—as explained on page 25—could make it harder to get a high achievement score for quality.

At least 1 quality measure should be an outcome measure. A measure that is listed as an intermediate outcome measure would suffice.

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

What if you can't report on 6 quality measures? If 6 quality measures aren't available, CMS expects you to report on as many measures as are applicable via your chosen reporting option. CMS defines applicable to mean "measures relevant to a particular MIPS eligible clinician's services or care rendered." If you are reporting by claims or a qualified registry, CMS will review whether you reported all the applicable measures that were available. CMS doesn't use a validation process for clinicians who report fewer than 6 measures via EHR-based reporting; CMS states that if you don't have enough measures to report via EHR, you should use a different reporting mechanism. CMS also isn't establishing a validation process for QCDR reporters because it assumes that the QCDR will provide you with enough applicable measures; the Academy has urged CMS to rethink this policy.

What if you report on more than 6 quality measures? If you report on 7 or more measures, CMS will determine which 6 of those measures will give you the highest number of measure achievement points based on your performance rates. Furthermore, if you report high-priority quality measures, the high-priority bonus points for those measures

can contribute to your score regardless of whether they are among the 6 measures that contribute to your measure achievement score. The high-priority bonus is subject to a 6- or 7-point cap (see "Bonuses for High-Priority Measures and CEHRT," page 26).

Report more than 6 quality measures to give yourself a margin of error. You can hedge your bets by reporting more than 6 quality measures. 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. If it doesn't have enough data to create that benchmark, you won't be able to score more than 3 points for that measure (see "Watch for Measures That Don't Yet Have Benchmarks," next page).

Meet Quality's Data Submission Thresholds

You should aim to meet both a measure's case minimum requirement and its data completeness criteria.

The case minimum requirement is 20 patients. The exception is the All-Cause Hospital Readmission (ACR) measure, which has a 200-patient case minimum; fall short of that and the ACR measure won't be included in your quality score calculation.

The data completeness criteria—report on at least 60% of applicable patients. For each measure that you report, submit data on at least 60% of measure-applicable patients who were seen during the entire 2018 calendar year.

Who are the applicable patients? That depends on the measure, and it also depends on your reporting mechanism. Suppose, for example, you are reporting measure 1: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%). The applicable patients for that measure would be those with diabetes who are 18-75 years old. If you are reporting by claims, 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 poor control. (For the specifications of each measure, see the 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 the measure, 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 1 patient, you will score 1 achievement point if you are part of a large practice (with 16 or more eligible clinicians) or 3 points if you are part of a small practice.

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 60% of applicable patients). If you did, CMS will give you an achievement score based on your performance.

Your achievement score (3-10 points) for a measure will depend on how you perform against the measure's benchmark. There are separate benchmarks for claims-based reporting, for reporting via manual data entry into a registry portal, and for EHR-based reporting (whether via

Table 7: Benchmarks for Scoring Quality Measure 12—POAG: Optic Nerve Evaluation

How many achievement points you score for a quality measure—in this case measure 12—will depend on how your performance rate compares to a benchmark. There are different benchmarks for claims-based reporting, EHR-based reporting (whether via IRIS Registry/EHR integration or via your EHR vendor), and manual entry via the IRIS Registry web portal (no EHR needed). For this measure, the performance rate represents "the percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during 1 or more office visits within 12 months."

Table 7A: Reporting by Claims

Decile	Benchmark	Achievement Points
3	98.99 - 99.99	3.0-3.9
4-9	Topped out	
10	100	10

Table 7B: Reporting by IRIS Registry/EHR Integration or EHR Vendor

Decile	Benchmark	Achievement Points
3	82.75 – 87.40	3.0-3.9
4	87.41 - 90.76	4.0-4.9
5	90.77 - 93.62	5.0-5.9
6	93.63 - 96.16	6.0-6.9
7	96.17 - 97.87	7.0-7.9
8	97.88 - 98.96	8.0-8.9
9	98.97 - 99.99	9.0-9.9
10	100	10

Table 7C: Manual Reporting Using the IRIS Registry Web Portal

Decile	Benchmark	Achievement Points
3	94.70 - 98.14	3.0-3.9
4	98.15 - 99.16	4.0-4.9
5	99.17 - 99.99	5.0-5.9
6-9	Topped out	
10	100	10

IRIS Registry integration or via your EHR vendor).

Each benchmark is broken into deciles, and the number of achievement points you receive will depend on which of those deciles you fall into:

- If you fall within the first 2 deciles, you will receive 3 achievement points if in a small practice; if in a large practice, you score 1 or 3 achievement points, depending on whether you meet the data completeness criteria.
- If you fall in deciles 3 through 9, you will receive partial achievement points depending on where you fall within that decile. (For instance, if you fall in the ninth decile, you could receive 9.0-9.9 points.)
- If you fall within the 10th decile, you'll receive the full 10 achievement points.

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 9-month assessment. After CMS has determined what changes will be made to the ICD-10 code set, it will determine 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, 2018, and Jan. 2, 2019. For the measures on that list, CMS would only evaluate your performance for those measures based on the first 9 months of 2018, before the ICD-10 codes were changed.

Watch for Measures That Don't Yet Have Benchmarks

For the 2018 performance year, a measure's benchmark will typically be based on performance data from 2016.

Some measures, however, don't have a historic benchmark. In some cases—particularly with QCDR measures—the measure didn't exist in 2016; in others, where wasn't enough performance data in 2016 to set a meaningful benchmark.

If a measure lacks a 2016 benchmark, CMS will try to set one based on data from the 2018 performance year. However, CMS won't assign a benchmark to a measure unless the performance data include a minimum of 20 individual clinicians or groups that met the 2 data submission thresholds and had a performance greater than zero.

Note: If a measure does not yet have a benchmark, there is a chance that, even if a benchmark is developed, the measure might be topped out—which would limit your ability to score highly.

Why you should report the QCDR measures. Although the QCDR measures don't yet have benchmarks, they still have a role. Report QCDR measures as extra measures, in addition to 6 measures that have benchmarks. You earn high-priority bonus points for most QCDR measures, and your reporting may help to establish benchmarks for them.

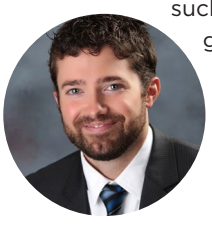
Watch for Measures That Are Topped Out

Some benchmarks reach, or almost reach, the maximum performance value well before the 10th decile. These are known as topped out measures.

Topped out measures can be hazardous to your quality score. When a benchmark is topped out, you need a perfect performance rate to score maximum points. If your performance is less than perfect, there is a ceiling on your

IRIS REGISTRY IN ACTION: Enhancing Patient Care

Identifying and following patients in Seymour, Indiana. "The IRIS Registry is helping us use our EHR system to its full potential," said Clifford W. Brooks III, MD, who practices at Conner Smith Eye Center, 1 hour south of Indianapolis. "It has specifically allowed us to better track important metrics regarding how well we follow our patients with chronic diseases such as diabetes, glaucoma, and age-related macular degeneration. Having the data meaningfully extracted directly from our EHR has been a substantial time-saver and allows us to drill down and identify specific patients whose record indicates an action item."



Clifford W. Brooks III, MD

Spot problems early. "Having this information in the context of a specialty-specific registry is of particular value to me, as I can quickly compare my data with that of my peers across the country, and I can identify gaps, trends, and more," said Dr. Brooks.

Address problems promptly. "Having the data at my fingertips allows me to share it with the other team members at my office," he said. "I can quickly relay items that we need to work on, such as firming up our 'close the loop' protocols for referrals and for communication with primary care providers, particularly for patients who need ongoing care and management of diabetes and diabetic retinopathy," he said.

Increase patient compliance. "Improved communication between physicians in my experience trickles down to better patient compliance," said Dr. Brooks. "Patients know that we are sharing information from each eye exam back to their primary care provider."

Enable research. "It's also exciting to know that data from my personal practice patterns are already being used to advance knowledge and public health through research of IRIS Registry data," he said.

maximum score—for example, with measure 12 (see Table 7, page 24), if your performance is not perfect the ceiling is 3.9 points for claims-based reporting and 5.9 points if reporting via the IRIS Registry web portal.

Topped out or not topped out? Some measures are both. Because there are different benchmarks for different reporting mechanisms, some measures are topped out for 1 reporting mechanism but not others.

Maximum achievement score is 7 or 10 points. For most topped out measures, the maximum achievement score is 10 points. However, CMS has identified 6 measures—including measure 224 for overutilization of imaging studies for melanoma—where the maximum achievement score will be 7 points. (For the 2019 performance year, this 7-point cap will be applied to all benchmarks that have been topped out for 2 or more consecutive years.)

Why CMS frowns on measures that are topped out. CMS is concerned that topped out measures 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 measures. If a measure is topped out for a given reporting mechanism for 3 consecutive performance years, it will cease to be an option for that reporting mechanism in the fourth year. For most measures, the earliest that might happen is 2021, but measure 224 has been flagged by CMS for special treatment and could be removed as early as 2020. The Academy has urged CMS to only remove topped out measures if replacement measures are available.

Fortunately, CMS allows QCDRs, such as the IRIS Registry, to adjust their QCDR measures annually, which may enable the Academy to fine-tune the specifications of topped out QCDR measures so they are no longer topped out.

Bonuses for High-Priority Measures and CEHRT

For each quality measure, you typically can score up to 10 achievement points based on performance, but you may also be able to score additional bonus points.

Bonus points for reporting high-priority measures. You get no bonus points for your first high-priority measure (whch should be an outcome measure, if one is available), but after that you can get:

- 2 points for an outcome or patient experience measure, and/or
- 1 point for the following measures: appropriate use, care coordination, efficiency, or patient safety.

Note: There is no bonus point for the first high-priority measure because you are required to report at least 1 outcome measure (or, if no outcome measure is available, an alternate high-priority measure).

You must meet the submission thresholds. To score bonus point(s) for a measure, you must meet the case minimum requirement (at least 20 patients) and the data completeness criteria (at least 60% of applicable patients during 2018), and have a performance rate greater than zero.

You can score high-priority bonus points for measures that don't contribute to your measure achievement points. If you report more than 6 quality measures, CMS will base your total measure achievement points on the 6 measures that score highest, but you also can earn high-priority bonus points for quality measures that aren't among those 6.

Bonus points for using CEHRT. You also can earn 1 bonus point for each measure that is submitted using "end-to-end electronic reporting" by means of CEHRT. This can include measures reported via IRIS Registry/EHR integration or your EHR vendor.

You can earn bonus points for topped out measures. Although CMS limits your ability to get a high number of achievement points for topped out measures, they can still earn you both CEHRT and high-priority bonus points.

You can score up to 12 (or 14) bonus points. Your high-priority and CEHRT bonuses are each capped at 6 points or—if you are scored on the ACR measure (see box on page 23)—7 points.

You Can Earn an Improvement Percent Score

If you participated in MIPS in 2017 and earned a score for the quality performance category, you may be able to earn a quality improvement percent score for your 2018 performance.

CMS checks whether your score for measure performance has improved. When comparing your 2018 score for quality with your 2017 score, CMS doesn't include any bonus points and nor does it include your improvement percent

Table 8: Calculating the Improvement Percent Score

	Quality Performance Category Achievement Percent Score*		Increase from 2017 to 2018	Rate of Improvement	Improvement Percent Score
	2017	2018			
Eligible Clinician #1	5%†	50%	20%†	20 ÷ 30 = 0.67	0.67 × 10 = 6.7%
Eligible Clinician #2	60%	66%	6%	6 ÷ 60 = 0.10	0.10 × 10 = 1.0%
Eligible Clinician #3	30%	70%	40%	40 ÷ 30 = 1.33	1.33 × 10 = 13.3% (capped at 10%)

* Quality performance category achievement percent score = total measure achievement points ÷ total available measure achievement points.

† Although the 2017 score is 5%, the increase in performance is compared against a floor of 30%.

score. For each of the 2 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.

How CMS determines your improvement percent score. Your improvement percent score = ([your increase in quality performance category achievement percent score from 2017 to 2018] / your 2017 quality performance category achievement percent score) x 10. (See Table 8 for examples.)

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%.

You must fully participate in quality reporting for 2018. To be eligible for an improvement adjustment percent score, you must submit all the required measures and report on at least 60% of applicable patients for each measure.

CMS sets a floor of 30% for your 2017 quality performance. In 2017, CMS allowed you to "pick your pace" of MIPS participation, which meant you could avoid the penalty by reporting 1 measure just 1 time. Consequently, an improved quality performance category achievement percent score in 2018 doesn't necessarily reflect improved clinical performance; it could just mean that a clinician has increased his or her MIPS participation (e.g., the clinician reported 1 quality measure in 2017 and 6 in 2018). To address this, when comparing your quality performance category achievement percent scores for 2018 and 2017, CMS will assume a minimum score of 30% for 2017.

CMS uses your MIPS identifier when comparing scores. When a practice's clinicians report as a group, their MIPS identifier is the practice's Tax Identification Number (TIN) alone; when they report individually, they each have their own MIPS identifier, which combines the TIN with their own National Provider Identifier (see "Use of TINs and NPIs as Identifiers," page 11).

What if your MIPS identifier changes? If your current MIPS identifier is different from your 2017 MIPS identifier, CMS will still try to evaluate whether you are eligible for an improvement adjustment. Suppose, for example, your practice reported as individuals in 2017 but reports as a group this year; CMS would calculate a group score for 2017 based on the average scores of the clinicians who are part of the group this year and would compare that score against your group score for 2018.

When You Have Fewer Than 6 Measures That You Can Report

When determining your quality performance category percent score, CMS takes the sum of your quality measure achievement points and quality measure bonus points and then divides that by a denominator—CMS calls this denominator the *total available measure achievement points*—which is typically 60 points (or 70 points, in the unlikely event that the ACR measure applies; see "The All-Cause Hospital Readmission Measure," page 23).

But if you reported fewer than 6 quality measures via a qualified registry or via claims, CMS will apply a validation process—the eligible measure applicability (EMA) process—to determine whether you could have reported additional quality measures. If CMS determines that you could not have reported more measures, then it reduces the denominator accordingly—for example, if you are only able to report 3 measures and the ACR measure doesn't apply, then the denominator would be 30.

However, if you are using EHR-based reporting (via your EHR vendor or IRIS Registry–EHR integration) and/or are using a QCDR, CMS won't reduce your denominator.

How CMS Calculates Your Quality Score

This can be described as a 6-step process:

1. CMS determines your *total measure achievement points,* which is the sum of your achievement points for up to 6 quality measures that you reported plus—if applicable—your achievement score for the ACR measure (the ACR population measure only applies to large practices, and only if they meet the 200-patient case minimum; see page 23).
2. CMS determines your *total measure bonus points* (see "Bonuses for High-Priority Measures and CEHRT," page 26).
3. CMS calculates your numerator, which is your total measure achievement points plus your total measure bonus points.
4. CMS calculates your denominator, also known as your *total available measure achievement points,* which—assuming that you had at least 6 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 6 quality measures to report and can reduce that denominator

Table 9: Calculating Your Quality Performance Category Percent Score

$$\frac{\text{Total measure achievement points} + \text{Total measure bonus points}}{\text{Total available measure achievement points}} + \text{Improvement percent score} = \text{Quality performance category percent score*}$$

* This score is capped at 100%.

accordingly (see "When You Have Fewer Than 6 Measures That You Can Report," page 27).
5. CMS determines your *improvement percent score* (see "You Can Earn an Improvement Percent Score," page 26).
6. CMS divides your numerator by your denominator, turns the resulting fraction into a percentage, and then adds the improvement percent score.

