ACUMEN

MACRA Episode-Based Cost Measures:
Comprehensive Reevaluation
Public Comment Summary Report

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1 OVERVIEW

1.1 Project Title

Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act of 2015 (MACRA) Episode-Based Cost Measures: Comprehensive Reevaluation.

1.2 Dates

The Call for Public Comment ran from February 25, 2022, to May 28, 2022.

1.3 Project Overview

The Centers for Medicare & Medicaid Services (CMS) has contracted with Acumen, LLC, to develop and maintain episode-based cost measures for the Merit-based Incentive Payment System (MIPS). The contract name is "Physician Cost Measures and Patient Relationship Codes (PCMP)." The contract number is 75FCMC18D0015, Task Order 75FCMC19F0004.

As part of the measure maintenance process, Acumen requested interested parties to submit comments on episode-based cost measures first implemented in MIPS in 2019. Acumen sought input from the public on the technical specifications of the eight measures listed below to identify potential updates for the measures to remain up-to-date in assessing clinician cost performance. The Call for Public Comment included a set of questions about the measures as a starting point, but interested parties were encouraged to provide any feedback about the measure specifications.[1]

The measure maintenance process allows developers to ensure measures continue to function as intended and to consider refinements to the measure. On an annual basis, we review the MIPS measures that have been adopted and make minor updates to the cost measures to keep them up-to-date (e.g., coding updates). Every three years, measures are considered for comprehensive reevaluation. During comprehensive reevaluation, measure developers can more holistically review the measure, seek public comment, and consider many aspects of the measure specifications, not just the updates done through annual maintenance. In some instances, a measure might only need minor or no change to specifications, while other measures may undergo more substantive changes to improve the measure's importance, scientific acceptability, or usability.

The first eight episode-based cost measures were added to the MIPS cost performance category in performance year 2019. As such, they have now been in MIPS for 3 years and are being considered for comprehensive reevaluation. The measures are listed in Table 1.

[1] Episode-based Cost Measures: Call for Public Comment for Measure Reevaluation (2022), https://www.cms.gov/files/document/episode-based-cost-measures-call-public-comment-measure-reevaluation.pdf

Table 1. Cost Measures Considered for Comprehensive Reevaluation

MIPS ID	Cost Measure
COST_EOPCI_1	Elective Outpatient Percutaneous Coronary Intervention (PCI)
COST_KA_1	Knee Arthroplasty
COST_CCLI_1	Revascularization for Lower Extremity Chronic Critical Limb Ischemia
COST_IOL_1	Routine Cataract Removal with Intraocular Lens (IOL) Implantation
COST_SSC_1	Screening/Surveillance Colonoscopy
COST_ICHI_1	Intracranial Hemorrhage or Cerebral Infarction
COST_SPH_1	Simple Pneumonia with Hospitalization
COST_STEMI_1	ST-Elevation Myocardial Infarction (STEMI) with Percutaneous Coronary Intervention (PCI)

This document summarizes stakeholder feedback through the public comment process, and will inform next steps in the reevaluation process, including conducting additional information gathering and testing to determine the scope of reevaluation, and reconvening Clinician Expert Workgroups, as needed, to discuss stakeholder feedback and other updates.

1.4 Information about the Comments Received

We solicited public comments and conducted education and outreach using the following methods:

- Posting a Call for Public Comment on the CMS Measures Management System (MMS) Currently Accepting Comment webpage
- Sending multiple email notifications to various relevant stakeholders and email lists (i.e., Quality Payment Program listserv, MMS listserv)

  We received 20 comments via email and survey response.

- We received comments from 16 organizations and 4 individuals.
- The verbatim text of each submitted comment is presented in Appendix A.

2 STAKEHOLDER COMMENTS: FEEDBACK ON WAVE 1 MEASURES

This section summarizes the feedback broadly applicable across multiple measures (Section 2.1) and feedback specific to the measures considered for comprehensive reevaluation: Routine Cataract Removal with Intraocular Lens Implantation (Section 2.2), ST-Elevation Myocardial Infarction with Percutaneous Coronary Intervention/ Elective Outpatient Percutaneous Coronary Intervention (Section 2.3), Screening/Surveillance Colonoscopy (Section 2.4), Revascularization for Lower Extremity Chronic Critical Limb Ischemia (Section 2.5), Intracranial Hemorrhage or Cerebral Infarction (Section 2.6), Simple Pneumonia with Hospitalization (Section 2.7), and Knee Arthroplasty (Section 2.8).

2.1 Cross-Cutting Measure Feedback

This section summarizes feedback broadly applicable across multiple measures. Commenters shared input relating to defining episode groups (Section 2.1.1), accounting for patient heterogeneity (Section 2.1.2), attributing episodes to clinicians (Section 2.1.3), assigning costs to episode groups (Section 2.1.4), measure development and maintenance (Section 2.1.5), information about MIPS Cost measures (Section 2.1.6), and alignment with Federal initiatives and priorities (Section 2.1.7).

2.1.1 Defining Episode Groups

Several commenters provided general feedback about opportunities to redefine episode groups to measure similar types of care together and minimize gaps in measurement. Most cautioned against expanding the scope of existing cost measures, urging that measure validity and reliability be prioritized over increasing measure scope. Commenters noted concerns about whether expanded patient cohorts could result in unintended consequences for clinicians or patients. A commenter also noted that it may not be appropriate to expand cost measures to align quality measures, explaining quality measures differ from cost measures because quality performance is not affected by additional treatment costs required to achieve outcomes. However, one commenter noted that expanding the scope of existing cost measures could be beneficial in ensuring that clinicians have cost measures applicable to the care they provide.

2.1.2 Accounting for Patient Heterogeneity

Commenters noted that risk adjustment methodologies should be employed to ensure clinicians are not penalized for caring for complex patients, which could lead to care stinting or adverse patient selection (i.e., selectively choosing patients based on their risk profile). Many

commenters provided examples of determinants of health beyond clinical comorbidities that should be considered for risk adjustment, such as:

- Social determinants: Food access, structural racism, neighborhood social cohesion, cultural beliefs, housing access
- Physical determinants: Air pollution, workplace conditions
- Health services: Health insurance, access/distance to care, language access, health literacy
- Individual behaviors/factors: Family support, income, occupation, education, number of household members, physical and leisure activities, number of social contacts, sleep quality
- Biology/genetics: Gender

In addition to input about incorporating additional variables, commenters provided the following feedback:

- Risk adjustment should be attributed at the "level of the care team" or "unit of accountability," rather than at the clinician-level.
- A case minimum of 10 episodes may not be sufficient to account for low volume providers who treat complex patients.
- The current sets of measure-specific risk adjustment variables are appropriate and should continue to be used.

2.1.3 Attributing Episodes to Clinicians

Commenters suggested potential improvements for the attribution methodology, as well as recommended conducting additional analyses to ensure episodes are appropriately attributed to clinicians. Some commenters highlighted the importance of encouraging team-based care, such as by attributing episodes at the group-level or higher and not at the clinician-level. A commenter suggested that group-level attribution could encourage clinicians to provide more efficient care, while clinician-level attribution could lead to unintended consequences such as competition among team members or adverse patient selection.