The resulting percentage is your *quality performance category percent score*, which is capped at 100%. It contributes up to 50 points to your final score.

For an example that runs through these 6 steps, see Table 10, below.

Table 10: Example of 6-Step Process Used to Calculate Quality Score

	High Priority?	Measure Achievement Points	Contribution to Total Measure Achievement Points	Measure Bonus Points		Available Measure Achievement Points
				High Priority	CEHRT	
Measure 1	Outcome (required)	4.1	4.1	0	1	10
Measure 2		5.8	5.8	0	1	10
Measure 3		5.4	5.4	0	1	10
Measure 4		5.3	5.3	0	1	10
Measure 5		4.8	4.8	0	1	10
Measure 6	Outcome	4.6	4.6	2	1	10
Measure 7	Outcome	3	0	2	0	0
Total			30	4	6	60

In this example, a clinician who is participating in MIPS for the first time reports 7 quality measures. She opted to report as an individual (rather than as part of a group), which means the ACR measure (see page 23) doesn't apply. She reported via IRIS Registry/EHR integration.

Here's the 6-step process that CMS uses to determine her quality performance category percent score.

1. Total measure achievement points = 30 points. Only 6 measures can contribute to your total measure achievement points, so CMS selects the 6 measures that would produce the highest score—with the caveat that at least 1 measure should be an outcome measure (or, if no outcome measure is available, another high-priority measure).

2. Total measure bonus points = 10 points. She scored 4 high-priority bonus points. She doesn't score bonus points for the first outcome measure (which is required), but she does score bonus points for each of the other high-priority measures (even though measure 7 isn't contributing to her total measure achievement points). She reported her measures via IRIS Registry/EHR integration, and this earns her 6 CEHRT bonus points (1 point per measure, capped at 6 points; the cap would have been 7 points if she was also being scored on the ACR measure).

3. Numerator = 40 points. This is the sum of the total measure achievement points (30 points) plus total measure bonus points (10 points).

4. Denominator = 60 points. Up to 10 achievement points are available for each of 6 quality measures. This denominator is also known as the total available measure achievement points. (This denominator would have been 70 points if she had been scored on the ACR measure.)

5. Improvement percent score = 0%. She didn't participate in MIPS in 2017 and therefore could not be assessed for improvement.

6. Numerator / denominator = 0.66, or 66.6%. Add the quality improvement percent score, which is 0% in this case.

Quality performance category percent score = 66.6%. This would contribute 33 points (66.6% of 50 points) to her MIPS final score.

$$\frac{\underset{\text{(total measure achievement points)}}{\mathbf{30}} + \underset{\text{(total measure bonus points)}}{\mathbf{10}}}{\underset{\text{(total available measure achievement points)}}{\mathbf{60}}} + \underset{\text{(improvement percent score)}}{\mathbf{0}} = \underset{\text{(quality performance category percent score*)}}{\mathbf{66.6\%}}$$

* This score is capped at 100%.

MIPS and QCDR Quality Measures—At a Glance

The Academy identified the 31 MIPS quality measures in Table 11 as those most useful for ophthalmic practices. The 30 QCDR quality measures in Table 12 (see page 31) were developed by the Academy in conjunction with subspecialty societies for reporting via the IRIS Registry.

Which quality measures should you report? If you are reporting quality via IRIS Registry/EHR integration, after the performance year is over, an automated process determines which measures will give you the best score. If you are using other reporting mechanisms, you should skim through these 2 tables to see which measures you are most likely to (a) satisfy the case minimum requirement of 20 patients, (b) satisfy the 60%-data completeness criteria, and (c) achieve a high performance rate. Factors to keep in mind include the following:

1) Report an outcome measure. You must include at least 1 outcome measure (or if no outcome measure is available, another type of high-priority measure).

2) Earn bonus points. After reporting the initial, mandatory high-priority measure, you earn bonus points for reporting additional high-priority measures and for submitting measures using CEHRT (see page 26).

3) Watch for topped out measures. When a measure is topped out, you can typically score 10 points with a perfect performance; but if you are less than perfect, there is a ceiling on the number of achievement points that you can score. For example, if a measure is topped out at less than decile 3 (< d3), the ceiling for a less-than-perfect performance would be 3 points; if it is topped out at decile 3, the ceiling would be 3.9 points; if it is topped out at decile 4, the ceiling would be 4.9 points, etc. Note: Special scoring applies to measure 224, which has a maximum achievement score of 7 points (see page 26), though you also can score high-priority and CEHRT bonus points.

4) Measure 384, measure 385, and the QCDR measures have no benchmark. CMS will try to establish a benchmark based on this year's performance data. However, if not enough clinicians report these measures, CMS won't have enough data to create a meaningful benchmark and your maximum score for these measures will be 3 points.

Learn about each measure. For each measure in Tables 11 and 12, the Academy has created a detailed web page. There are 2 easy ways to access those dedicated web pages: 1) go to aao.org/eyenet/mips-manual-2018, download a PDF of Tables 11 and 12, and click on a measure's title or 2) go to aao.org/medicare/quality-reporting-measures.

Some measures have changed since last year. Make sure you check the measure description to see what you might need to do differently. In particular, CMS flags the following measures as having undergone substantive changes: 110, 128, 226, 238, and 374.

Some measures are inverse measures. With an inverse measure (e.g., Measure 1), a higher percentage indicates a worse performance.

Table 11: 30 MIPS Quality Measures—At a Glance

ID: Measure Title	High-Priority Measure (Bonus Points)	Can Be Reported Via:			
		IRIS Registry (IR)		EHR Vendor	Claims
		IR/EHR	IR Web Portal		
1: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%)	Intermediate Outcome (+2)		IR portal	EHR vendor	Claims
12: Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation		IR/EHR	IR portal *Topped out at d5*	EHR vendor	Claims *Topped out at d3*
14: Age-Related Macular Degeneration (AMD): Dilated Macular Examination			IR portal *Topped out at d7*		Claims *Topped out at d3*
18: Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy		IR/EHR		EHR vendor	
19: Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care	Care Coordination (+1)	IR/EHR	IR portal *Topped out at d7*	EHR vendor	Claims *Topped out at < d3*
110: Preventive Care and Screening: Influenza Immunization*		IR/EHR	IR portal	EHR vendor	Claims

Table continued on next page.

Table 11: 30 MIPS Quality Measures—At a Glance

Continued from previous page.

ID: Measure Title	High-Priority Measure (Bonus Points)	Can Be Reported Via:			
		IRIS Registry (IR)		EHR Vendor	Claims
		IR/EHR	IR Web Portal		
111: Pneumococcal [Pneumonia] Vaccination Status for Older Adults		IR/EHR	IR portal	EHR vendor	Claims
117: Diabetes: Eye Exam		IR/EHR	IR portal *Topped out at d6*	EHR vendor	Claims *Topped out at d4*
128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan*		IR/EHR	IR portal	EHR vendor	Claims *Topped out at d8*
130: Documentation of Current Medications in the Medical Record	Patient Safety (+1)	IR/EHR	IR portal *Topped out at d7*	EHR vendor	Claims *Topped out at d5*
137: Melanoma: Continuity of Care—Recall System	Care Coordination (+1)		IR portal *Topped out at d5*		
138: Melanoma: Coordination of Care	Care Coordination (+1)		IR portal *Topped out at d6*		
140: Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplement			IR portal *Topped out at d8*		Claims *Topped out at d3*
141: Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% or Documentation of a Plan of Care	Outcome (+2)		IR portal *Topped out at d7*		Claims *Topped out at < d3*
191: Cataracts: 20/40 or Better Visual Acuity Within 90 Days Following Cataract Surgery	Outcome (+2)	IR/EHR	IR portal *Topped out at d8*	EHR vendor	
192: Cataracts: Complications Within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures	Outcome (+2)	IR/EHR *Topped out at d3*	IR portal *Topped out at d4*	EHR vendor *Topped out at d3*	
224: Melanoma: Overutilization of Imaging Studies in Melanoma	Efficiency (+1)		IR portal *Topped out at < d3**		
226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention*		IR/EHR	IR portal	EHR vendor	Claims *Topped out at d5*
238: Use of High-Risk Medications in the Elderly*	Patient Safety (+1)	IR/EHR *Topped out at d7*	IR portal *Topped out at d8*	EHR vendor *Topped out at d7*	
265: Biopsy Follow-Up	Care Coordination (+1)		IR portal *Topped out at d6*		
317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented			IR portal	EHR vendor	Claims *Topped out at d8*
318: Falls: Screening for Future Fall Risk	Patient Safety (+1)	IR/EHR		EHR vendor	

Table continued on next page.

Table 11: 30 MIPS Quality Measures—At a Glance

Continued from previous page.

ID: Measure Title	High-Priority Measure (Bonus Points)	Can Be Reported Via:			
		IRIS Registry (IR)		EHR Vendor	Claims
		IR/EHR	IR Web Portal		
374: Closing the Referral Loop: Receipt of Specialist Report*	Care Coordination (+1)	IR/EHR		EHR vendor	
384: Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the OR Within 90 Days of Surgery	Outcome (+2)		IR portal *Does not have a benchmark*		
385: Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery	Outcome (+2)		IR portal *Does not have a benchmark*		
388: Cataract Surgery With Intraoperative Complications (Unplanned Rupture of Posterior Capsule Requiring Unplanned Vitrectomy)	Outcome (+2)		IR portal *Topped out at <d3*		
389: Cataract Surgery: Difference Between Planned and Final Refraction	Outcome (+2)		IR portal		
397: Melanoma Reporting	Outcome (+2)		IR portal *Topped out at d3*		Claims *Topped out at d4*
402: Tobacco Use and Help with Quitting Among Adolescents			IR portal		
419: Overuse of Neuroimaging for Patients With Primary Headache and a Normal Neurological Examination	Efficiency (+1)		IR portal *Topped out at d4*		Claims

* Has undergone substantive changes since 2017. † Measure 224 has a maximum achievement score of 7 points (see page 26).

Table 12: 30 QCDR Quality Measures—At a Glance

Note: QCDR measures don't have historic benchmarks. Report 6 measures from Table 11 that have benchmarks and aren't topped out at a low level, and report additional measures from Table 12 for their high-priority bonus points.

	ID: Measure Title	High-Priority Measure (Bonus Points)	Can Be Reported By:
Cataract	**IRIS27:** Adverse Events After Cataract Surgery	Outcome (+2)	IR Portal, IR/EHR*
	IRIS28: Regaining Vision After Cataract Surgery	Outcome (+2)	
Cornea	**IRIS1:** Endothelial Keratoplasty: Postoperative Improvement in Best-Corrected Visual Acuity to 20/40 or Greater	Outcome (+2)	IR Portal, IR/EHR*
Glaucoma	**IRIS2:** Intraocular Pressure (IOP) Reduction	Outcome (+2)	IR Portal, IR/EHR*
	IRIS3: Visual Field Progression	Outcome (+2)	IR Portal
	IRIS4: Intraocular Pressure Reduction Following Laser Trabeculoplasty	Outcome (+2)	IR Portal, IR/EHR*
Neuro-Ophthalmology	**IRIS20:** Idiopathic Intracranial Hypertension: No Worsening or Improvement of Mean Deviation	Outcome (+2)	IR Portal

Table continued on next page.

Table 12: 30 QCDR Quality Measures—At a Glance *Continued from previous page.*

	ID: Measure Title	High-Priority Measure (Bonus Points)	Can Be Reported By:
Neuro-Ophthalmology	**IRIS21:** Ocular Myasthenia Gravis: Improvement of Ocular Deviation or Absence of Diplopia or Functional Improvement	Outcome (+2)	IR Portal
	IRIS22: Giant Cell Arteritis: Absence of Fellow Eye Involvement After Treatment		
Oculoplastics	**IRIS5:** Surgery for Acquired Involutional Ptosis: Patients With an Improvement of Marginal Reflex Distance	Outcome (+2)	IR Portal
	IRIS6: Acquired Involutional Entropion: Normalized Lid Position After Surgical Repair	Outcome (+2)	
Pediatrics/ Strabismus	**IRIS7:** Amblyopia: Interocular Visual Acuity	Outcome (+2)	IR Portal
	IRIS8: Surgical Esotropia: Postoperative Alignment	Outcome (+2)	
Refractive	**IRIS23:** Refractive Surgery: Postoperative Improvement in Uncorrected Visual Acuity of 20/20 or Better	Outcome (+2)	IR Portal, IR/EHR*
	IRIS24: Refractive Surgery: Postoperative Correction Within +/- 0.5 Diopter of the Intended Correction	Outcome (+2)	IR Portal
Retina	**Age-Related Macular Degeneration (AMD)**		
	IRIS10: Exudative AMD: Loss of Visual Acuity	Outcome (+2)	IR Portal, IR/EHR*
	IRIS11: Nonexudative AMD: Loss of Visual Acuity	Outcome (+2)	
	IRIS34: AMD: Disease Progression	Outcome (+2)	
	Diabetic Retinopathy (DR) and Diabetic Macula Edema (DME)		
	IRIS9: DR: Documentation of the Presence or Absence of Macular Edema and the Level of Severity of Retinopathy	Not a high-priority measure (+0)	IR Portal, IR/EHR*
	IRIS13: DME: Loss of Visual Acuity	Outcome (+2)	IR Portal, IR/EHR*
	Epiretinal Membrane (ERM)		
	IRIS29: Improved Visual Acuity After ERM Treatment Within 90 Days	Outcome (+2)	IR Portal, IR/EHR*
	IRIS30: Return to OR Within 90 Days After ERM Surgical Treatment	Outcome (+2)	
	Macular Hole		
	IRIS32: Evidence of Anatomic Closure of Macular Hole Within 90 Days After Surgery as Documented by OCT	Outcome (+2)	IR Portal
	IRIS33: Return to OR Within 90 Days After Macular Hole Surgery	Outcome (+2)	IR Portal, IR/EHR*
Uveitis	**IRIS16:** Acute Anterior Uveitis: Post-Treatment Visual Acuity	Outcome (+2)	IR/EHR*
	IRIS17: Acute Anterior Uveitis: Post-Treatment Grade 0 Anterior Chamber Cells	Outcome (+2)	IR Portal
	IRIS18: Chronic Anterior Uveitis: Post-Treatment Visual Acuity	Outcome (+2)	IR Portal, IR/EHR*
Resource Use	**IRIS25:** Adenoviral Conjunctivitis: Avoidance of Antibiotics	Appropriate Use (+1)	IR Portal, IR/EHR*
	IRIS26: Avoidance or Routine Antibiotic Use in Patients Before or After Intravitreal Injections	Appropriate Use (+1)	IR Portal
	IRIS31: Avoidance of Genetic Testing for Age-Related Macular Degeneration	Appropriate Use (+1)	

* You may be able to report this measure via IRIS Registry/EHR integration but only if the IRIS Registry is able to extract the relevant data from your EHR. An initial data mapping process will determine whether this is feasible.