A commenter raised a concern about using specialty information in attribution rules as it may not accurately reflect the nature of clinical practice. The specific example given was that mid-level providers (e.g., Nurse Practitioners, Physician Assistants) can be classified as primary care providers when those practitioners are actually practicing in specialty settings.

2.1.4 Assigning Costs to Episode Groups

Commenters provided feedback on assigning cost to episode groups. The majority of commenters provided feedback about the approach to assigning medication costs in the Cataract Removal measure, which is described in Section 2.2.2. Commenters also questioned whether it

was appropriate to assign the costs of services provided by someone other than the attributed clinician, as these services may be outside of their control.

2.1.5 Measure Development and Maintenance

Several commenters provided general feedback on measure development and maintenance. Some commenters suggested proceeding cautiously with making updates to the measures, noting limited clinician experience with the measures due to the cost category being reweighted in 2020 and 2021, and the need to reconvene a workgroup to review public input before making measure changes. Commenters also provided recommendations for future development and maintenance:

- Measure maintenance should include a mechanism to consistently assign costs associated with new products to relevant episode groups.
- Additional data sources, such as registry data, should be considered for use in measures.
- CMS should assess and compare the current episode-based cost measures development approach to other approaches to determine how various approaches support the goals of MIPS.

2.1.6 Information about MIPS Cost Measures

Several commenters expressed a desire for more information about MIPS cost measures, noting the following:

- More publicly available data about MIPS cost measure performance, such as performance distributions and breakdowns by various factors such as specialty and practice size, would help stakeholders the ongoing use of the measure and evaluating if it continues to operate as intended.
- MIPS performance feedback reports would be more actionable if they contained more detailed information, and if there were increased education and outreach efforts to make clinicians aware of MIPS feedback reports and how to access them.
- Clinicians would benefit from additional information about how cost and quality measures affect MIPS performance scores, and clarification about whether quality measures are used to adjust cost measure scores.

2.1.7 Alignment with Federal Initiatives and Priorities

Stakeholders suggested considering how cost measures align with other Federal initiatives and priorities. Commenters pointed to Federal priorities to reverse the opioid epidemic and increase access to non-opioid analgesics, and suggested that cost measures should not conflict with these goals. Commenters also noted that the Food and Drug Administration (FDA) grants pass-through status to certain new products to incentivize their use. The commenters expressed concern that including pass-through products in cost measures could negate incentives and cause clinicians to avoid using these products. As such, they suggested not including any pass-through products in cost measures.

2.2 Routine Cataract Removal with Intraocular Lens (IOL) Implantation

This section summarizes the feedback on the Routine Cataract Removal with IOL Implantation (Cataract Removal) measure. The following subsections describe feedback received about expanding the patient cohort (Section 2.2.1) and assigning medication costs to the episode group (Section 2.2.2).

2.2.1 Expanding the Patient Cohort to Include Complex Cataract Cases

Commenters did not support expanding the patient cohort to include complex cataract removal cases, either by adding additional trigger codes or removing measure exclusions. If the patient cohort is expanded, commenters noted the need for additional analyses ensure the measure is still valid and reliable. This section highlights commenters' rationale for continuing to use the existing patient cohort as defined by the trigger codes and measure exclusions.

Commenters provided the following rationale to support the current patient cohort:

- The existing trigger code (66984, removal of cataract with insertion of lens) captures the majority of cataract procedures.
- Routine cases require comparable and homogenous treatment, so the measure can capture clinicians who vary from established treatment options.
- Complex cataract removal procedures may not be comparable to routine procedures due to complex cases having greater variability of patient medical risk factors (e.g., prescription use, comorbidities) and complication rates.
- Complex cases would also have different costs due to different services needed and treatment options. These include additional services during and after the cataract removal procedure (e.g., iris hooks and retractors, Malyugin ring, vitrectomy).
- There is no evidence of a need to expand the patient cohort to safeguard against potential unintended consequences that may result from having limited trigger codes and many exclusion codes. MIPS measure benchmarks for clinically relevant quality measures have not declined since the measure was implemented.

Some commenters expressed concerns about the impact of expanding the patient cohort, particularly without sufficiently accounting for patient heterogeneity. Specifically, the following scenarios were raised as potential unintended consequences:

- Clinicians treating higher-risk patients might receive worse scores which could discourage care for these patients.
- Changes in access to care could lead to delayed care and increased costs to Medicare.
- Small and independent practices and those that perform low volumes of cataract procedures would be disproportionately affected, as higher costs associated with treating complex cases may have a larger impact on their measure score.

- Clinician burden will increase, as clinicians will have to devote more time to considering resource use to avoid worse performance scores associated with treating complex/high-risk patients.
- Clinicians may face ethical dilemmas if choosing to treat high-risk/complex patients will negatively affect their cost performance score.
- Clinicians would be more likely to be measured on a procedure which only reflects a small portion of the care they provide. Retina surgeons would be attributed under an expanded patient cohort, though they do not frequently perform cataract removal.

2.2.2 Assigning Medication Costs to the Episode Group

Commenters provided feedback on whether and how to assign medication costs to the Cataract Removal measure. Alignment with other CMS and Federal priorities (i.e., addressing the opioid epidemic, FDA pass-through status) is further discussed in Section 2.1.7.

Stakeholders mostly recommended removing phenylephrine and ketorolac intraocular solution 1.0%/0.3% (OMIDRIA®) from the list of assigned services for the Cataract Removal measure, and did not support adding other drugs such dexamethasone intraocular suspension 9% (DEXYCU®) and dexamethasone ophthalmic insert 0.4 mg (DEXTENZA®). Commenters noted the medications are beneficial and lead to better patient outcomes, improved patient adherence to post-operative care, and cost savings due to reduced need for other medications during and after the procedure. Commenters expressed concern that including these drugs could dis-incentivize their use, leading to unintended consequences such care stinting and poor patient outcomes. Commenters also noted OMIDRIA can reduce the need for opioid analgesics and suggested removing the drug from the measure to align with Federal priorities (Section 2.1.7). However, one commenter noted it is appropriate to continue to include OMIDRIA, as it is unnecessary for most cataract procedures, does not negate the need for postoperative medications, and is an expensive alternative to other medications used to dilate the pupil, which are already included in the facility fee.

Commenters also urged that we proceed cautiously when determining whether to assign Part D prescription drug costs to episode groups:

- Prior to including Part D prescription drugs in additional measures, additional analyses should be conducted to assess impact to the cost measures and to consider whether there may be any unintended consequences.
- Creating measures that incorporate Part D prescription drugs and accurately compare performance will be challenging in the absence of a methodology that allows for standardization of drug prices, includes variables that affect prescribing practices, and accounts for whether patients are enrolled in Part D coverage.
- Part D prescription drugs should not be included in cost measures, as clinicians do not yet have access to transparent and timely drug pricing information required to make informed

prescribing choices. There is not agreement on the extent to which clinicians can influence costs associated with prescription drugs.