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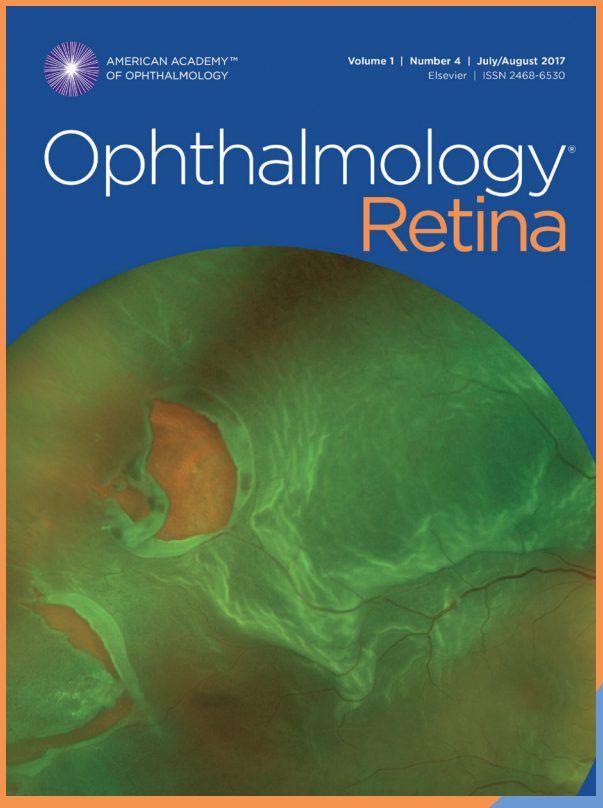

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THERE ARE SEVERAL ROUTES TO A HIGH ACI SCORE

How to Report Advancing Care Information

BY REBECCA HANCOCK, FLORA LUM, MD, CHRIS MCDONAGH, CHERIE MCNETT, JESSICA PETERSON, MD, MPH, AND SUE VICCHRILLI, COT, OCS, OCSR.

The advancing care information (ACI) performance category evolved out of the meaningful use (MU) program for electronic health records (EHRs). It contributes up to 25 points to your 2018 MIPS final score.

Getting Started

You must have an EHR system that is a certified EHR technology (CEHRT). What certification do you need? During the 2018 performance year, your EHR system must have 2014- or 2015-edition certification; modular EHR systems can have a mixture of 2014- and 2015-edition modules. New this year: You can get a bonus for using a 2015-edition CEHRT (see "There are 3 Bonuses Available," page 36).

Check your EHR system's certification. To check whether your EHR system is a 2014- or 2015-edition CEHRT, visit https://chpl.healthit.gov/#/search.

Select a reporting mechanism. The Academy recommends that you attest to your ACI measures via the IRIS Registry web portal, but you also can do so via the CMS web portal or possibly via your EHR vendor.

There is no automated reporting of ACI measures; you must do so manually. Regardless of your reporting mechanism, you will report your ACI measures manually. Ask your EHR vendor for a report that supplies the data that you need to submit when reporting the ACI measures.

There Are 2 Measure Set Options for ACI

This year, you will report measures either from:

- the 2018 ACI transition measure set (see Table 15, page 38), or
- the ACI measure set (see Table 16, page 40).

ACI's 2 measure sets were adapted from the EHR meaningful use program. The ACI transition measures were adapted from the modified stage 2 meaningful use measures, and the ACI measures were adapted from the stage 3 meaningful use measures. This year's measures are largely the same as last year's, with a few small changes.

The set of measures that you can report depends on

Table 13: Calculating Your ACI Score

			2018 ACI Transition Measure Set	ACI Measure Set
	Base score	0% or 50%	Of 4 base score measures, there are 2 that you *must* report and you may be able to claim exclusions for the other 2.	Of 5 base score measures, there are 2 that you *must* report and you may be able to claim exclusions for the other 3.
+	performance score	0%-90%	Report up to 7* performance score measures.	Report up to 9* performance score measures.
+	registry/agency bonus score	0% or 5%	Report at least 1 bonus score measure involving active engagement with a clinical data registry or public health agency.	
+	CEHRT for improvement activities bonus score	0% or 10%	Use CEHRT functionality to complete an improvement activity that is eligible for the ACI bonus (see Table 17, page 44).	
+	2015-CEHRT bonus score	0% or 10%	During your ACI performance period, report the ACI measure set using only 2015-edition CEHRT.	
=	ACI score	0%-100%	Your ACI score is capped at 100%	

Your ACI score contributes up to 25 points to your MIPS final score (0-100 points). For instance, an ACI score of 80% contributes 20 points to your MIPS final score.

* New option: Instead of using the Immunization Registry Reporting performance score measure, you can engage with a public health agency or clinical data registry and report an alternate measure (see page 36).

whether you have 2014- or 2015-edition CEHRT:

- If your EHR system has 2014-edition certification, it will have the functionality to support reporting of the 2018 ACI transition measure set.
- If your EHR system has 2015-edition certification, you can choose whether you want to report the ACI measure set or the 2018 ACI transition measure set.
- If you took the modular approach and have a mixture of 2014- and 2015-edition CEHRT modules, you can choose either the ACI measure set or the 2018 ACI transition measure set, provided your EHR system is able to support the measures that you select.

The Performance Period Is At Least 90 Days

Pick a performance period of at least 90 consecutive days and no more than a calendar year. Because CMS anticipates that many practices will be moving from 2014- to 2015-edition CEHRT in the next year, the performance period for 2019 is also slated for 90 days. CMS has said that it will consider a 90-day performance period for ACI in 2020, but ultimately it plans to implement a 12-month performance period.

There Are Different Levels of ACI Participation

Under ACI, there is a base score and a performance score:

- The base score represents a mandatory core level of participation.
- The performance score involves a second level of participation where you are rewarded for your performance rate.

You also can earn 3 bonus scores. You can earn a 5% bonus by being actively engaged with a registry or a public health agency. The second bonus relates to how you perform in another performance category: Improvement activities. If you use specific CEHRT functionalities to complete at least 1 ACI bonus–eligible improvement activity, you'll earn a 10% ACI bonus. You also can earn a 10% bonus if you report the ACI measure set using only 2015-edition CEHRT. (You can learn more about these bonuses on page 36.)

Table 14: ACI's Decile-Based Scoring for Performance Score Measures

Performance Rate (Numerator/ Denominator)	Your Score
0%*	0%
1%-10%	1%
11%-20%	2%
21%-30%	3%
31%-40%	4%
41%-50%	5%
51%-60%	6%
61%-70%	7%
71%-80%	8%
81%-90%	9%
91%-100%	10%

Note: This scoring applies to ACI performance score measures and 2018 ACI transition performance score measures that score from 0%-10%.

* If your performance rate is greater than 0% but less than 1%, it will be rounded up to 1%.

Meet ACI's Base Score Requirements

First, you must achieve full marks for the ACI base score, which is worth 50% of the maximum ACI score. To be successful with this core level of ACI participation, you must perform (or claim exclusions for) the base score measures.

Tackle either 4 or 5 base measures, depending on which measure set you use. The 2018 ACI transition measure set includes 4 base score measures (see Table 15, page 38), and the ACI measure set includes 5 (see Table 16, page 40).

Report the Security Risk Analysis base score measure by submitting a "yes." You will be attesting that you conducted or reviewed a security risk analysis, implemented security updates as necessary, and corrected security deficiencies as part of your risk management process. You need to attest "yes" to successfully report this measure.

Other base score measures involve reporting a numerator and denominator. For the e-Prescribing measure, for example, the denominator is the number of prescriptions written for drugs during the performance period and the numerator is the number of those prescriptions that were 1) generated, 2) queried for a drug formulary, and 3) transmitted using a certified EHR. You need a numerator of at least 1 to successfully report a base score measure. A numerator greater than 1 won't improve your base score; however, for those base score measures that are also performance score measures, a numerator greater than 1 could improve your performance score.

Exclusions are available for some base score measures. Some clinicians are seldom involved in transfers of care or referrals, while there are clinicians in some specialties who write few, if any, prescriptions. CMS recognized this and, late last year, updated the rules to allow such clinicians exclusions to 2 of the 2018 ACI transition measures (see page 38) and 3 of the ACI measures (see page 40).

The base score is all or nothing (0% or 50%)—and if it is 0%, your entire ACI score is 0%. To earn the full base score of 50%, successfully report—or, in some cases, obtain an exclusion for—each of the base score measures in the measure set that you are reporting. If you don't, you will score 0% for both the base score and the overall ACI score.

Editor's note: A base score of 50% doesn't indicate that you only got half of the points available for the base score; 50% is the maximum possible base score and represents 50% of the maximum ACI score.

Next, You Can Earn an ACI Performance Score

You are eligible for the performance score only if you achieved the base score.

Most performance score measures are optional. However, some performance score measures are also

required for the base score.

Report as many as 7 or 9 performance score measures, depending on which measure set you use. The 2018 ACI transition measure set contains 7 performance score measures—1 is strictly mandatory; 1 is typically required, but you may be able to claim an exclusion; and 5 are optional (see Table 15, page 38). The ACI measure set contains 9 performance score measures—1 is strictly mandatory; 2 are typically required, but you may be able to claim exclusions; and 6 are optional (see Table 16, page 40).

Your score for a performance score measure will typically depend on your performance rate. Most performance score measures are assigned a score of 0%-10% using decile-based scoring: You get a score of 1% if your performance rate is in the first decile (1%-10%), 2% if it is in the second decile (11%-20%), etc. If your performance rate falls between deciles, it is rounded off to the nearest integer; if it is below 1% but greater than 0%, it is rounded up to 1%.

How the performance rate is scored. Suppose you report the Patient-Specific Education measure, which can contribute up to 10% to your performance score. During the performance period, perhaps you see 600 unique patients—this is the denominator. You provided patient-specific educational resources to 200 of those patients (or to their authorized representatives) electronically using clinically relevant information identified from your EHR—this is your numerator. To calculate your performance rate, divide the numerator by the denominator and turn the resulting fraction into a percentage. In this case, your performance rate would be 33.3% (200/600), and—as indicated in Table 14 (page 35)—this measure will contribute 4% to your ACI score.

Exception to performance rate–based scoring. You earn 10% toward your performance score by either performing the Immunization Registry Reporting measure or—more feasible for ophthalmologists—engaging with a clinical data registry, such as the IRIS Registry, or a public health agency and reporting an alternate measure (see "A New Way to Boost Your ACI Performance Score").

There Are 3 Bonuses Available

Earn the registry/agency measure bonus (5%). There are bonus measures that involve active engagement with a clinical data registry or a public health agency (see Table 15 on page 38 and Table 16 on page 40).

What constitutes *active engagement*? CMS describes 3 options for meeting this requirement:

Option 1—You've completed your registration to submit data. You register to submit data to a clinical data registry or public health agency; your registration is completed within 60 days after the start of the performance period; and you are awaiting an invitation to begin testing and validation. (Note: If you registered with the agency or registry in previous years, you don't have to submit an additional registration to meet this requirement for each performance period.)

Option 2—Testing and validation. You are in the process of testing and validating the electronic submission of data to a clinical data registry or public health agency. If the registry or agency sends you a request, you must respond within 30 days.

Option 3—Production. You have completed testing and validation of the electronic submission process and you are electronically submitting data.

For example, if you integrate your EHR with the IRIS Registry and utilize its dashboard appropriately, you can report either the Specialized Registry Reporting measure (from the 2018 ACI transition measures set) or the Clinical Data Registry Reporting measure (from the ACI measure set). This would contribute 5% to your ACI score—but only if you weren't already using your participation in the IRIS Registry as an alternative to the Immunization Registry Reporting measure (see "No double dipping," below).

A New Way to Boost Your ACI Performance Score

Problem with the Immunization Registry Reporting measure. In ACI, both the ACI measure set and the 2018 ACI transition measure set include an Immunization Registry Reporting measure that can contribute 10% toward your performance score. During the course of 2017, CMS realized that there were parts of the country where immunization registries aren't available. This meant that some MIPS eligible clinicians, through no fault of their own, could score on 1 fewer performance score measures than their colleagues in other parts of the country.

CMS introduces an alternative to the Immunization Registry Reporting measure. New this year, CMS offers an alternate way to earn the 10% performance score that is associated with the Immunization Registry Reporting measure: Engage with any single clinical data registry, such as the IRIS Registry, or with a public health agency and then report 1 of the measures listed below:

From the 2018 ACI transition measure set: Syndromic Surveillance Reporting or Specialized Registry Reporting.

From the ACI measure set: Syndromic Surveillance Reporting, Electronic Care Reporting, Public Health Registry Reporting, and Clinical Data Registry Reporting.

If you are planning to use this alternative to the Immunization Registry Reporting measure, keep in mind the following:

It is capped at 10%. It can't contribute more to your performance score than the Immunization Registry Reporting measure would have done (10%), no matter how many measures you report or how many agencies and registries you report to. (However, you can earn a 5% registry/agency bonus for reporting to a second registry or agency.)

It is available to all. You can use this alternative even if an immunization registry is available to you.

No double dipping. You cannot earn points in both the performance score and bonus score by reporting to the same public health agency or clinical data registry.

Earn the CEHRT for improvement activities bonus (10%). This bonus is based on what you report in the improvement activities performance category. Of the 24 improvement activities that you can report via the IRIS Registry web portal, several can qualify you for this bonus (see Table 17, page 44). If you use CEHRT functionality to perform 1 or more of those activities, you will get a 10% bonus for your ACI score.

Earn a bonus (10%) for using only 2015-edition CEHRT. In 2018, you can use 2014- and/or 2015-edition CEHRT, but if you report the ACI measure set exclusively using 2015-edition CEHRT for at least 90 consecutive days, you can earn a 10% bonus for your ACI score.

Several Pathways to a High ACI Score

Although your ACI score is capped at 100%, a total of 165 percentage points are available—50% from the base score, 90% from the performance score, 5% from the registry bonus score, 10% from the CEHRT for improvement activities bonus score, and a 10% bonus for only using 2015-edition CEHRT. CMS designed this scoring system so that you would have more than 1 way to achieve a high score.

Example: Suppose, for instance, you successfully meet the requirements for:

- the base score (50%) and
- the CEHRT for improvement activities bonus (10%).

So far, you have attained an ACI score of 60% (50% + 10%), which means you would only need to accrue a performance score of 40% (from the 90% available) to get a perfect score (100%) for ACI. In this scenario, if you reported all the available performance score measures—and did OK on all of them, even if you didn't excel in any—you would be able to achieve a high ACI score. Alternatively, you may decide to focus your efforts on those performance score measures where you're most likely to be successful.

Your ACI score (0%-100%) contributes up to 25 points to your MIPS final score. For example, if your ACI score was 80%, it would contribute 20 points to your MIPS final score.

Some Clinicians May Be Excused From ACI

In limited circumstances, you may be able to skip ACI reporting and still potentially earn the maximum MIPS final score of 100 points. Typically, if you don't report ACI measures, your ACI score will be zero and your maximum MIPS final score would be 75. However, there are some exceptions to that (see next column). If you fall within 1 of those exceptions, you would be excused from ACI and the performance category's weighting toward your MIPS final score could be reduced to 0. If ACI is the only performance category that is being reweighted to 0, its weight is transferred to the quality performance category, which would now contribute up to 75 points toward your MIPS final score.

If you do any ACI reporting during the 2018 performance year, you will have waived your right to any exception from ACI. In the situations described above, clinicians would only be excused from ACI if they don't report any ACI measures or 2018 ACI transition measures; if they do report any of those measures, CMS will assume that they have decided to participate in the performance category and will assign them an ACI score that will contribute up to 25 points to their 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 ACI unless all MIPS eligible clinicians in the group are excused.