More broadly, commenters requested consistency in how medication costs are assigned within an episode group. They highlighted the following considerations:

- Similar medications, such as those that have been granted pass-through status or have similar indications, should be assigned in the same manner.
- Selective inclusion of drugs within a measure may influence clinician decision-making, introduce bias, negatively impact validity, and provide a financial advantage to manufacturers of drugs not included in the measure.

2.3 ST-Elevation Myocardial Infarction with Percutaneous Coronary Intervention (STEMI-PCI)/ Elective Outpatient PCI

This section summarizes the feedback on the ST-Elevation Myocardial Infarction with PCI (STEMI-PCI) and Elective Outpatient PCI (Elective PCI) measures. The following subsections describe feedback received about defining episode groups (Section 2.3.1), service assignment (Section 2.3.2), and reliability and validity (Section 2.3.3).

2.3.1 Defining Episode Groups

Commenters suggested alternative approaches to define episode groups to measure PCI and other related cardiac care. One commenter recommended a cost measure to focus on more common conditions, such as acute myocardial infarction (MI). The commenter expressed that only a portion of cardiologists perform PCI, and that significantly more would be assessed under a measure for MI.

Specific to the STEMI-PCI measure, a commenter noted the current approach for defining the episode group—pairing Medicare Severity Diagnosis Related Groups (MS-DRGS) 246-251 with numerous diagnosis codes—could be replaced with a single CPT/Healthcare Common Procedure Coding System (HCPCS) code:

- 92941: Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel

2.3.2 Service Assignment

One commenter suggested removing some diagnosis codes used to assign services for the STEMI-PCI and Elective PCI measures. They noted the diagnoses are unrelated to PCI (Table 2).

Table 2: Diagnoses Codes Suggested for Removal from Service Assignment

ICD-10 CM 3-Digit Diagnosis Code	Description
H81	Disorders Of Vestibular Function
R50	Fever Of Other And Unknown Origin
E86	Volume Depletion
D50	Iron Deficiency Anemia
D65	Disseminated Intravascular Coagulation [defibrination Syndrome]
K55	Vascular Disorders Of Intestine
R78	Findings Of Drugs And Other Substances, Not Normally Found In Blood

2.3.3 Reliability and Validity

Commenters questioned whether clinicians are measured on sufficient cases to reliably distinguish performance. A commenter also referenced a study[2] showing a statistically significant difference in clinician costs for Elective PCI episodes, but questioned the clinical significance of the results. The commenter noted other studies show a regression to the mean and that clinicians did not tend to score similarly across years, but did not provide citations. The commenter questioned whether the measure reliably distinguishes between high- and low-cost clinicians.

2.4 Screening/Surveillance Colonoscopy

One commenter provided feedback on the Screening/Surveillance Colonoscopy (Colonoscopy) measure. The commenter recommended aligning the Colonoscopy measure with the updated United States Preventive Services Task Force (USPSTF) colorectal cancer screening guidelines, which were released after the initial development of the Colonoscopy measure.[3] The commenter also expressed opposition to expanding the measure to include diagnostic colonoscopy for the following reasons:

- There is heterogeneity in care between screening/surveillance and diagnostic colonoscopies which would be difficult to fairly compare.
- It is questionable whether meaningful information can be provided to clinicians about this procedure, and could undervalue diagnostic colonoscopy.

[2] Sandhu AT, Do R, Lam J, Blankenship JC, VanDecker W, Rich J, Gonzales O, Wu L, Pershing S, MaCurdy TE, Bhattacharya J, Nagavarapu S. Development of elective outpatient percutaneous coronary intervention episode-based cost measure. Circ Cardiovasc Qual Outcomes 2021;14e006461. DOI: 10.1161/circoutcomes.119.006461.
[3] USPSTF (2021), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening

- Variation in indications and adverse events would create challenges for defining pre- and post-trigger periods.
- There are cost differences due to the setting in which a procedure is performed and the condition for which a diagnosis being sought.
- It would be more appropriate to assess diagnostic colonoscopies in measures focusing on a condition; for instance, diagnostic colonoscopies for lower gastrointestinal bleeding are captured by the Lower Gastrointestinal Hemorrhage episode-based cost measure. Other potential concepts are acute measures for conditions like unexplained diarrhea and chronic measures for conditions like inflammatory bowel disease.

2.5 Revascularization for Lower Extremity Chronic Critical Limb Ischemia

One commenter provided feedback about the Revascularization for Lower Extremity Chronic Critical Limb Ischemia measure, noting the importance of measuring care related to peripheral artery disease. The commenter stated that the measure appropriately captures multiple specialties and does not favor or disadvantage providers based on specialty. The commenter further stated they did not recommend updates to the measure specifications. The commenter additionally encouraged the continued involvement of interventional radiologists in maintaining the measure due to their role in caring for patients with chronic critical limb ischemia.

2.6 Intracranial Hemorrhage or Cerebral Infarction

One commenter provided feedback about the stroke measure indicating support for focus on medical management of stroke. The commenter further noted support for the current approach to exclude episodes for patients with structural diseases or subarachnoid hemorrhage.

2.7 Simple Pneumonia with Hospitalization

No feedback specific to the Simple Pneumonia with Hospitalization measure was received during the public comment period.

2.8 Knee Arthroplasty

No feedback specific to the Knee Arthroplasty measure was received during the public comment period.

3 OVERALL ANALYSIS AND RECOMMENDATIONS

We appreciate the engagement of stakeholders with this call for public comment for the reevaluation of eight episode-based cost measures that were originally developed in Wave 1 and have been in use in MIPS since 2019. We considered all the feedback received during the public comment period and conducted empirical analyses to evaluate and further explore the potential direction for reevaluating measures. Based on the public comments, exploratory analyses, and agency priorities, CMS has approved the following cost measures to undergo a comprehensive reevaluation process including convening clinical expert workgroups: (i) Routine Cataract Removal with IOL Implantation, (ii) Simple Pneumonia with Hospitalization, and (iii) ST-Elevation Myocardial Infarction with Percutaneous Coronary Intervention.

The workgroups will convene in the coming months to provide input on specific topics for reevaluation. These will cover potential specifications changes as raised by interested parties and where empirical analyses suggest there could be impactful changes that would address measurement gaps and/or fulfill program needs.

All measures will be maintained as usual through the annual maintenance process. This typically involves coding updates to reflect any new or different codes that are released during the year. We encourage interested parties to reach out to the QPP Service Center (QPP@cms.hhs.gov) or email macra-cost-measures-info@acumenllc.com with feedback about measure specifications so that we can consider this in any future maintenance or reevaluation activities for any of the measures in the MIPS cost performance category.

APPENDIX A: PUBLIC COMMENT VERBATIM REPORT

This appendix contains the verbatim texts of the comments received. The information is provided in a list format and presented in order of the comment number, or assigned identification number for the comment. The list presents the name, affiliated organization, and date of submission (date of receipt of the comment via email or survey submission). The submitter name for each comment is the name of the person who submitted the letter or filled out the survey. For some comment submissions, the person who signed the comment letter is not the same as the person who submitted the comment nor the same as the contact person provided in the comment.

Please note that the verbatim text has been edited to improve the readability of this report. We omitted letter template details (e.g., company logo), email signatures, and sensitive personally identifiable information (e.g., phone numbers and e-mail addresses). Also, respondents' complete survey responses were concatenated together.

3.1 List of Verbatim Comments

3.1.1 Comment Number 1

- **Date:** 5/5/2022
- **Submitter Name, Credentials, and Organization:** Kathy Lester, JD, MPH, Counsel at Omeros Corporation and Rayner Surgical Group
- **Comment Text:**

On behalf of Omeros Corporation ("Omeros") and Rayner Surgical Group ("Rayner"), I appreciate the opportunity to provide comments on the "Episode-based Cost Measures: Call for Public Comment for Measure Reevaluation." As we have discussed with the Centers for Medicare & Medicaid Services (CMS), we are concerned that the current Routine Cataract Removal with Intraocular Lens (IOL) Implantation measure ("Cataract Removal resource use measure") used in the Merit-based Incentive Payment System (MIPS) creates an unintended disincentive against using a non-opioid pain management medication, Omidria®, instead of opioids. In addition, the disparate treatment of similarly situated ophthalmic products Dexycu® and Dextenza®, by excluding them from the measure, is inappropriate and should be addressed by removing Omidria from the measure as we have explained previously in our discussions with CMS. If Omidria remains part of the measure, then Dexycu and Dextenza must also be included, although there are related arguments as to why all three of these Part B drugs should be excluded. Omeros and Rayner also request that CMS address the time gap that the current reevaluation process creates by waiting for a review period to address new products that come to market. We suggest that CMS establish a mechanism that allows it to address such products

when they come to market to avoid favoring new drugs over existing treatment options that are included in the specifications.

In response to the questions in the call for comments, Omeros and Rayner ask that CMS modify the Cataract Removal resource use measure used in the MIPS by removing Omidria from the specifications because its inclusion: (1) effectively takes away physicians' discretion to use the most appropriate drug for their patients, (2) incentivizes the use of inexpensive opioids contrary to other CMS policies and inconsistent with the Administration's priority to end the opioid crisis, and (3) is inequitable given that Dexycu and Dextenza, both used during cataract surgery, are excluded from MIPS, creating a situation by which CMS is inadvertently but meaningfully conferring a commercial advantage to one or more drugs over another. The inclusion of Omidria, an FDA-approved non-opioid pain management drug, is contrary to the Administration's priorities to address the opioid epidemic. It also stands in contrast to the decision by CMS to exclude non-opioid pain management drugs from the hospital outpatient prospective payment systems (HOPPS) packaging policy, intended by CMS to incentivize the use of non-opioid pain management medications, such as Omidria, in ambulatory surgery centers (ASCs).

In response to Question 5 ("Should medications including Dexycu and Dextenza be included in the Cataract Removal measure? Are there any other intra- or peri-operative drugs that should be considered for inclusion in the Cataract Removal measure?"), Omeros and Rayner support treating similarly situated products consistently by excluding the Part B drugs Omidria, Dexycu, and Dextenza from the specifications for the Cataract Removal resource use measure. The inclusion of Omidria, in particular, creates a barrier to the use of non-opioid pain management medications in cataract surgery.

I. Omeros and Rayner recommend removing Omidria from the Cataract Removal resource use measure to eliminate the measure from being a barrier to providing proper care for patients and to the use of non-opioid pain management medications.

Peer-reviewed publications have shown that Omidria – a non-opioid pain management drug – reduces the need for the opioid fentanyl during surgery and reduces post-surgery opioid prescriptions. The Food and Drug Administration (FDA) approved Omidria for use during cataract surgery or intraocular lens (IOL) replacement. The label indications include "maintaining pupil size by preventing interoperative miosis and reducing postoperative pain." Omidria is added to "an irrigation solution used during cataract surgery or intraocular lens replacement."[4] Omidria reduces both the need for patients to receive fentanyl, a powerful opioid,

[4] Omidria's FDA-approved label is available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205388s006lbl.pdf.

during cataract surgery[5,6] and the number of opioids prescribed to manage postoperative pain.[7] Omidria also prevents both intraoperative floppy iris syndrome (IFIS)[8] and complications including sight-threatening cystoid macular edema (CME).[9] [10]

Omidria is administered during a surgical procedure in the ASC and HOPD settings and, as of October 1, 2020, Omidria is paid separately by CMS as a "non-opioid pain management drug" when furnished in the ASC setting.

The Biden-Harris Administration and CMS have prioritized policies that eliminate or reduce barriers to the use of non-opioid pain management medications; the Cataract Removal resource use measure in MIPS should be adjusted to promote the same policy priority. In 2017, the President's Commission on Combating Drug Addiction and Opioid Crisis recommended that "CMS review and modify rate-setting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate postsurgical pain."[11] In response, CMS determined that it is "appropriate to pay separately for evidence-based non-opioid pain management drugs that function as a supply in a surgical procedure in the ASC setting to address the decreased utilization of these drugs and to encourage use of these types of drugs rather than prescription opioids."[12] CMS applied this exclusion to the packaging policy to Omidria first for CY 2021, continuing its application to Omidria for CY 2022.[13]

[5] Donnenfeld ED, Shojaei RD. Effect of intracameral phenylephrine and ketorolac 1.0%/0.3% on intraoperative pain and opioid use during cataract surgery. *Clin Ophthalmol*. 2019;13:2143–2150.
[6] Donnenfeld E, et al. Pain control and reduction of opioid use associated with intracameralphenylephrine/ketorolac 1.0%/0.3% administered during cataract surgery. J Cataract Refract Surg 2021; doi:10.1097/j.jcrs.0000000000000855
[7] Jackson K, et al. Real-world opioid prescribing after cataract surgery among patients who received intracameral phenylephrine and ketorolac 1.0/0.3. Curr Med Res Opin. 2020;36(12):2047-2052.
[8] Silverstein SM, et al. Effect of phenylephrine 1.0%-ketorolac 0.3% injection on tamsulosin-associated intraoperative floppy-iris syndrome. J Cataract Refract Surg. 2018; 44(9):1103-1108
[9] Walter K, et al. Rate of pseudophakic cystoid macular edema using intraoperative and topical nonsteroidal anti-inflammatory drugs alone without steroids. J Cataract Refract Surg. 2020; 46: 350-354
[10] Visco D, et al. Effect of intracameral phenylephrine/ketorolac 1.0%/0.3% on postoperative cystoid macular edema, iritis, pain and photophobia following cataract surgery. J Cataract Refract Surg 2020; 46: 867–872
[11] President's Commission on Combating Drug Addiction and the Opioid Crisis Report. 14 (Recommendation 19) (Nov. 2017) available at https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf
[12] 83 Fed. Reg. 58818, 59071, 59068 (Nov. 21, 2018).
[13] 86 Fed. Reg. 42018 (Aug. 04, 2021).

The opioid epidemic has worsened during the COVID-19 pandemic with opioid overdose deaths on the rise. The Centers for Disease Control and Prevention (CDC) estimate that there were more than 100,000 overdose deaths from opioids between April 2020 and April 2021.