Some ACI Exceptions Must Be Applied For

You may *apply* for a significant hardship exception. Clinicians facing a significant hardship, such as insufficient internet access or extreme and uncontrollable circumstances (see page 13), can apply for CMS to reweight their ACI score. If you were approved for this exception in 2017, the approval doesn't roll over to 2018—you need to reapply annually.

New—CMS invites small practices to *apply* for a significant hardship exception. If your practice has 15 or fewer eligible clinicians, you can apply for an ACI exception. In this application, you are expected to demonstrate that there are "overwhelming barriers" that prevent you from complying with the ACI requirements. What would CMS consider to be an overwhelming barrier? The regulations offer little guidance, but they do say, "we do not intend to require documentation of the overwhelming barriers."

New—if your EHR system loses its CEHRT certification, you may *apply* for an exception. If your EHR system is decertified in 2017 or 2018, you can apply for an exception from ACI in 2018. In your application, you are expected to demonstrate that you made a good faith effort to implement a replacement CEHRT.

Submit your application by Dec. 31, 2018. Based on last year's timeline, you can expect CMS to start accepting applications in August, and the submission link will probably be posted at https://qpp.cms.gov/mips/advancing-care-information/hardship-exception.

Some Exceptions Are Automatic

Hospital- and ASC-based clinicians get an *automatic* exception. CMS will automatically excuse hospital-based clinicians and ambulatory surgical center (ASC)–based clinicians from having to report the ACI performance category. Clinicians are assigned to those categories if, based on a review of historic data, at least 75% of their covered professional services have Place of Service codes that represent hospitals or ASCs, respectively. CMS has said that it will notify you if it determines that you are a hospital- or ASC-based clinician.

NPs, PAs, CNSs, and CRNAs get an *automatic* exception. Nurse practitioners, physician assistants, clinical nurse specialists, and certified registered nurse anesthetists weren't part of the EHR meaningful use program. Consequently, CMS isn't sure whether they have enough applicable measures to succeed at ACI and has automatically excused them from ACI in 2017 and 2018.

Non–patient-facing clinicians get an *automatic* exception. If you don't interact with patients face-to-face and fall under the definition of non–patient-facing MIPS eligible clinician (see page 42), CMS will automatically apply the significant hardship exception.

Table 15: The 2018 ACI Transition Measure Set—At a Glance

If your EHR system is a 2014- or 2015-edition CEHRT, it can support the 2018 ACI transition measure set.

- **The 4 red measures** are base score measures. To get a base score of 50% (the maximum possible), you must (a) perform and report the 2 strictly mandatory measures and (b) either perform and report or claim an exclusion for the 2 other measures. Fall short and your base score and entire ACI score will both be 0%.
- ***The 7 italicized measures*** are performance score measures; 2 of them are also base score measures.
- **The 2 blue measures** can contribute to your performance score if reported instead of the Immunization Registry Reporting measure (see sidebar on page 36) *and/or* earn you a registry/agency bonus. If, for example, you engage with the IRIS Registry, reporting the Specialized Registry Reporting measure earns 10% for your performance score; engage with a second registry and the same measure can earn you a 5% registry/agency bonus.

How to report 2018 ACI transition measures. Some require you to attest that you did successfully perform the measure (attest "yes"); others require you to submit a numerator (n) and a denominator (d). For most performance score measures, your score will be based on your performance rate (the n/d ratio).

Base Score	Measure	How to Report	Required or Optional?	*Performance Score*	Registry/Agency Bonus Score
0% or 50%	Security Risk Analysis	Yes/No	Strictly mandatory		
	e-Prescribing	n/d	Possible exclusion*		
	Provide Patient Access	*n/d*	*Strictly mandatory*	*0%-20%*	
	Health Information Exchange	*n/d*	*Possible exclusion**	*0%-20%*	
	View, Download, or Transmit (VDT)	*n/d*	*Optional*	*0%-10%*	
	Patient-Specific Education	*n/d*	*Optional*	*0%-10%*	
	Secure Messaging	*n/d*	*Optional*	*0%-10%*	
	Medication Reconciliation	*n/d*	*Optional*	*0%-10%*	
	Immunization Registry Reporting	*Yes/No*	*Optional*	*0% or 10%*	
	Syndromic Surveillance Reporting	Yes/No	Optional	See sidebar on page 36	0% or 5%†
	Specialized Registry Reporting	Yes/No	Optional		0% or 5%†

Base score (0% or 50%) + ***Performance score*** *(0%-90%)* + registry/agency bonus (0% or 5%) + **CEHRT for improvement activities bonus** (0% or 10%; see page 37) + **2015-edition CEHRT bonus** (0% or 10%; see page 37) = **ACI score** (which is capped at 100%).

* You may be able to claim an exclusion for this measure (see below). † Note: The registry bonus is capped at 5%.

You May Be Able to Claim Exclusions for the e-Prescribing and Health Information Exchange 2018 ACI Transition Measures

Toward the end of the 2017 performance year, CMS added exclusions for 2 base score measures from the 2018 ACI transition measure set (see below) and for 3 base score measures from the ACI measure set (see page 40). These exclusions have been carried over to the 2018 performance year. If you are eligible for a measure's exclusion, you'll be able to attain the base score even though you don't meet the requirements of that measure.

Exclusion for the Health Information Exchange measure if you transfer a patient to another setting or refer a patient fewer than 100 times during your ACI performance period.

Exclusion for e-Prescribing measure if you write fewer than 100 prescriptions during your ACI performance period. (This won't apply to many ophthalmologists.)

Are these exclusions available if you are reporting as part of a group? Yes. When reporting as a group, you need to aggregate data for all the eligible clinicians in that group for whom you have data in CEHRT. If one of those clinicians meets the exclusion criteria for a measure, his or her data can be excluded from the calculation of that particular measure.

The 2018 ACI Transition Measure Set

Base Score Measures

These 2 measures contribute to your base score.

Security Risk Analysis. Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI [electronic protected health information] data created or maintained by certified EHR technology in accordance with requirements in 45 CFR164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the MIPS eligible clinician's risk management process. [Editor's note: If you are not fluent in CMS regulatory lingo, you can read a more digestible account of this measure at aao.org/medicare/advancing-care-information-measure/aci_trans_pphi_1-security-risk-analysis.]

e-Prescribing. At least 1 permissible prescription written by the MIPS eligible clinician is queried for a drug formulary and transmitted electronically using certified EHR technology.

- Exclusion available: See page 38.

Base Score/Performance Score Measures

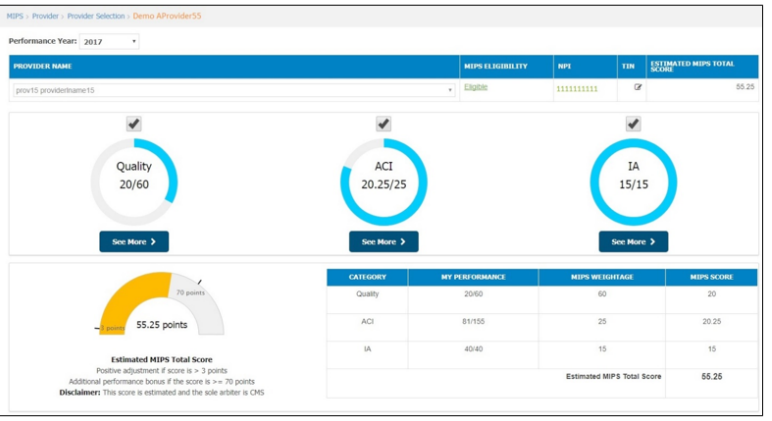
These 2 measures contribute to both your base score and your performance score.

Provide Patient Access. At least 1 patient seen by the MIPS eligible clinician during the performance period is provided timely (within 4 business days of being available to the MIPS eligible clinician) access to view online, download, and transmit to a third party their health information subject to the MIPS eligible clinician's discretion to withhold certain information.

- Contribution to performance score: 0%-20%

Health Information Exchange. The MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider (1) uses CEHRT to create a summary of care record; and (2) electronically transmits such summary to a receiving health care clinician for at least 1 transition of care or referral.

- Contribution to performance score: 0%-20%
- Exclusion available: See page 38.



Performance Score Measures

These 5 measures contribute to your performance score.

View, Download, or Transmit (VDT). At least 1 patient seen by the MIPS eligible clinician during the performance period (or patient-authorized representative) views, downloads or transmits their health information to a third party during the performance period.

- Contribution to performance score: 0%-10%

Patient-Specific Education. The MIPS eligible clinician must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide access to those materials to at least 1 unique patient seen by the MIPS eligible clinician.

- Contribution to performance score: 0%-10%

Secure Messaging. For at least 1 unique patient seen by the MIPS eligible clinician during the performance period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the performance period.

- Contribution to performance score: 0%-10%

Medication Reconciliation. The MIPS eligible clinician performs medication reconciliation for at least 1 transition of care in which the patient is transitioned into the care of the MIPS eligible clinician.

- Contribution to performance score: 0%-10%

Immunization Registry Reporting. The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data.

- Contribution to performance score: 0% or 10%

Alternative to Immunization Registry Reporting. You can use 1 of the bonus/performance score measures to earn 10% toward your performance score (see page 36).

- Contribution to performance score: 0% or 10%

Bonus/Performance Score Measures

These measures can earn you a 5% registry/agency bonus and, as an alternative to Immunization Registry Reporting, 10% toward your performance score. But note that:

- this bonus is capped at 5%, no matter how many agencies or registries you report to, and
- to earn the bonus, you can't report to the same registry or agency as you did for the Immunization Registry Reporting measure or its reporting alternative.

Syndromic Surveillance Reporting. The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data.

Specialized Registry Reporting. The MIPS eligible clinician is in active engagement to submit data to specialized registry

Table 16: The ACI Measure Set—At a Glance

If your EHR system is a 2015-edition CEHRT, it should have the functionality to support the ACI measure set.

- The 5 red measures are base score measures. You must (a) perform and report the 2 strictly mandatory measures and (b) either perform and report or claim an exclusion for the 3 other measures. Fall short and your base score and entire ACI score will both be 0%.
- ***The 9 italicized measures*** are performance score measures; 3 of them are also base score measures.
- The 4 blue measures can contribute to your performance score (see sidebar on page 36) *and* earn you a bonus. If, for example, you engage with the IRIS Registry, reporting the Clinical Data Registry Reporting measure earns 10% for your performance score; engage with a second registry and the same measure can earn you a 5% registry/agency bonus.

How to report ACI measures. Some require you to attest that you did successfully perform the measure (attest "yes"); others require you to submit a numerator (n) and a denominator (d).

Base Score	Measure	How to Report	Required or Optional?	*Performance Score*	Registry/Agency Bonus Score
0% or 50%	Security Risk Analysis	Yes/No	Strictly mandatory		
	e-Prescribing	n/d	Possible exclusion*		
	Provide Patient Access	*n/d*	*Strictly mandatory*	*0%-10%*	
	Send a Summary of Care	*n/d*	*Possible exclusion**	*0%-10%*	
	Request/Accept Summary of Care	*n/d*	*Possible exclusion**	*0%-10%*	
	Patient-Specific Education	*n/d*	*Optional*	*0%-10%*	
	View, Download, or Transmit (VDT)	*n/d*	*Optional*	*0%-10%*	
	Secure Messaging	*n/d*	*Optional*	*0%-10%*	
	Patient-Generated Health Data	*n/d*	*Optional*	*0%-10%*	
	Clinical Information Reconciliation	*n/d*	*Optional*	*0%-10%*	
	Immunization Registry Reporting	*Yes/No*	*Optional*	*0% or 10%*	
	Syndromic Surveillance Reporting	Yes/No	Optional	See sidebar on page 36	0% or 5%†
	Electronic Care Reporting	Yes/No	Optional		0% or 5%†
	Public Health Registry Reporting	Yes/No	Optional		0% or 5%†
	Clinical Data Registry Reporting	Yes/No	Optional		0% or 5%†

Base score (0% or 50%) + ***Performance score*** *(0%-90%)* + registry/agency bonus (0% or 5%) + **CEHRT for improvement activities bonus** (0% or 10%; see page 37) + **2015-edition CEHRT bonus** (0% or 10%; see page 37) = **ACI score** (which is capped at 100%).

* You may be able to claim an exclusion for this measure (see below). † Note: The registry bonus is capped at 5%.

Exclusions Available for 3 ACI Base Score Measures: e-Prescribing, Send a Summary of Care, and Request/Accept Summary of Care

Exclusion for e-Prescribing measure if you write fewer than 100 prescriptions during your ACI performance period.

Exclusion for the Send a Summary of Care measure if you transfer a patient to another setting or refer a patient fewer than 100 times during your ACI performance period.

Exclusion for the Request/Accept Summary of Care measure if you can claim this exclusion if you receive transitions of care or referrals or have patient encounters in which you have never before encountered the patient fewer than 100 times during your ACI performance period.

The ACI Measure Set

Base Score Measures

These 2 measures contribute to your base score.

Security Risk Analysis. For definition, see page 39.

e-Prescribing. For definition, see page 39.

- Exclusion available: See page 40.

Base Score/Performance Score Measures

These 3 measures contribute to both your base score and your performance score.

Provide Patient Access. For at least 1 unique patient seen by the MIPS eligible clinician: (1) The patient (or the patient authorized representative) is provided timely (within 4 business days of being available to the MIPS eligible clinician) access to view online, download, and transmit his or her health information; and (2) The MIPS eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programing Interface (API) in the MIPS eligible clinician's certified EHR technology.

- Contribution to performance score: 0%-10%

Send a Summary of Care. For at least 1 transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider (1) creates a summary of care record using certified EHR technology; and (2) electronically exchanges the summary of care record.

- Contribution to performance score: 0%-10%
- Exclusion available: See page 40.

Request/Accept Summary of Care. For at least 1 transition of care or referral received or patient encounter in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician receives or retrieves and incorporates into the patient's record an electronic summary of care document.

- Contribution to performance score: 0%-10%
- Exclusion available: See page 40.

Performance Score Measures

These 6 measures contribute to your performance score.

Patient-Specific Education. The MIPS eligible clinician must use clinically relevant information from certified EHR technology to identify patient-specific educational resources and provide electronic access to those materials to at least 1 unique patient seen by the MIPS eligible clinician.

- Contribution to performance score: 0%-10%

View, Download, or Transmit (VDT). During the performance period, at least 1 unique patient (or patient-authorized representatives) seen by the MIPS eligible clinician actively engages with the EHR made accessible by the MIPS eligible clinician by either (1) viewing, downloading, or transmitting to a third party their health information; or (2) accessing their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the MIPS eligible clinician's certified EHR technology; or (3) a combination of (1) and (2).

- Contribution to performance score: 0%-10%

Secure Messaging. For definition, see page 39.

- Contribution to performance score: 0%-10%

Patient-Generated Health Data. Patient-generated health data or data from a nonclinical setting is incorporated into the certified EHR technology for at least 1 unique patient seen by the MIPS eligible clinician during the performance period.

- Contribution to performance score: 0%-10%

Clinical Information Reconciliation. For at least 1 transition of care or referral received or patient encounter in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician performs clinical information reconciliation. The MIPS eligible clinician must implement clinical information reconciliation for the following 3 clinical information sets: (1) Medication. Review of the patient's medication, including the name, dosage, frequency, and route of each medication. (2) Medication allergy. Review of the patient's known medication allergies. (3) Current problem list. Review of the patient's current and active diagnoses.

- Contribution to performance score: 0%-10%

Immunization Registry Reporting. The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

- Contribution to performance score: 0% or 10%

Alternative to Immunization Registry Reporting: You can use 1 of the bonus/performance score measures to earn 10% toward your performance score (see page 36).

Bonus/Performance Score Measures

These measures can earn a 5% registry/agency bonus and/or, as an alternative to the Immunization Registry Reporting measure (see above), 10% toward your performance score. The bonus is capped at 5%, and there is no "double dipping" (see page 36).

Syndromic Surveillance Reporting. The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting.

Electronic Case Reporting. The MIPS eligible clinician is in active engagement with a public health agency to electronically submit case reporting of reportable conditions.

Public Health Registry Reporting. The MIPS eligible clinician is in active engagement with a public health agency to submit data to public health registries.

Clinical Data Registry Reporting. The MIPS eligible clinician is in active engagement to submit data to a clinical data registry.

YOU SHOULD MAX OUT YOUR SCORE FOR THIS PERFORMANCE CATEGORY

How to Report Improvement Activities

BY REBECCA HANCOCK, FLORA LUM, MD, CHRIS MCDONAGH, CHERIE MCNETT, JESSICA PETERSON, MD, MPH, AND SUE VICCHRILLI, COT, OCS, OCSR.

In 2018, maxing out the improvement activities performance category will be enough to avoid a 2020 payment penalty. To do so, you will need to successfully perform 1 to 4 performance activities—the amount depends on how those activities are weighted, as well as the size and location of your practice. However many you do, they should all be done during the same performance period, which must be at least 90 consecutive days. Your score for improvement activities contributes up to 15 points to your 2018 MIPS final score.

How You'll Be Scored

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 for an improvement activity if they are:

- in a small practice (fewer than 16 eligible clinicians),
- in a rural practice (as defined by CMS),
- in a 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. To be one, you would have to bill Medicare for no more than 100 patient-facing encounter codes—including Medicare telehealth services—in a designated period. For group (or virtual group) reporting, if more than 75% of the NPIs who bill under the group's TIN (or virtual group's identifier) during the determination period are non–patient-facing, then the ensemble as a whole is considered non–patient-facing.

Zero Penalties in 2020

Every ophthalmologist can get a 2018 MIPS final score of 15 points, which would be enough to avoid the 2020 payment penalty. You can, for example, earn 15 points to your final score by maxing out on improvement activities. Every ophthalmologist should be able to do that, regardless of practice size and subspecialty, and whether or not they have electronic health records.

Maximum score is capped at 40 points. If you don't score double, you can accrue the maximum score of 40 points by performing either:

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

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

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

Each improvement activity is all or nothing. You won't score points for an improvement activity unless it is performed for 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 2 categories in 2018.

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 20 points would be 50%). This contributes up to 15 points to your MIPS final score (e.g., a score of 50% would contribute 7.5 points).

Decide How You Will Report

Consider reporting as a group. You can report improvement activities either as an individual, as a group, or as a virtual group. When you report as a group (or virtual group), all MIPS eligible clinicians who participate in that group (or virtual group) will receive the same score for improvement activities. And if at least 1 of those clinicians satisfies the requirements for a particular improvement activity, then the whole group can score points for that activity. Note: You must participate in MIPS in the same way—as an individual, a group, or a virtual group—for all MIPS performance categories.

Select a reporting mechanism. The Academy recommends that you attest to your improvement activities performance via the IRIS Registry, but you also can use the CMS web portal, or possibly your electronic health record (EHR) vendor (ask your vendor whether it will offer this option).

You attest that you successfully completed improvement activities. Whichever reporting mechanism you choose, it is your responsibility to attest that you appropriately completed the improvement activities that you choose to perform. If that mechanism is run by 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 improvement activities. Note: You also should document your performance of those activities so you'll be prepared for a possible audit in the future.

Select, Perform, and Document Your Improvement Activities

You can use the same improvement activities that you used in 2017. 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 24 improvement activities that are most meaningful for ophthalmology practices. These include 5 high-weighted activities and 19 of medium weight (see Table 17, page 44).

Select which activities you will perform. In order to score full marks, the number of improvement activities that you need to perform can range from 1 to 4, depending on the activities' weights and whether you score double (see "How You'll Be Scored," see previous page).

If your EHR system is a CEHRT, go for the ACI bonus. When selecting improvement activities, you should note that some of them can earn you a bonus for your ACI score if you use the functionalities of a certified EHR technology (CEHRT) to help you perform those activities (see Table 17, page 44). For example, suppose you decide to perform the "Provide 24/7 access" improvement activity (see the third activity in Table 17, page 44); if you use your CEHRT's secure messaging functionality to provide 24/7 access for advice about urgent and emergent care (e.g., sending or responding to secure messages outside business hours), this would qualify you for the 10% ACI bonus. You only need to use CEHRT for 1 improvement activity to score the full 10% ACI bonus. This bonus accrues to your ACI score, not your improvement activities score.

Some improvement activities involve integrating your EHR system with the IRIS Registry. If you fully integrate your EHR system with the IRIS Registry and utilize its dashboard, you could qualify for activities that involve or include the use of a registry (see Table 17, page 44).

CMS has stated that "If you choose to participate in MIPS via a QCDR [such as the IRIS Registry], you must select and achieve each improvement activity separately. You will not receive credit for multiple activities just by selecting one activity that includes participation in a QCDR."

Are you already performing MIPS improvement activities? There are several improvement activities that practices may have been performing and documenting as a matter of course. These include the following:

- IA_AHE_1: Engagement of new Medicaid patients and follow-up.
- IA_EPA_1: Provide 24/7 access to eligible clinicians or groups who have real-time access to patient's medical record.
- IA_CC_2: Implementation of improvements that contribute to more timely communication of test results.
- IA_CC_8: Implementation of documentation improvements for practice/process improvements.

You must perform improvement activities for at least 90 consecutive days. In order to score points for an improvement activity, you—or one of your colleagues, if you are reporting as part of a group or virtual group—must perform that activity for at least 90 consecutive days. The MIPS regulations state: "Activities, where applicable, may be continuing (that is, could have started prior to the performance period and are continuing) or be adopted in the performance period as long as an activity is being performed for at least 90 days during the performance period."

Document your improvement activities. To make sure you're ready for a future audit, you should maintain documentation that shows you performed the improvement activities. (For documentation suggestions, see aao.org/medicare/improvement-activities.)

Get Credit for MIPS *and* MOC

The ABO will help you to implement the Maintenance of Certification (MOC) Part IV improvement activity. If you have an EHR system, and have integrated it with the IRIS Registry, you can use data from your IRIS Registry dashboard to design and implement a quality improvement project. This is a medium-weight improvement activity.

Design your plan. Start by identifying 1 or 2 IRIS Registry measures that you would like to improve, set goals for those measures, and decide what steps you would take to achieve those goals. The American Board of Ophthalmology (ABO) can provide you with details of what needs to be in your plan.

Submit your plan to the ABO no later than Aug. 31, 2018. The ABO has said that you should expect the review and approval process to take *at least* 4 weeks.

Implement your plan for 90-120 days. Use the IRIS Registry dashboard to check on your progress, and fine-tune your processes if necessary. Once the project is complete, review its effectiveness.

Give the ABO your feedback. After you've completed the project, the ABO will ask you to complete a short survey about your experience and the project's impact.

Read the IRIS Registry's overview of the process: aao.org/iris-registry/maintenance-of-certification.

Visit the ABO's website to learn more: https://abop.org/IRIS.

Table 17: 24 Improvement Activities—At a Glance

	Improvement Activity (Activity ID)	Weighting	Eligible for ACI Bonus?	Credit for IRIS/ EHR Integration?
See page 45	Engagement of new Medicaid patients and follow-up (IA_AHE_1).	High		
	Collection and follow-up on patient experience and satisfaction data on beneficiary engagement (IA_BE_6).	High		
	Provide 24/7 access to eligible clinicians or groups who have real-time access to patient's medical record (IA_EPA _1).	High	ACI bonus	
	Use of QCDR for feedback reports that incorporate population health (IA_PM_7).	High		IRIS/EHR credit
	Participation in CAHPS [Consumer Assessment of Healthcare Providers and Systems] or other supplemental questionnaire (IA_PSPA_11).	High		
	Engagement of patients through implementation of improvements in patient portal (IA_BE_4).	Medium	ACI bonus	
See page 46	Regularly assess the patient experience of care through surveys, advisory councils, and/or other mechanisms (IA_BE_13).	Medium		
	Use of tools to assist patient self-management (IA_BE_17).	Medium		
	Tobacco use (IA_BMH_2).	Medium		
	Implementation of use of specialist reports back to referring clinician or group to close referral loop (IA_CC_1).	Medium	ACI bonus	
	Implementation of improvements that contribute to more timely communication of test results (IA_CC_2).	Medium		
	TCPI participation [CMS Transforming Clinical Practice Initiative] (IA_CC_4).	Medium		
	Use of QCDR [Qualified Clinical Data Registry] to promote standard practices, tools, and processes in practice for improvement in care coordination (IA_CC_6).	Medium		IRIS/EHR credit
	Implementation of documentation improvements for practice/ process improvements (IA_CC_8).	Medium	ACI bonus	
See page 47	Practice improvements for bilateral exchange of patient information (IA_CC_13).	Medium	ACI bonus	
	Collection and use of patient experience and satisfaction data on access (IA_EPA_3).	Medium		
	Use of QCDR data for quality improvement such as comparative analysis reports across patient populations (IA_PM_10).	Medium		IRIS/EHR credit
	Participation in MOC Part IV (IA_PSPA_2).	Medium		
	Annual registration in the Prescription Drug Monitoring Program (IA_PSPA_5).	Medium		
	Use of QCDR data, for ongoing practice assessment and improvements (IA_PSPA_7).	Medium		IRIS/EHR credit
See page 48	Implementation of an antibiotic stewardship program (IA_PSPA_15).	Medium		
	Use of decision support and standardized treatment protocols (IA_PSPA_16).	Medium	ACI bonus	
	Measurement and improvement at the practice and panel level (IA_PSPA_18).	Medium		
	Leadership engagement in regular guidance and demonstrated commitment for implementing practice improvement changes (IA_PSPA_20).	Medium		

Table 18: 24 Improvement Activities—Detailed Listings

Note: At time of press, CMS had not published the 2018 validation criteria and documentation suggestions, but they are expected to be similar to those from 2017. Once they're available, an updated version of this Table 18 will be posted online. For documentation requirements and other guidance, you also can check the online listings of improvement activities at aao.org/medicare/improvement-activities.

Engagement of new Medicaid patients and follow-up (IA_AHE_1).

Scoring: High weight.
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

Collection and follow-up on patient experience and satisfaction data on beneficiary engagement (IA_BE_6).

Scoring: High weight.
Description: Collection and follow-up on patient experience and satisfaction data on beneficiary engagement, including development of improvement plan.

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

Scoring: High weight; eligible for ACI bonus.
Description: Provide 24/7 access to MIPS eligible clinicians, groups, or care teams for advice about urgent and emergent care (for example, 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 1 or more of the following:
- Expanded hours in evenings and weekends with access to the patient medical record (for example, coordinate with small practices to provide alternate hour office visits and urgent care); and/or
- Use of alternatives to increase access to care team by MIPS eligible clinicians and groups, such as telehealth, phone visits, group visits, home visits, and alternate locations (for example, 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

Eligible for ACI bonus. You can earn an ACI bonus if you complete this improvement activity using CEHRT.
Related ACI measures. CMS has listed the following ACI measures as being related to this improvement activity:
- Provide Patient Access
- Send a Summary of Care
- Request/Accept Summary of Care
- Secure Messaging

Use of QCDR for feedback reports that incorporate population health (IA_PM_7).

Scoring: High weight; credit for IRIS Registry/EHR integration.
Description: Use of a Qualified Clinical Data Registry (QCDR) [e.g., the IRIS Registry] to generate regular feedback reports that summarizes local practice patterns and treatment outcomes, including for vulnerable populations.
Editor's note: If you have integrated your EHR system with the IRIS Registry, you could use data from its dashboard in performing this improvement activity.

Participation in CAHPS or other supplemental questionnaire (IA_PSPA_11).

Scoring: High weight.
Description: Participation in the Consumer Assessment of Healthcare Providers and Systems Survey or other supplemental questionnaire items (e.g., Cultural Competence or Health Information Technology supplemental item sets).
Editor's note: Because it can be burdensome to implement, the CAHPS survey is most often utilized by large practices and medical centers.

Engagement of patients through implementation of improvements in patient portal (IA_BE_4).

Scoring: Medium weight.
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.

Eligible for ACI bonus. You can earn an ACI bonus if you complete this improvement activity using CEHRT.
Related ACI measures. CMS has listed the following ACI measures as being related to this improvement activity:
- Provide Patient Access
- Patient-Specific Education

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Regularly assess the patient experience of care through surveys, advisory councils and/or other mechanisms (IA_BE_13).
Scoring: Medium weight. **Description:** Regularly assess the patient experience of care through surveys, advisory councils, and/or other mechanisms.
Use of tools to assist patient self-management (IA_BE_17).
Scoring: Medium weight. **Description:** Use of tools to assist patients in assessing their need for support for self-management (e.g., the Patient Activation Measure or How's My Health).
Tobacco use (IA_BMH_2).
Scoring: Medium weight. **Description:** Regular engagement of MIPS eligible clinicians or groups in integrated prevention and treatment interventions, including tobacco use screening and cessation interventions (refer to NQF #0028) for patients with co-occurring conditions of behavioral or mental health and at risk factors for tobacco dependence.
Implementation of use of specialist reports back to referring clinician or group to close referral loop (IA_CC_1).
Scoring: Medium weight; eligible for ACI bonus. **Description:** Performance of regular practices that include providing specialist reports back to the referring 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. **Editor's note:** In 2017, this improvement activity's description stated that the reports "could be document or noted in the certified EHR technology." The current description omits the word "certified" because CMS doesn't believe this improvement activity should be limited to EHRs that have been certified. However, if you do use a certified EHR technology (CERHT), you may qualify for the ACI bonus. **Eligible for ACI bonus.** You can earn an ACI bonus if you complete this improvement activity using CEHRT. **Related ACI measures.** CMS has listed the following ACI measures as being related to this improvement activity: • Send a Summary of Care • Request/Accept Summary of Care • Clinical Information Reconciliation
Implementation of improvements that contribute to more timely communication of test results (IA_CC_2).
Scoring: Medium weight. **Description:** Timely communication of test results defined as timely identification of abnormal test results with timely follow-up.
Transforming Clinical Practice Initiative (TCPI) participation (IA_CC_4).
Scoring: Medium weight. **Description:** Participation in the CMS Transforming Clinical Practice Initiative.
Use of QCDR to promote standard practices, tools and processes in practice for improvement in care coordination (IA_CC_6).
Scoring: Medium weight; credit for IRIS Registry/EHR integration. **Description:** Participation in a QCDR [e.g., the IRIS Registry], demonstrating performance of activities that promote use of standard practices, tools, and processes for quality improvement (e.g., documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups).
Implementation of documentation improvements for practice/process improvements (IA_CC_8).
Scoring: Medium weight; eligible for ACI bonus. **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). **Related ACI measures.** CMS has listed the following ACI measures as being related to this improvement activity: • Secure Messaging • Send a Summary of Care • Request/Accept Summary of Care • Clinical Information Reconciliation

Practice improvements for bilateral exchange of patient information (IA_CC_13).