This was an increase from 78,056 the previous 12-month period.[14] The Commonwealth Fund estimates that total overdose deaths reached record levels in March 2020 – "opioid-related deaths drove these increases, specifically synthetic opioids such as fentanyl."[15] Opioids accounted more than 70 percent of all overdose deaths.[16]

In response to this ongoing crisis, President Biden has committed to, among other things, "stop overprescribing while improving access to effective and needed pain management."[17] The Administration's Statement of Drug Policy Priorities for Year One reiterates that "President Biden has made clear that addressing the overdose and addiction epidemic is an urgent priority for his administration."[18] CMS has supported this priority in the ASC settings by excluding from packaging policies certain non-opioid pain management drugs, including Omidria. We believe the same rationale supports excluding Omidria in the HOPD setting as well.

As the COVID-19 pandemic continues and the opioid crisis in America worsens, it is important that CMS programs work together to ensure that all Medicare policies – including the MIPS program – eliminate incentives to use opioids unnecessarily, including getting rid of clear disincentives to use non-opioid pain management drugs where and as appropriate.

The Cataract Removal resource use measure's specific inclusion of Omidria has created a substantial disincentive for physicians to use Omidria because the measure financially penalizes surgeons who choose to use the non-opioid pain management drug Omidria. This, in turn, provides an incentive to cataract surgeons to use and prescribe addictive opioid medications, including fentanyl, perioperatively. CMS in its payment policy has recognized that financial reimbursement amounts (including payment cuts) drive physician behavior. When CMS packaged Omidria in 1Q 2018, CMS claims fell by approximately 80 percent in only two quarters. Not until Congress reinstated the drug's pass-through status as part of the

[14] Centers for Disease Control and Prevention. "Drug Overdose Deaths in the U.S. Top 100,000 Annually." NCHS Pressroom. https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2021/20211117.htm. (Nov. 17, 2021).
[15] Jesse C. Baumgartner & David C. Radley. "The Spike in Drug Overdose Deaths During the COVID-19 Pandemic and Policy Options to Move Forward." The Commonwealth Fund. https://www.commonwealthfund.org/blog/2021/spike-drug-overdose-deaths-during-covid-19-pandemic-and-policy-options-move-forward (March 25, 2021).
[16] Centers for Disease Control and Prevention. "Drug Overdose Deaths." https://www.cdc.gov/drugoverdose/deaths/index.html (Feb. 22, 2022).
[17] "The Biden Plan to End the Opioid Crisis" (2019) available at https://joebiden.com/opioidcrisis.
[18] "The Biden-Harris Administration's Statement of Drug Policy Priorities for Year One" (2021) available at https://www.whitehouse.gov/wp-content/uploads/2021/03/BidenHarris-Statement-of-Drug-Policy-Priorities-April-1.pdf

Consolidated Appropriations Act of 2018, Pub. L. No. 115-141, did surgeons once again appropriately use Omidria again for their patients. CMS acknowledged the impact payment policy has on the use of Omidria when it excluded the drug from being packaged when used in ASCs through the non-opioid pain management drug exclusion.

Omeros and Rayner are seeing a similarly negative effect on Omidria utilization as a result of the Cataract Removal resource use measure in MIPS. Omeros has heard from a substantial number of cataract surgical practices throughout the United States that the Cataract

Removal resource use measure penalizes practices for using Omidria. Further, they are well aware that the cost component of the MIPS score has a higher weighting in 2022 than in previous years, leading cataract surgeons and their practice administrators to believe that, if others are not using Omidria and they are, Omidria-utilizing surgeons and practices will look like a high-cost outlier. As a result, many of these surgeons and practices no longer provide it to any of their patients. One physician wrote:

> As we've discussed, the surgeons at _____ Surgery Center have decided to stop using Omidria immediately due to their concern that it will negatively affect their MIPS scores and ultimately their Medicare reimbursement. I have observed an increase in complications and challenging cases when we don't use Omidria and will continue to monitor cases. I support the use of Omidria at _____ Surgery Center. Let me know when new information becomes available.
> Director of ____ Surgery Center Chief of Anesthesia .[19]

Another physician put it more bluntly:

> It has come to my attention through the ASCRS website I will be penalized for using Omidria during Cataract Surgery. Therefore, I will no longer be using Omidria until it has been removed from the calculation. I believe in the product and have seen wonderful results. It is not the quality of the medication.[20]

Another wrote:

> I revisited Omidria usage today with our surgeons. **They will not reconside using Omidria until it has been confirmed that it no longer counts against them in the cost category of MIPS.** (Emphasis added)
> Sincerely,
> Administrator[21]

Omeros and Rayner have worked with physicians and facilities to try to help them understand the importance of using Omidria when it is medically necessary for patients, but the

[19] Email on file with author.
[20] Email on file with author.
[21] Email on file with author.

express reference to the product in the measure specifications has created an insurmountable barrier for many facilities and physicians. The following statement represents the growing concern regarding this barrier.

> Actually the MIPS White Paper did a very good job attempting to show how things could be offset based on other quality measures. **The only problem is we are in the upper echelon of MIPS on those other quality measures and because of that, we would gain no advantage by "improving" quality on those other measures.** It might be a good offset for practices who are not scoring well on those other measures. Thanks Mike. Up until this came up, the program was most definitely a win win. **Darn Government. Makes no sense what they decided to do on this.**
> (Emphasis added)
> *Director_____ Eye and Laser Center*[22]

These are only a few examples of the communications that Omeros has received from surgeons who believe in the clinical use of Omidria but will not use it because of the financial disincentive caused by the Cataract Removal resource use measure.

This result is not surprising. In fact, the Measures Application Partnership (MAP) presciently raised the concern that the measure could result in the inappropriate stinting of care.

MAP recognized the importance of cost measures to the MIPS program. The MAP conditionally supported this Routine Cataract Removal with Intraocular Lens (IOL) Implantation cost measure pending NQF endorsement. During the NQF endorsement review, the MAP encourages the Cost and Resource Use Standing Committee to specifically consider the appropriateness of the risk adjustment model to ensure clinical and social risk factors are reviewed and included when appropriate. MAP cautioned about the potential stinting of care and noted that appropriate risk adjustment could help safeguard against this practice. The Standing Committee should also examine the exclusions in this measure to ensure appropriate attribution.[23] (Emphasis added)

In addition to the MAP, the professional societies for cataract surgeons – the American Society of Cataract and Refractive Surgery (ASCRS) and the Outpatient Ophthalmic Surgery Society (OOSS) –have weighed in with CMS, raising concerns about the financial disincentives created by the Cataract Removal resource use measure for drugs reimbursed outside of packaging for a policy purpose, such as the non-opioid pain management exclusion. In fact, the negative impact of including a drug specifically in the Cataract Removal resource use measure specifications is borne out by the fact that two other manufacturers promote their products by

[22] Email on file with author.
[23] MAP 2017-2018 Preliminary Recommendations (emphasis added).

indicating that their respective drugs will not affect surgeons' reimbursement because of being "excluded from the MIPS calculation" or that use "is not counted toward the MIPS composite score."[24]

Given the fact that the MAP warned about the Cataract Removal resource use measure resulting in a stinting of care and the affirmation by cataract surgeons, their professional societies, and manufacturers of drugs that are not included in MIPS that such stinting is occurring today, Omeros and Rayner ask that Omidria be removed from the measure.