Scoring: Medium weight; eligible for ACI bonus.
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
Editor's note: CMS updated the description to include the example of Open Notes, which relies on an EHR-facilitated process to give patients open access to clinical notes. For a quick introduction to how this might work in practice, see "The OpenNotes Movement—Why Doctors Are Sharing Clinical Notes With Patients," (*EyeNet*, June 2016; aao.org/eyenet/article/opennotes-movement-why-doctors-are-sharing-clinica?june-2016).)
Eligible for ACI bonus. You can earn an ACI bonus if you complete this improvement activity using CEHRT.
Related ACI measures. CMS has listed the following ACI measures as being related to this improvement activity:
• Send a Summary of Care
• Request/Accept Summary of Care
• Clinical Information Reconciliation

Collection and use of patient experience and satisfaction data on access (IA_EPA_3).

Scoring: Medium weight.
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.

Use of QCDR data for quality improvement such as comparative analysis reports across patient populations (IA_PM_10).

Scoring: Medium weight; credit for IRIS Registry/EHR integration.
Description: Participation in a QCDR [e.g., the IRIS Registry], clinical data registries, or other registries run by other government agencies such as FDA, or private entities such as hospital or medical or surgical society. Activity must include use of QCDR data for quality improvement (e.g., comparative analysis across specific patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcome).
Editor's note: If you integrate your EHR system with the IRIS Registry, you can use its dashboard to review your progress.

Participation in MOC Part IV (IA_PSPA_2).

Scoring: Medium weight; credit for IRIS Registry/EHR integration.
Description: Participation in Maintenance of Certification (MOC) Part IV for improving professional practice including participation in a local, regional or national outcomes registry or quality assessment program. Performance of monthly activities across practice to regularly assess performance in practice, by reviewing outcomes addressing identified areas for improvement and evaluating the results.
Editor's note: If you have an EHR system, and have integrated it with the IRIS Registry, you can work with the ABO on this improvement activity. For more information on using the IRIS Registry for MOC Part IV, see page 43. Read the IRIS Registry's overview of this process at aao.org/iris-registry/maintenance-of-certification.

Read the ABO's summary of the process at https://abop.org/IRIS.

Annual registration in the Prescription Drug Monitoring Program (IA_PSPA_5).

Scoring: Medium weight.
Description: Annual registration by eligible clinician or group in the prescription drug monitoring program of the state where they practice. Activities that simply involve registration are not sufficient. MIPS eligible clinicians and groups must participate for a minimum of 6 months.

Use of QCDR data, for ongoing practice assessment and improvements (IA_PSPA_7).

Scoring: Medium weight; credit for IRIS Registry/EHR integration.
Description: Use of QCDR data [e.g., IRIS Registry data], for ongoing practice assessment and improvements in patient safety.
Editor's note: If you've integrated your EHR system with the IRIS Registry, the dashboard provides a convenient way to review your performance for quality measures, including measures 130, 192, and 238, which are related to patient safety.

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Implementation of an antibiotic stewardship program (ASP) (IA_PSPA_15).

Scoring: Medium weight.
Description: Leadership of an antibiotic stewardship program (ASP) that includes implementation of an ASP that measures appropriate use of antibiotics for several different conditions (such as but not limited to upper respiratory infection treatment in children, diagnosis of pharyngitis, bronchitis treatment in adults) according to clinical guidelines for diagnostics and therapeutics. Specific activities may include:
• Develop facility-specific antibiogram and prepare report of findings with specific action plan that aligns with overall facility or practice strategic plan.
• Lead the development, implementation, and monitoring of patient care and patient safety protocols for the delivery of ASP including protocols pertaining to the most appropriate setting for such services (i.e., outpatient or inpatient).
• Assist in improving ASP service line efficiency and effectiveness by evaluating and recommending improvements in the management structure and workflow of ASP processes.
• Manage compliance of the ASP policies and assist with implementation of corrective actions in accordance with facility or clinic compliance policies and facility or practice medical staff by-laws.
• Lead the education and training of professional support staff for the purpose of maintaining an efficient and effective ASP.
• Coordinate communications between ASP management and facility or practice personnel regarding activities, services, and operational/clinical protocols to achieve overall compliance and understanding of the ASP.
• Assist, at the request of the facility or practice, in preparing for and responding to third-party requests, including but not limited to payer audits, governmental inquiries, and professional inquiries that pertain to the ASP service line.
• Implementing and tracking an evidence-based policy or practice aimed at improving antibiotic prescribing practices for high-priority conditions.
• Developing and implementing evidence-based protocols and decision-support for diagnosis and treatment of common infections.
• Implementing evidence-based protocols that align with the recommendations in the Centers for Disease Control and Prevention's Core Elements of Outpatient Antibiotic Stewardship guidance.

Use of decision support and standardized treatment protocols (IA_PSPA_16).

Scoring: Medium weight.
Description: Use decision support and standardized treatment protocols to manage workflow in the team to meet patient needs.
Eligible for ACI bonus. You can earn an ACI bonus if you complete this improvement activity using CEHRT.
Related CEHRT functionality. CMS has listed the following CEHRT function as being related to this improvement activity:
• Clinical Decision Support

Measurement and improvement at the practice and panel level (IA_PSPA_18).

Scoring: Medium weight; credit for IRIS Registry/EHR integration.
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 1 or more of the following:
• Regularly review measures of quality, utilization, patient satisfaction, and other measures that may be useful at the practice level and at the level of the care team or MIPS eligible clinician or group (panel); and/or
• Use relevant data sources to create benchmarks and goals for performance at the practice level and panel level.
Editor's note: If you've integrated your EHR system with the IRIS Registry, the dashboard provides a convenient way to review your performance for quality measures.

Leadership engagement in regular guidance and demonstrated commitment for implementing practice improvement changes (IA_PSPA_20).

Scoring: Medium weight.
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.

NO REPORTING NEEDED FOR THIS PERFORMANCE CATEGORY

How CMS Evaluates Cost

BY CHERIE MCNETT, CHRIS MCDONAGH, AND JESSICA PETERSON, MD, MPH.

The cost performance category contributes up to 10 points to your MIPS final score (0-100 points). It is 1 of 4 performance categories that contribute to that score, and it is the only one where you don't have to do any reporting or attesting. Instead, CMS uses administrative claims data to evaluate your performance. The performance period is the full calendar year.

Cost's Role In MIPS Is Slated to Grow

Cost in 2017. For the 2017 performance year, CMS assigned you a cost score but did not factor it into your MIPS final score.

Cost in 2018. In 2018, your cost score is weighted at 10% of your MIPS final score (0-100 points). In other words, it can contribute up to 10 points to that final score.

Cost during 2019-2021. Over the next 3 years, CMS can decide on a year-by-year basis how much weight to give the cost performance category when calculating MIPS final scores. However, this flexibility is limited as follows:

- At minimum, cost's contribution to the final score would be weighted at 10%, with quality weighted at 50%, advancing care information (ACI) weighted at 25%, and improvement activities weighted at 15%.
- At most, cost's contribution to the final score would be weighted at 30%, with quality weighted at 30%, advancing care information (ACI) weighted at 25%, and improvement activities weighted at 15%.

Cost in 2022. Starting in 2022, cost's contribution to your final score will be weighted at 30%.

5 Quick Facts About Cost

No reporting requirements. CMS will evaluate you based on Medicare claims data for patients that it attributes to you.

CMS will evaluate your performance either at the virtual group level, group level, or individual level. You will be scored at the same level for all 4 performance categories.

You will be scored on up to 2 measures. You will be scored on the Total Per Capita Cost measure and the Medicare Spending Per Beneficiary measure, provided you meet their 20-patient and 35-episode case minimums, respectively.

The performance period for cost is a full calendar year. Cost and quality both have a 12-month performance period, while ACI and improvement activities have a 90-day performance period.

Your cost score contributes up to 10 points to your MIPS final score. However, if you fail to meet the case minimum for both the Total Per Capita Cost measure and the MSPB measure, your performance categories will be reweighted, with those 10 potential points being shifted to quality (see Table 3, page 12).

In 2018, You'll Be Scored on 2 Measures

Your 2018 cost will be based on up to 2 measures: the *Total Per Capita Cost* measure and the *Medicare Spending Per Beneficiary* measure. Both of these flawed measures were carried over from the Value-Based Modifier program, with some changes to their attribution methods.

Episode-based measures are expected to return in 2019. In the past, CMS had used a third type of measure for evaluating resource use: episode-based measures. Although such measures aren't currently in use, CMS is developing new episode-based measures—including a measure for routine cataract surgery—that it plans to incorporate into MIPS in 2019.

Total Per Capita Cost

The Total Per Capita Cost measure takes into account all Medicare Part A and Part B costs incurred during 2018 for Medicare patients who are attributed to you. Here, in brief, is how it works.

Which Medicare patients are included? A patient's costs will only be factored into this score if he or she receives primary care services during the performance period. Evaluation and management (E&M) office visits are viewed by CMS as primary care services.

Which patients are attributed to you? CMS uses a 2-step process to attribute patients—and their costs—to clinicians. First, CMS attributes the patients to the primary care physician, nurse practitioner, physician assistant, or clinical nurse specialist who provides the most primary care services to that patient; if the patient didn't receive any primary care services from those types of clinicians, he or she will be attributed to

the non–primary care clinician who provided the most office visits.

Because CMS will be counting E&M services as primary care services, the E&M codes (CPT codes 99201-99215) will be factored into the attribution process; the ophthalmic exam codes (CPT 92002-92014) won't. Regardless of whether you use E&M or ophthalmic exam codes, you should bill the level of exam that your documentation supports.

CMS tries to level the playing field. In an effort to compare providers fairly, CMS takes into account a number of factors. These include:

- payment factors that are unrelated to the care provided (e.g., geographic variations in Medicare payment policy);
- patients who weren't Medicare beneficiaries for the full year (these have their costs annualized; for example, if they were only in Medicare for 6 months their costs would be doubled);
- extreme outliers (these are determined through statistical methods);
- risk factors that can affect medical costs; and
- a physician's specialty.

There is a 20-patient case minimum. In order to get a score for this measure, at least 20 patients must be attributed to you.

You score 1-10 points. Your score will depend on how your performance compares with other MIPS participants during the current performance year.

A problematic measure. The Academy, along with other physician associations, has pointed out a number of flaws with this measure. The risk adjustment methodology is problematic, and attribution strategies are unreliable, with ophthalmologists held responsible for hospitalizations that may not be related to eye care. The measure excludes outpatient prescription drugs, which skews scoring against physicians whose treatment options include procedural interventions rather than putting patients on maintenance drugs.

Medicare Spending Per Beneficiary

The Medicare Spending Per Beneficiary (MSPB) measure focuses on costs associated with hospital admission. CMS has stated that very few ophthalmologists are likely to meet this measure's 35-episode case minimum.

What is an MSPB episode of care? An MSPB episode of care starts 3 days before a patient is admitted to hospital and ends 30 days after he or she is discharged.

What costs are included? All Medicare Part A and Part B charges.

Which episodes of care are attributed to you? An episode of care—along with its associated costs—is attributed to you if you provided the most Medicare Part B covered services during the hospitalization, even if the hospital admission is unrelated to ophthalmology.

As with the Total Per Capita Cost measure, CMS attempts to account for some factors that might unfairly skew how this measure is scored.

There is a 35-episode case minimum. In order to get a score for this measure, at least 35 episodes of care must be attributed to you.

You score 1-10 points. As with the Total Per Capita Cost measure, your score will depend on how your performance compares with other MIPS participants during the current performance year.

A problematic measure. Given the prevalence of chronic eye conditions in the Medicare population, potentially many MSPB episodes of care could be unfairly attributed to ophthalmologists.

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

Calculating Your Cost Score

If you meet the case minimum for both cost measures, you will have scored up to 10 points for the Total Per Capita Cost measure and up to 10 points for the MSPB measure. CMS will divide the sum of those scores by 20, and turn the resulting fraction into a percentage.

If you meet the case minimum for just 1 cost measure, CMS will divide your score for that measure by 10, and turn the resulting fraction into a percentage.

Your cost score contributes up to 10 points to your MIPS final score.

Note: If you don't meet the case minimum for both of the cost measures, cost's contribution to your final score will be reweighted to zero, and quality's contribution will be reweighted upward (see Table 3, page 12).

A Potential Way to Track Costs: Clinical Data Registries

Looking to the future: A better way to evaluate cost. CMS is statutorily obliged to evaluate MIPS eligible clinicians on their resource use. However, the current cost measures aren't meaningful measures of ophthalmologists' resource use; because of that, the measures aren't actionable for ophthalmology practices.

In its advocacy to CMS, the Academy has pointed out that the IRIS Registry, along with similar clinical data registries used by other specialties, would provide a better way for physicians and their staff to track and improve resource use.

Clinical data registries can collect data on resource use. The IRIS Registry, like many other clinical data registries, not only collects your clinical data but also can access your practice's administrative database. This means that many practice expenses, visits, procedures, preoperative evaluations, lab results, and returns to the operating room could be accurately and completely captured. This would make it possible to appropriately measure resource use for many common ophthalmological diseases and conditions.

Clinical data registries provide a window on resource use. The IRIS Registry can provide a better way for clinicians to understand what they need to do to keep costs in line and improve their resource use.

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WILL MIPS GIVE YOUR 2020 PAYMENTS A BOOST?

How CMS Will Calculate Bonuses and Penalties

BY REBECCA HANCOCK, FLORA LUM, MD, CHRIS MCDONAGH, CHERIE MCNETT, JESSICA PETERSON, MD, MPH, AND SUE VICCHRILLI, COT, OCS, OCSR.

The Merit-Based Incentive Payment System (MIPS), now in its second year, is starting to ramp up its bonuses and penalties.

Your 2018 final score will impact your 2020 Medicare reimbursement. In brief, your 2020 payments may be subject to a negative payment adjustment (if your final score is less than 15 points), a positive payment adjustment (if your score is higher than 15 points), or a positive payment adjustment plus an exceptional performance payment adjustment (if your score is 70 points or higher). Here's how CMS will determine what payment adjustment it will apply to your payments.

First, CMS Calculates Your MIPS Final Score

Your MIPS final score can range from 0 to 100 points. It is a composite score that will be based on your scores in 4 performance categories along with 2 bonus scores.

Typically, your scores for the 4 performance categories are weighted as follows:

- **Your quality score** contributes up to 50 points to your MIPS final score.
- **Your advancing care information (ACI) score** contributes up to 25 points.
- **Your improvement activities score** contributes up to 15 points.
- **Your cost score** contributes up to 10 points.

In limited circumstances, CMS may recalibrate how it weights your performance category scores. This year, CMS has added new ways to opt out of reporting the ACI performance category (see "Some Clinicians May Be Exempt From ACI," page 37). If your application for an ACI exception is approved, then CMS reweights your quality score so it could contribute up to 75 points to your MIPS final score, with your improvement activities score and cost score still contributing 0-15 points and 0-10 points, respectively. It would be rarer for CMS to grant you an exclusion for any of the other 3 performance categories (see "Quakes, Fires, and Other Disasters!," page 13), but if it did do so, it would reweight how the remaining performance categories contribute to your MIPS final score (see "Table 3: Reweighting the Performance Categories," page 12).

Small practices get a 5-point bonus. You get this 5-point bonus if you report data for at least 1 performance category *and* CMS determines—based on historical data—that you are part of a small practice (see "Small or Large Practice?" page 12).

Get up to 5 bonus points for patient complexity. If you report MIPS data for at least 1 performance category, you may be eligible for a complex patient bonus (see "Extra Points for Treating Complex Patients," page 53).

Your MIPS final score. Your final score, which is capped at 100 points, is the sum of your performance category scores (0-100 points) plus your complex patient bonus (0-5 points) plus your small-practice bonus (0 or 5 points).

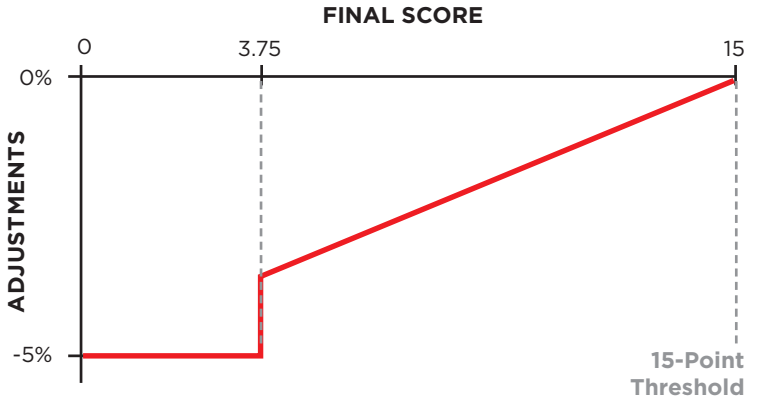
Penalty, Small Bonus, or Modest Bonus?

CMS checks whether your 2018 final score exceeds, meets, or falls below a 15-point *performance threshold.* This will determine whether your 2020 payment adjustment factor is positive, neutral, or negative (see "Under the Payment

Table 19: Payment Penalty

If your 2018 final score is less than the 15-point performance threshold, your 2020 Medicare payments will be reduced as follows:

- Final score larger than 3.75 points, your penalty will be based on a sliding scale as shown below.
- Final score of 3.75 points or less, the sliding scale becomes a precipice and you receive the maximum –5% payment adjustment.



Adjustment Factor, Bonuses and Penalties Will Be Budget Neutral," below). Note: During the next 4 performance years, CMS is obliged to steadily raise this threshold; by the 2022 performance year, the threshold will be at a level where about half of MIPS eligible clinicians may be above the threshold and about half would fall below it.

CMS also sees how you stack up against the 70-point *additional performance threshold.* If you score 70 or more points, you will get a 2020 *additional payment adjustment factor,* which is also known as the exceptional performance bonus (see "The Additional Payment Adjustment Factor: Tap Into a $500M-Bonus Pool," page 55).

Under the Payment Adjustment Factor, Bonuses and Penalties Will Be Budget Neutral

The payment adjustment factor will result in bonuses for some clinicians and penalties for others.

CMS compares your 2018 final score against the 15-point performance threshold to determine your 2020 *payment adjustment factor.* If your final score is:

- **0-3.75 points,** your payment adjustment factor is –5%;
- **more than 3.75 points and less than 15 points,** you will get a negative payment adjustment (penalty) based on a linear sliding scale (see red line on Table 19);
- **15 points,** your payment adjustment factor is neutral (no penalty, no bonus); or
- **more than 15 points,** you will get a small positive adjustment factor (bonus), based on a linear sliding scale (see the blue line on Table 20A.)

This process for calculating payment adjustments is designed to be budget neutral, which means that bonuses for those with final scores above 15 points will be funded by the penalties imposed on those who fall below that threshold.

The maximum negative payment adjustment factor is 5%. If your final score is 3.75 points or less, the maximum 5% penalty will be applied.

During the next 2 years, the maximum penalty will steadily increase. The maximum negative payment adjustment factor is scheduled to increase as follows:

- 5% for the 2020 payment year (2018 performance year)
- 7% for 2021
- 9% for 2022

To ensure budget neutrality, the maximum positive payment adjustment factor will be determined after each performance year is over. For the coming payment years, the maximum payment adjustment factor will be as follows:

- +5% × scaling factor for the 2020 payment year (2018 performance year)
- +7% × scaling factor for 2021
- +9% × scaling factor for 2022

CMS will use a scaling factor that is greater than 0 but not greater than 3. In 2019, after calculating the 2018 final scores of all MIPS participants, CMS will determine the scaling factor—and thus the maximum payment adjustment factor—for the 2020 payment year. Because the 15-point performance threshold is relatively low, CMS has said that it expects the scaling factor to be below 1.0. If this prediction is correct, the maximum payment adjustment would be less than 5%, though you may be eligible for an additional payment adjustment factor for exceptional performance (see page 55).

Bonuses will be based on a linear sliding scale. If your final score meets or exceeds the 15-point performance threshold, your payment adjustment factor will be based on a linear sliding scale, starting at 0% for a final score of 15 points and increasing to the maximum payment adjustment

Extra Points for Treating Complex Patients

Why a bonus for complex patients? CMS hopes this bonus will achieve 2 overlapping goals: 1) safeguard access to high-quality care for complex patients, and 2) avoid putting clinicians who look after complex patients at a disadvantage when scoring their MIPS performance.

Two risk scores determine patient complexity. CMS determines your complex patient bonus based on 2 indicators.

CMS calculates your average HCC risk score. CMS takes into account medical complexity, based on the average Hierarchical Condition Category (HCC) risk score of your patients. The HCCs have previously been used for risk-adjustment models in several Medicare programs, such as Medicare Advantage. For the 2018 performance period, CMS reviews the beneficiaries that you cared for over a 12-month period (Sept. 1, 2017, to Aug. 31, 2018). CMS will assign each of them an HCC risk score, based on the beneficiary services that they received during calendar year 2017, and then will calculate the average score.

CMS calculates a "dual eligibles" score, based on the proportion of beneficiaries eligible for both Medicare and Medicaid. Reviewing the same 12-month period (Sept. 1, 2017, to Aug. 31, 2018), CMS calculates the proportion of beneficiaries who were dual eligible. This is a population that tends to have complex needs. CMS multiplies that dual-eligible ratio by 5 to give you a second score for complexity.

You can score 0-5 points for the complex patient bonus. Your complex patient bonus—which is capped at 5 points—is the sum of your average HCC risk score and your dual-eligibility score.

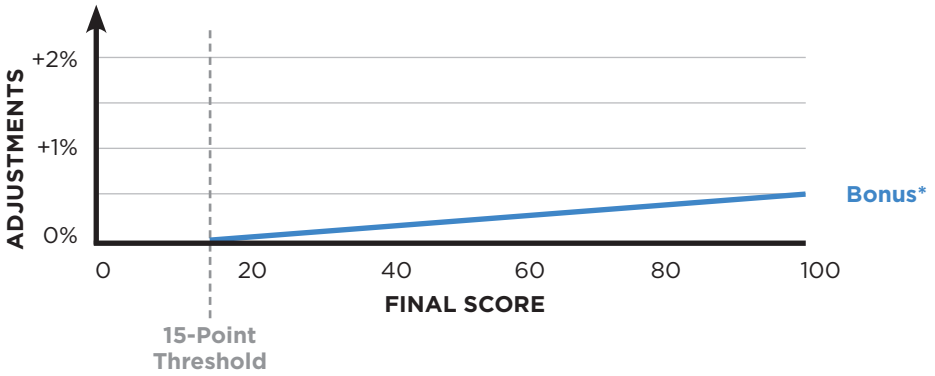
Who can get the bonus? The bonus is available to MIPS eligible clinicians, groups, and virtual groups that report at least 1 quality measure, ACI measure, or improvement activity.

The CMS complex patient bonus is a work in progress. CMS plans to review this bonus annually to see if it should be continued and whether it should be restructured. The Academy has expressed strong concerns to CMS about how patient complexity is calculated, and it urges CMS to push for rapid identification of additional risk factors that influence how patients respond to care.

Table 20: Payment Bonuses (Illustrative Only)

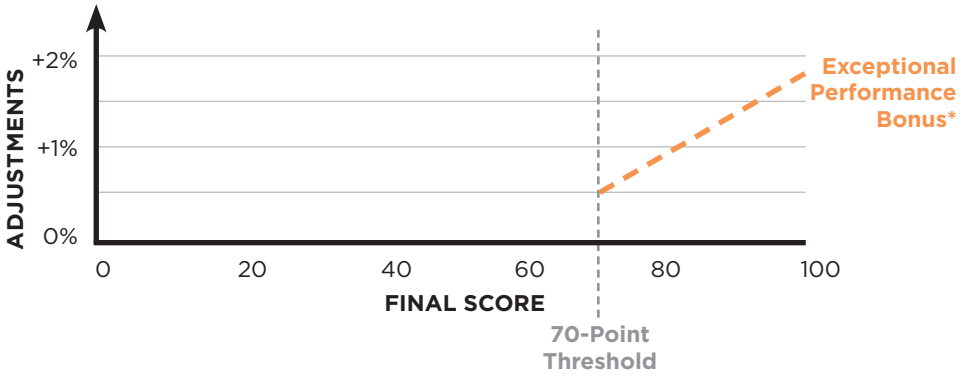
Your payment adjustment factor (bonus) and additional payment adjustment factor (exceptional performance bonus) will depend on how your 2018 final score compares against 2 thresholds.

Table 20A



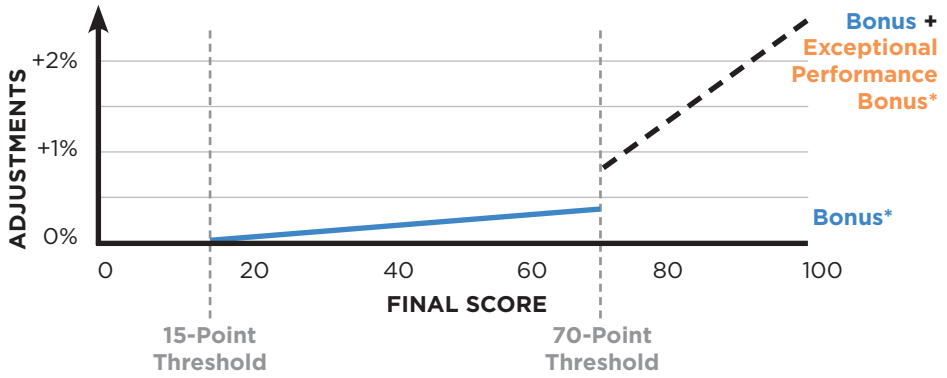
Bonus: Exceed the 15-point payment adjustment threshold, and you can expect a small positive payment adjustment based on a linear sliding scale (blue line).

Table 20B



Exceptional performance bonus: Meet or exceed the 70-point additional performance threshold, and you will receive an additional payment adjustment factor based on a linear sliding scale (orange dotted line).

Table 20C



Bonuses are cumulative. If you score at least 70 points, the sum of both bonuses (black dotted line) will be applied to your 2020 Medicare payments.

* **Please note:** These sliding scales are merely illustrative. CMS won't define these 2 sliding scales until 2019, after it has assigned 2018 final scores to all of this year's MIPS participants.

factor for a final score of 100 points. Table 20A shows an example of what this sliding scale might look like (see the blue line).

Example. Suppose the scaling factor for the 2020 payment adjustment factor turns out to be 0.096. The maximum payment adjustment factor would be 0.48% (5.0 × 0.096). This would be applied to you if you have a 2018 final score of 100 points and would be the upper limit of the sliding scale. (The blue line on Table 19A uses a scaling factor of 0.096, but only for illustrative purposes; as mentioned above, the actual scaling factor won't be known until 2019.)

Due to budget neutrality, the sliding scale is expected to get steeper over the coming years. As the performance threshold increases, it will become more challenging to avoid the penalty, which means that the bonus pool for the payment adjustments will increase; consequently, the scaling factor will be higher, the maximum positive payment adjustment will be higher, and the gradient of the sliding scale will be higher.

Clinicians without an EHR system *may* have a 25-point handicap. If you don't have an EHR system, you won't be able to report ACI measures. You will only score points for quality measures (up to 50 points), improvement activities (up to 15 points), and cost (up to 10 points), so your maximum score will be 75 points. As CMS increases the performance threshold over the coming years, this 25-point handicap will become increasingly important.

Note: There are limited circumstances where clinicians without an EHR system might have their performance categories reweighted, which could allow them to score up to 100 points (see "Some Clinicians May Be Excused From ACI," page 37, and "Table 3: Reweighting the Performance Categories," page 12).

Use 2018 to get up to speed, before CMS starts ramping up the financial rewards and risks. Over the next few years, the bonus pool will increase dramatically, funded by a sharp increase in payment penalties. This growth in penalties will be because:

- reporting requirements will become more stringent;
- quality measures that are "topped out" may be eliminated;
- the performance threshold will be raised; and
- the maximum penalty is scheduled to increase rapidly (–9% by performance year 2020/payment year 2022).

The Additional Payment Adjustment Factor: Tap Into a $500M-Bonus Pool

The 70-point additional performance threshold sets the bar for exceptional performance. If your 2018 final score is 70 points or higher, an additional payment adjustment factor will be applied to your 2020 Medicare payments. If you don't have an EHR system, scoring 70 points will be an extreme challenge unless you successfully apply to be exempt from the ACI performance category (see "Some Clinicians May Be Excused From ACI," page 37).

Not budget neutral. These additional bonuses are funded by an additional $500 million per year that is being provided during the first 6 payment years of the program. The money will be paid out during payment years 2019-2024, based on final scores during performance years 2017-2022.

This extra bonus will be based on a linear sliding scale. CMS won't define that sliding scale until after the performance year is over. The regulations state that the scale is likely to be +0.5% at the lower end (if your final score is 70 points) and it can't exceed +10% at the higher end (if your final score is 100 points). CMS may reduce that +10% upper limit using a scaling factor. Table 20B shows a hypothetical sliding scale (orange dotted line) for the additional payment adjustment factor.

Example. In 2019, after CMS has calculated the final scores for all the MIPS participants, it calculates the scaling factor that would be needed to distribute the $500 million-bonus pool among those who scored at least 70 points. Suppose it determines that the scaling factor is 0.175. This means that the maximum additional payment adjustment factor is reduced from +10% to +1.75% (10.0 × 0.175). This would be applied to your 2020 payments if you have a 2018 final score of 100 points (and it would be applied in addition to the payment adjustment factor that you receive for exceeding 15 points).

How the Bonuses and Penalties Will Be Applied

You can choose to report and be scored as an individual or as part of a group. If you opt to be 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 decide to be scored as a group, the group's TIN will be used as your identifier for scoring purposes.

This year, there was also a virtual group option but you needed to form that group by Dec. 31, 2017.

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 received a final score as an individual or as part of a MIPS group.

Your 2018 final score will follow you to your next practice. Your 2018 final score will determine your 2020 payment adjustment, and—unlike PQRS—this is the case even if you move to a new practice after the 2018 performance year is over. In other words, when CMS applies your payment adjustment in 2020, it will look at the 2018 final score that was associated with the TIN you were using in 2018, rather than the 2020 final score that is associated with your new practice's TIN.

What if you change practices in 2018, and consequently have 2 TIN/NPI combinations during the performance year, and then move to a third practice by the 2020 payment year? CMS has said that it will calculate the final score for both TIN/NPI combinations and use the higher of the 2 when determining your 2020 payment adjustment.

How the payment adjustments will be applied. CMS will start applying the MIPS payment adjustments in 2020. They will be applied throughout the year to each claim that you submit.

TAKING THE ALTERNATE PATHWAY

APMs in Brief

BY SARAH CARTAGENA.