II. Question 5: Should medications including Dexycu and Dextenza be included in the Cataract Removal measure? Are there any other intra- or -peri-operative drug that should be considered for inclusion in the Cataract Removal measure?

If CMS were to decide to include Omidria in the Cataract Removal resource use measure then consistency warrants inclusion of Dexycu and Dextenza as well. As the request for comments notes, since the Cataract Removal resource use measure was initially endorsed,

Dexycu and Dextenza, which are also administered during the intra/perioperative period and billed separately under pass-through status, have become available. They are clinically related to cataract removal and are similarly situated drugs to Omidria, which is the only one of these three drugs included in the measure.

The lack of parity has created a distortion in the market. The Dexycu marketing materials actually highlight that using the product will have no negative impact for a surgeon under MIPS. The materials for Dextenza also imply that physicians will not suffer MIPS-related cuts by using their product.

The inclusion of one product while other similar products are excluded creates the appearance that CMS is favoring these two products over Omidria, yet there is no clear justification as to why these products should be excluded when Omidria is included. The inclusion of Omidria, in particular, creates a barrier to the use of non-opioid pain management medications in cataract surgery. If Omidria were to remain in the measure, which we believe would not be appropriate given the efforts to incentivize the use of non-opioid pain management medications, then Dexycu and Dextenda should be added. To be clear, however, Omeros and Rayer, support the exclusion of all three drugs from the Cataract Removal resource use measure.

We also encourage the contractor and CMS to develop a mechanism that either excludes all separately billed products or includes them automatically when they enter the market. Without a clear policy, the measure distorts medical practice by incentivizing the use of products that are not approved during the review period but subsequently become approved during the intervening

[24] These examples are from marketing materials for DEXYCU® and DEXTENZA® and are available from the author.

time period until the next review. All products should be treated the same unless there is a substantial policy reason – such as eliminating incentives to use opioids –to exclude certain products.

3.1.2 Comment Number 2

- **Date:** 3/23/2022
- **Submitter Name, Credentials, and Organization:** Rachel Groman, American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS)
- **Comment Text:**

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), representing more than 4,000 neurosurgeons in the United States, we appreciate the opportunity to provide feedback in response to the Acumen's effort to re-evaluate episode-based cost measures developed during Wave 1 and in use under the Merit-based Incentive Payment System (MIPS) since 2019.

Representatives of the AANS and the CNS were involved in developing the Wave 1 Intracranial Hemorrhage or Cerebral Infarction cost measure. We continue to support the focus of this measure on medical management of stroke and its exclusion of both structural disease and subarachnoid hemorrhage.

Our comments focus on our broader concerns regarding the ongoing lack of national data summarizing performance on the cost measures used in MIPS — specifically, the distribution and median/mean performance scores for each cost measure by specialty, practice type and practice size. Without these data, it is challenging, if not impossible, to understand which clinicians are being captured by each measure and whether they are being targeted appropriately and in alignment with the intent of each measure. We are aware of the Public Use Files (PUF) that the Centers for Medicare & Medicaid Services (CMS) makes available to the public. However, the most current file includes data from 2018, which was before the adoption of any episode-based cost measures. Due to the size of the PUF, it is also challenging to navigate. It would be helpful if CMS could provide specialty-specific summary data in the form of a supplemental report to the PUF. CMS did release a 2019 QPP Experience Report last fall, but unfortunately, the data presented were very high-level and not specific to any individual cost measure or specialty. In the past, CMS provided specialty-specific data in the Experience Reports issued as part of the Value Modifier Program.

We strongly encourage Acumen to work with CMS once again to provide this level of detail to the public. For cost measures, in particular, which are calculated automatically by CMS and not self-selected by physicians, CMS must provide more transparent, timely and detailed data

regarding their application and impact so that the public can meaningfully evaluate their appropriateness.

3.1.3 Comment Number 3

- **Date:** 4/30/2022
- **Submitter Name, Credentials, and Organization:** Pourhamidi, MS, MPH, American College of Cardiology (ACC)
- **Comment Text:**

The American College of Cardiology (ACC) is providing the following comments to the Centers for Medicare and Medicaid Services (CMS) and its contractors on the Episode-based Cost Measures: Call for Public Comment for Measure Reevaluation. We applaud CMS for its endeavors to undertake a comprehensive reevaluation every three years to ensure that substantive measure improvements may be captured.

The ACC is a 58,000-member medical society that is the professional home for the entire cardiovascular care team. The mission of the College is to transform cardiovascular care and improve heart health. The ACC leads in the formation of health policy, standards, and guidelines. The College operates national registries to measure and improve care, provides professional medical education, disseminates cardiovascular research, and bestows credentials upon cardiovascular specialists who meet stringent qualifications. The ACC also produces the Journal of the American College of Cardiology, ranked number one among cardiovascular journals worldwide for its scientific impact.

The College has submitted comments in the past concerning the episode-based measure development process and has engaged in the clinical subgroups convened by Acumen. Many clinician organizations have expertise in quality measure development, but not specifically pertaining to cost measure development. The ACC continues to advocate that specialty societies should be supplied with the appropriate resources, such as technical assistance from Acumen, to support external cost measure development.

The College recognizes that creating and refining episode-based measures is a challenging endeavor. We also recognize that we are uniquely positioned to provide invaluable input from the perspective of practicing clinicians and cardiovascular administrators. This perspective is crucial to the development and maintenance of realistic and accurate episode-based measures, as the needs and characteristics of the patients who will be attributed to these groups vary widely.

While the following comments focus on general recommendations for the episode-based cost measures, our main focus is on the Elective Outpatient Percutaneous Coronary Intervention (PCI) and ST-Elevation Myocardial Infarction (STEMI) with PCI episode-based measures.

Risk Adjustment: The ACC supports efforts to improve the standardization and collection of risk adjustors, such as socioeconomic (SDOH) or biological, to improve our understanding of additional factors that may influence health outcomes. Resources such as the NQF MAP Health Equity Advisory Group and Best Practices for Testing Risk Adjustment Models white paper may be useful in determining the appropriate socioeconomic risk factors and highlight considerations such as standardization, resource availability, and implementation issues. We also appreciate efforts to date in working with experts from external organizations in the development and use of health equity data and algorithms. Although there are numerous challenges in the collection, sharing, and use of SDOH data, we are hopeful that CMS and/or other external entities will be in a position to establish a uniform approach to defining, assessing, and measuring SDOH with the least amount of burden and resource use.