There are 2 ways to participate in Medicare's Quality Payment Program: 1) via MIPS, which is the pathway that most ophthalmologists will take this year, and 2) as an advanced alternative payment model (APM).

What is an APM? APMs are voluntary models that change the way CMS pays physicians. They add incentives that are intended to reward high-quality, cost-effective care. Some examples may include accountable care organizations, patient-centered medical homes, and bundled payment models.

Advanced APMs

What is an advanced APM? CMS defines an advanced APM as a model that:

- requires participants to use certified EHR technology (CEHRT);
- provides payment for covered professional services based on quality measures comparable to those used in the quality performance category of MIPS; and
- either (a) is a Medical Home Model expanded under CMS Innovation Center authority or (b) requires participating APM entities to bear more than a nominal amount of financial risk for monetary losses.

MIPS lists several models of advanced APM, including:

- Comprehensive Primary Care Plus
- Medicare Shared Savings Program (tracks 2 and 3)
- Medicare ACO track 1+
- Next Generation ACO Model
- Oncology Care Model (OCM) 2-Sided Risk Arrangement

What is a qualifying APM participant (QP)? A QP is a MIPS eligible clinician determined by CMS to have met or exceeded the relevant QP payment amount threshold or QP patient count threshold for a year based on participation in an advanced APM entity. QPs can qualify for a 5% Medicare Part B incentive payment, and would be exempt from MIPS payment adjustments for payment years 2019-2024.

What is a partial qualifying APM participant (partial QP)? A partial QP is a MIPS eligible clinician determined by CMS to have met the relevant partial QP threshold for a year. CMS has established lower thresholds for partial QP status. This status allows these clinicians to opt out of the MIPS payment adjustments but does not confer all the benefits of QP status. CMS is providing "partial credit" to encourage participation in advanced APM entities even if that participation is not sufficient to earn the APM bonus.

MIPS APMs

What is a MIPS APM? APMs that don't qualify as "advanced" are evaluated as MIPS APMs. These hold their participants accountable for the cost and quality of care provided to Medicare beneficiaries.

In addition, most advanced APMs are also MIPS APMs. This means that MIPS eligible clinicians who are participating in an advanced APM and do not meet the QP threshold are scored under MIPS according to the APM scoring standard.

Different reporting requirements and scoring. These models can have MIPS data submission requirements and MIPS category scoring weights differing from those of other MIPS eligible clinicians. For MIPS APMs, the performance categories are weighted as follows—quality contributes up to 50 points; ACI contributes up to 20 points; and improvement activities contribute up to 30 points.

Different types of MIPS APM. CMS listed 8 models in their final rule that qualify as a MIPS APM, including:

- Comprehensive Primary Care Plus
- Medicare Shared Savings Program (tracks 1, 2, and 3; note that track 1 did not qualify as an advanced APM)
- Next Generation ACO Model
- Oncology Care Model (1- and 2-Sided Risk Arrangement)

MIPS tip. If you are part of an ACO that is considered a MIPS APM, you should report quality measures independently of the ACO and can do so using the IRIS Registry. 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 quality reporting can safeguard you from the 5% payment penalty.

All Payer Combination

Starting in performance year 2019 (payment year 2021), your MIPS eligible clinicians may become QPs through a combination of participation in advanced APMs and other payer advanced APMs. This will be known as the All Payer Combination option. This option would allow eligible clinicians to become QPs by meeting a relatively low threshold based on Medicare Part B covered professional services through advanced APMs and an overall threshold based on services through both advanced APMs and other payer advanced APMs. Medicare Advantage plans will be considered under this option.

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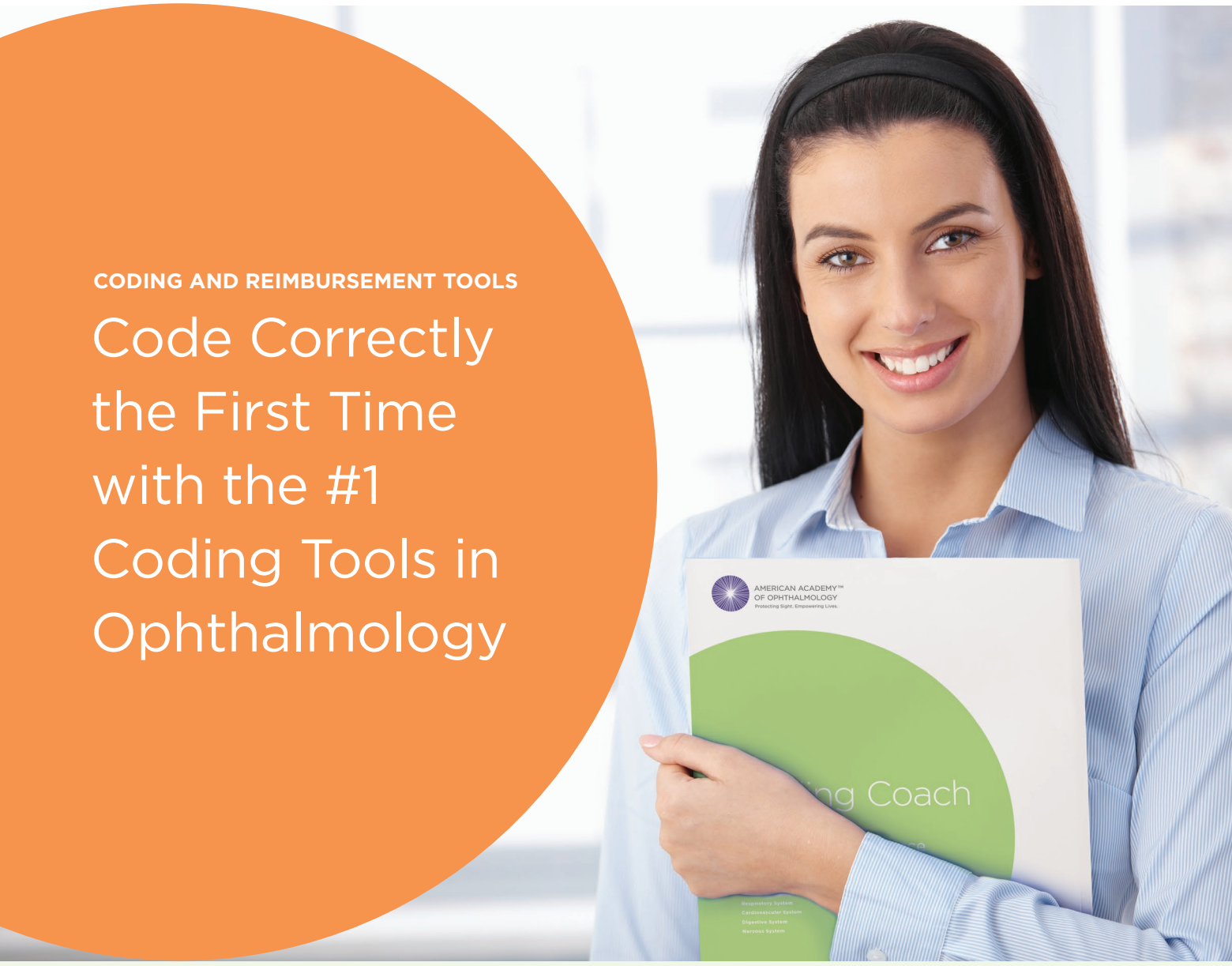

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THE ACADEMY CAN HELP YOU SUCCEED

Your 9-Step To-Do List for MIPS Resources

Use 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 the Centers for Medicare & Medicaid Services (CMS).

Start Today

1. Bookmark aao.org/medicare. From this hub page, you can navigate to a rich range of ophthalmic-specific resources, including:

- Subspecialty-specific lists of quality measures
- A dedicated web page for each of the 30 MIPS quality measures most relevant to ophthalmology and the 30 QCDR quality measures. These web pages feature:
  - –reporting options
  - –measure type
  - –instructions
  - –lists of relevant ICD-10, CPT Category I, HCPCS, and CPT Category II codes
  - –benchmarks
- Guidance on the quality, advancing care information (ACI), and improvement activities performance categories
- 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.

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. Furthermore, at the end of the performance year, the IRIS Registry will determine which measures are likely to give you the highest score for quality.

The IRIS Registry web portal can meet all your MIPS reporting needs. 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 web portal. ACI measures and improvement activities can only be reported manually.

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**.** If you aren't already participating in the 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 web portal, you have until Oct. 31 to register for that. (Note: If you sign up for IRIS Registry/EHR integration, you don't have to sign up separately for the web portal.)

3. Check your email. Each Thursday, the *Washington Report Express* will help to keep you current on all the latest regulatory developments. And watch for *Medicare Physician Payment Update* on the first Saturday of each month.

4. Use the email hotline. You can send MIPS questions to mips@aao.org.

5. Share tips and crowdsource solutions via the AAOE's e-Talk. If you are a member of the AAOE (join at aao.org/member-services/join), you can use the e-Talk listserv to find out how other practices are tackling MIPS (go to www.aao.org/practice-management and click "Listservs").

6. Schedule yourself some MIPS time at AAO 2018 (aao.org/2018). If you are attending AAO 2018 in Chicago (Oct. 27-30, 2018), sit in on this year's MIPS sessions. You also can bring your MIPS questions to the Academy Resource Center, where you can also ask for an IRIS Registry demo.

7. Bookmark aao.org/eyenet/mips-manual-2018. The online version of *EyeNet*'s MIPS manual includes a downloadable PDF of quality measures (Tables 11 and 12 on pages 29-32) that includes live links to the Academy's dedicated web pages for those measures. You can also download similar PDFs of the ACI measures (Tables 15 and 16 on pages 38-41) and improvement activities (Tables 17 and 18 on pages 44-48).

8. Watch for the 3-Minute MIPS series. The Academy is developing a series of succinct MIPS presentations.

9. Explore the CMS resources. You will find webinars, fact sheets, benchmark data, and more at https://qpp.cms.gov and at www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Resource-library.html. 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.

EYLEA®
(aflibercept) Injection
For Intravitreal Injection

BRIEF SUMMARY—Please see the EYLEA package insert for full Prescribing 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) in Patients with DME

4 CONTRAINDICATIONS

4.1 Ocular or Periocular Infections

EYLEA is contraindicated in patients with ocular or periocular infections.

4.2 Active Intraocular Inflammation

EYLEA is contraindicated in patients with active intraocular inflammation.

4.3 Hypersensitivity

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

5 WARNINGS AND PRECAUTIONS

5.1 Endophthalmitis and Retinal Detachments. Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments [*see Adverse Reactions (6.1)*]. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately [*see Dosage and Administration (2.7) and Patient Counseling Information (17)*].

5.2 Increase in Intraocular Pressure. Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA [*see Adverse Reactions (6.1)*]. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with vascular endothelial growth factor (VEGF) inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately [*see Dosage and Administration (2.7)*].

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. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

6 ADVERSE REACTIONS

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

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

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

A total of 2711 patients treated with EYLEA constituted the safety population in seven phase 3 studies. Among those, 2110 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 floaters, intraocular pressure increased, and vitreous detachment.

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, active-controlled clinical studies (VIEW1 and VIEW2) for 12 months.

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

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

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

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

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

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

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

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

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

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

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

6.2 Immunogenicity. As with all therapeutic proteins, there is a potential for an immune response in patients treated with EYLEA. The immunogenicity of EYLEA was evaluated in serum samples. The immunogenicity data reflect the percentage of patients whose test results were considered positive for antibodies to EYLEA in immunoassays. The detection of an immune response is highly dependent on the sensitivity and specificity of the assays used, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to EYLEA with the incidence of antibodies to other products may be misleading.

In the wet AMD, RVO, and DME studies, the pre-treatment incidence of immunoreactivity to EYLEA was approximately 1% to 3% across treatment groups. After dosing with EYLEA for 24-100 weeks, antibodies to EYLEA were detected in a similar percentage range of patients. There were no differences in efficacy or safety between patients with or without immunoreactivity.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

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

Animal reproduction studies are not always predictive of human response, and it is not known whether EYLEA can cause fetal harm when administered to a pregnant woman. Based on the anti-VEGF mechanism of action for aflibercept [*see Clinical Pharmacology (12.1)*], treatment with EYLEA may pose a risk to human embryofetal development. EYLEA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

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

Data

Animal Data

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

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

8.2 Lactation

Risk Summary

There is no information regarding the presence of aflibercept in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production/excretion. Because many drugs are excreted in human milk, and because the potential for absorption and harm to infant growth and development exists, EYLEA is not recommended during breastfeeding.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for EYLEA and any potential adverse effects on the breastfed child from EYLEA.

8.3 Females and Males of Reproductive Potential

Contraception

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

Infertility

There are no data regarding the effects of EYLEA on human fertility. Aflibercept adversely affected female and male reproductive systems in cynomolgus monkeys when administered by intravenous injection at a dose approximately 1500 times higher than the systemic level observed humans with an intravitreal dose of 2 mg. A No Observed Adverse Effect Level (NOAEL) was not identified. These findings were reversible within 20 weeks after cessation of treatment [*see Nonclinical Toxicology (13.1)*].

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

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

17 PATIENT COUNSELING INFORMATION

In the days following EYLEA administration, patients are at risk of developing endophthalmitis or retinal detachment. If the eye becomes red, sensitive to light, painful, or develops a change in vision, advise patients to seek immediate care from an ophthalmologist [*see Warnings and Precautions (5.1)*].

Patients may experience temporary visual disturbances after an intravitreal injection with EYLEA and the associated eye examinations [*see Adverse Reactions (6)*]. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

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

Issue Date: June 2017
Initial U.S. Approval: 2011

Based on the May 2017 EYLEA® (aflibercept) Injection full Prescribing Information.

REGENERON

POWER TO PREVAIL

As demonstrated in phase 3 clinical trials evaluating BCVA,* as measured by ETDRS letters, in patients with Wet AMD, Macular Edema following RVO, DME, and by ETDRS-DRSS† in DR in Patients with DME,[1] as well as your clinical experience

Start with EYLEA for proven efficacy outcomes[1]

AMD = Age-related Macular Degeneration; DME = Diabetic Macular Edema;
DR = Diabetic Retinopathy; RVO = Retinal Vein Occlusion.

Dosing driving efficacy outcomes across all indications.[1]
Learn more at EYLEA.us/dose

INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

EYLEA® (aflibercept) Injection is indicated for the treatment of patients with

- Neovascular (Wet) Age-related Macular Degeneration (AMD): The recommended dose is 2 mg administered by intravitreal injection every 4 weeks (monthly) for the first 12 weeks (3 months), followed by 2 mg once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (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).
- Macular Edema following Retinal Vein Occlusion (RVO): The recommended dose is 2 mg administered by intravitreal injection every 4 weeks (monthly).
- Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR) in Patients with DME: The recommended dose is 2 mg administered by intravitreal injection every 4 weeks (monthly) for the first 5 injections, followed by 2 mg once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (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).

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

- Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA.

EYLEA®
(aflibercept) Injection
For Intravitreal Injection

- 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. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

ADVERSE REACTIONS

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

Please see adjacent Brief Summary.

*Best-corrected visual acuity.
†Early Treatment Diabetic Retinopathy Study–Diabetic Retinopathy Severity Scale: an established grading scale for measuring the severity of DR.

Reference: 1. EYLEA® (aflibercept) Injection full U.S. Prescribing Information. Regeneron Pharmaceuticals, Inc. May 2017.

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