The College believes that data collection efforts concerning SDOH should extend beyond examining race and ethnicity and include a host of other risk factors to better inform clinicians of patient outcomes. The "Heart Disease and Stroke Statistics - 2021 Update" provides a variety of examples of SDOH which impact cardiovascular disease. Other factors for consideration include access to healthy food, structured racism, income, occupation and work conditions, education level, physical and leisure activity, gender, cultural beliefs, language, number of social contacts, family support, neighborhood social cohesion, air pollution, number of household members, sleep quality, health insurance status, and access or distance to appropriate medical care (such as in the case of door to balloon times). We also believe that poverty plays a significant role in evaluating quality and outcomes, which can be measured via zip+4 code.

It is also important to factor in data about the pathophysiology and natural history of a disease or condition, genetic and hormonal influences, disease or condition symptoms, general stressors (which are critical in their impact on CV disease), optimal diagnostic testing, and benefits and risks of therapeutic interventions. As CMS examines race, ethnicity, and other disparities at the practice level, it may also be helpful to also identify those aspects of practice that are under a clinician's control but not influenced by SDOH, such as procedural complications.

The ACC recommends that CMS' performance reports contain more detailed information on risk scoring deciles and their associated data so as to be more actionable. Health systems and practices require this data to create assurances that their risk scores (both at the TIN and NPI level) are accurate. This in turn will ensure that providers are accurately capturing and understanding their patients' full spectrum of illness to better manage health care outcomes and earn appropriate incentives.

The ACC would also appreciate clarification if STEMI-related quality measures were used to adjust the cost score for the STEMI with PCI measure. An additional explanation of the details in

assessing which quality measures will help providers understand how quality and cost measures are associated with performance scores.

Attribution: The ACC strongly believes all cost measures should be attributed at the group practice level or higher. It is important that cost metrics capture what is actionable and within the control of practicing clinicians, which is extremely difficult to accurately gauge and technically challenging to capture at the individual clinician level. Healthcare costs are influenced not by the actions of one clinician but by the actions of multiple clinicians or the healthcare team as well as a patient's social, economic, and environmental factors. It is difficult, if not impossible, to determine the relative influence that an individual clinician has on a patient's expenses. Moreover, this goes against the team-based approach to care that ACC and many others have endorsed as the most effective care delivery framework for its propensity to coordinate care to improve patient outcomes, efficiency of care, and clinician satisfaction. Measuring what is actionable builds long-term buy-in with clinicians, feeds a cycle of participation in value-based programs, and mitigates concerns over possible dysfunctional behaviors such as patient "cherry picking." Stratifying and comparing separate types of costs such as indirect cost services under the control of the facility could help identify behaviors that correspond most with opportunities for improvement.

The "team" approach in cardiovascular care should include shared incentives. If the categories are attributed to an individual team member, the concern for unintended consequences, such as patient selection resulting in higher risk patients losing out, cannot be overstated. In addition, this may foster competition among group members, rather than promoting the team effort. Attribution of categories to the whole team should help raise the bar for the whole group. "Peer pressure" to improve performance of individual members can be highly effective if under-performers want to continue to be part of the care team.

The ACC recommends that, specifically for the ST-Elevation Myocardial Infarction (STEMI) with PCI measure, it would be beneficial to incorporate a breakdown of attribution results by NPI/TIN for providers such as hospitalists, critical care providers, general cardiologists, and interventional cardiologists, for example. This additional information given to providers will better assess how the care team operates and help administrators and providers make adjustments in their practice as necessary.

Unintended Consequences: As expected, there are possible unintended consequences of using cost measures in MIPS, but steps may be taken to avoid disadvantaging clinicians who assume the care of complex patients. Unintended consequences could include selection of less complex patients to artificially lower costs or reducing access to patients who may be at higher risk to reduced medical adherence due to lower socioeconomic status or education level. ACC recommends risk adjustment to account for patient comorbidities and risk stratification for

socioeconomic status and education attribution at the level of the care team, the "unit of accountability," rather than the individual level.

Other: The ACC recommends reporting additional information in the Service Use and Costs Clinical Themes section of the performance reports. Detailed, actionable data from this section would assist providers in understanding which costs matter, help shape future financial results, and provide an overall complete picture of the impact of costs. We believe this information should also include the national cost data for each of the themes (e.g., Aftercare, Rehab, Diagnostic Imaging, Part D Drugs, Outpatient Visits, etc.).

The ACC remains concerned that many providers are often are not aware that these performance reports are available to them. Providers must contact their practice or health system administrator to locate this information, but if there is a lack of awareness in the first place, this represents a missed opportunity to enact change. In addition, large health systems may not be equipped to pull individual provider data due to the complexity of managing a large network of providers. The ACC recommends that CMS provide educational materials such as videos and/or guides for providers so they are aware of the reports and how to read and interpret them. While specialty societies and other external organizations can do their part to educate providers, CMS is also in a position to reach individual providers and engage them fully with the Quality Payment Program.

CMS should also work with specialty societies to determine if clinical data registries such as the National Cardiovascular Data Registry (NCDR) may be used to measure quality and patient outcomes. This would require partnerships between CMS and specialty societies to match claims data to the valuable longitudinal clinical data in these registries. While the alignment of cost and quality is listed as the final component within the cost measure development framework, this is arguably one of the most important components. The NCDR's institutional outcomes reports could also serve as a model for CMS and its contractors to use for releasing performance data. These quarterly risk-adjusted benchmark reports include performance measures and quality metrics to compare an institution's performance with that of peer groups and the national experience.

Closing: The accurate and appropriate measurement of cost for physician performance continues to be an ongoing challenge. The ACC welcomes the opportunity to continue working with CMS and its contractors on the development of episode groups and cost measures for use under the QPP. The College has many practicing cardiologists and cardiovascular practice administrators willing to dedicate time to this effort. Incorporating their perspectives throughout the development and implementation of episode groups will help CMS to ensure that these measures work under a real-world application and do not unintentionally penalize clinicians or more importantly, do not affect patient's access to care.

3.1.4 Comment Number 4

- **Date:** 5/23/2022
- **Submitter Name, Credentials, and Organization:** William, H. Constad, Partner at Prism Vision Group (individual)
- **Comment Text:**

[3. Should additional trigger codes be added to align with related quality measures? If so, which codes?]

No

[4. Based on the similarity of the cost profiles and the potential cover more patients undergoing cataract removal procedures, is including complex cases an appropriate approach? If so, what are other updates that would be needed to the measure; for example, should these codes indicating significant ocular conditions be added as a risk adjustor? Are there services that are currently not included in the measure that would be important to include to reflect the care for complex procedures?]

No

[5. Should medications including Dexycu and Dextenza be included in the Cataract Removal measure? Are there any other intra- or peri-operative drugs that should be considered for inclusion in the Cataract Removal measure?]

Yes

[6. Are there any Part D drugs related to cataract surgery that should be considered for inclusion in the Cataract Removal measure?]

No

3.1.5 Comment Number 5

- **Date:** 5/23/2022
- **Submitter Name, Credentials, and Organization:** Jessica Peterson, MD, MPH, VP of Health Policy at Marsden Advisors
- **Comment Text:**

Cross-Cutting Questions

[1. Should there be any changes to the patient cohort for the measures, as defined by trigger codes and exclusions? For instance, given the set of cost measures in MIPS, are there any gaps in care that could appropriately be filled by expanding the scope of an existing measure? Has

clinical practice changed how these conditions and procedures are performed in a way that the patient cohort would need updating?]

a. Expanding the Scope of Existing Cost Measures

MA is concerned with the push to expand the scope of existing cost measures seen throughout this request for comment. We urge CMS and Acumen to prioritize validity and appropriate measurement, over scope of measurement. If we look at recent history, the Total Per Capita Cost (TPCC) measure was a tangible and painful example of how trying to encompass too large of a population for measurement causes significant misattribution problems. After years of misattribution, inappropriate measurement, and measure credibility and validity concerns, these problems had to be solved through vast exclusions. **The problems created by trying to encompass too large of a population for measurement in the TPCC example not only affected clinician reimbursements, but also created more work and incurred additional cost to the government to correct.**

b. Attribution Issues of Existing and Future Cost Measures

In the Cost performance category, there are several measures that are attributed only to certain specialties. These measures classify mid-level providers – NPs, PAs, and CCNSs – as primary care providers. This is problematic for specialty practices that employ mid-level providers. While we understand the thought process behind this designation, we represent multiple practices that employ NPs or PAs but provide no primary care. For instance, we have a dermatology practice that employs PAs and NPs who bill under the practice TIN. Under current policies, this universal designation of mid-levels as primary care providers would inappropriately score specialty practices on primary care measures. **We urge CMS and Acumen to address this problem before finalizing any additional measures that rely on these designations or to allow these clinicians and practices to submit targeted reviews to show that they are not providing primary care.**

Cataract-Specific Questions

[3. Should additional trigger codes be added to align with related quality measures? If so, which codes? a. Adding Additional Trigger Codes]

MA does not believe that additional trigger codes should be added to the Cataract Cost measure. When this measure was developed, our VP of Health Policy was staffing one of the committee co-chairs. **Limiting the trigger code to 66984 was done after careful consideration**

to avoid unintended consequences, while capturing the overwhelming majority (92.1%[25]) of cataract surgeries performed in the United States.

b. CMS' Concern About Unintended Consequences

One major concern with expanding the list of trigger codes is that including more complicated cataracts in the measure will have negative consequences for patient access to care. These more complicated cases may be appropriate for Quality measures, but that is only because quality measures do not penalize clinicians for the additional treatment costs required to reach a desirable outcome.

With most ophthalmologists in small or independent practices that operate on small financial margins, incurring a penalty for a low MIPS Cost score would be cost-prohibitive. We heard many concerns about this taking place before the cataract cost measure's first year in MIPS and we were able to reassure ophthalmologists that they would not be inappropriately penalized under this measure**. In these circumstances, if the trigger codes are expanded to include complex cataracts, there is a real possibility that patients requiring these procedures will be pushed to tertiary care treatment, resulting in delayed patient care and increased costs to Medicare.**

Our second major concern is that complex cataracts are also done by clinicians and practices for which cataract is an extremely low percentage of their care, for instance, cataract surgeries performed by retina surgeons for patients with retinal complications or comorbidities. **In this case, retina surgeons would get inappropriately picked up on this measure, causing 30% of their MIPS score to be based on the complicated cataract patients which make up only a small portion of the surgeons' practice.**

In the discussion about adding additional trigger codes, CMS and Acumen state the following:

c. CMS' Desire to Align With Quality Measures for MVPs

Being more inclusive with the patient cohort could help safeguard against potential unintended consequences that may result from having limited trigger codes and many exclusion codes. The Routine Cataract with IOL Implantation episode-based Cost measure has been in use in MIPS for three years. **After three years in use, we have not seen any impact on quality outcomes.** In fact, review of the CMS historical benchmarks files shows that the average performance on cataract Quality measures has either improved or remained roughly the same since the 2018 performance year – the year prior to the cataract Cost measure's first year in

[25] Part B National Summary Data File https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Part-B-National-Summary-Data-File/Overview

MIPS. **If there is something more specific that Acumen and CMS are concerned about, we would appreciate the opportunity to evaluate and respond to those concerns more fully.**

Given these significant concerns with the inclusion of additional trigger codes in the cataract cost measure, we believe that exact alignment with the CPTs used in the cataract quality measures is inappropriate. Indeed, we do not believe that perfect CPT code alignment is necessary to an MVP. If CMS is committed to exact alignment of Quality and Cost cataract measure CPT codes, to avoid the negative impacts on patient care and cost outlined above, we would recommend limiting the quality measures to 66984. This would capture 92.1% of cataract surgeries[26] and provide the perfect CPT alignment CMS desires.

[4. Based on the similarity of the cost profiles and the potential to cover more patients undergoing cataract removal procedures, is including complex cases an appropriate approach? If so, what are other updates that would be needed to the measure; for example, should these codes indicating significant ocular conditions be added as a risk adjustor? Are there services that are currently not included in the measure that would be important to include to reflect the care for complex procedures?]

MA does not believe that removing the exclusions is appropriate at this time. When this measure was developed, our VP of Health Policy was staffing one of the committee co-chairs. Limiting the measure to episodes that do not include patients with significant ocular comorbidities was intentional to avoid unintended consequences, such as pushing patients to tertiary care. For further discussion on these concerns, please see our response to question 3, subsection a. Moreover, when combined with the low case minimum required for this measure, removing the exclusions would likely result in a disproportionate negative impact on low-volume small practices. Removing these exclusions would not only likely push these practices over the 10-case minimum, but also do so solely because of more complex cases. In these practices, these complex cases would make up a larger percentage of the cases that comprise their Cost score, putting them at higher risk for a low score due to an unavoidable complication in a patient with significant ocular comorbidities.

Finally, CMS and Acumen are requesting input on adding services that are not currently included in the measure to accurately capture costs for more complex procedures. Part of CMS' and Acumen's rationale for wanting to remove these exclusions is that analyses of the episodes show similar costs to episodes without exclusions. However, if CMS and Acumen include these more complicated cases in the cataract cost measure *and* include additional services in the cost measurement, that would invalidate the application of those analyses to this scenario as it would directly increase the captured cost for these more complex cases. **We strongly recommend**

[26] Part B National Summary Data File https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Part-B-National-Summary-Data-File/Overview

CMS not both remove the exclusions and add services for complex cases to cost measurement as doing both without appropriate and applicable analyses would result in meaningful potential validity issues.

[5. Should medications including Dexycu and Dextenza be included in the Cataract Removal measure? Are there any other intra- or peri-operative drugs that should be considered for inclusion in the Cataract Removal measure?]

Drugs such as Dexycu or Dextenza should not be included in the cost measure. These drugs improve the quality of care and are greatly preferred by both physicians and patients.[27,28,29] The purpose of pass-through status is to encourage and measure the use of innovative treatments within Medicare, to ensure a high level of quality care for Medicare beneficiaries. Once passthrough status expires, the cost of these drugs will be bundled into the facility fee and, thus, not included in the calculation of Cost measures. While we appreciate CMS' desire to encourage cost-conscious care, **we believe disincentivizing the use of Dexycu and Dextenza would limit the access of Medicare beneficiaries to valuable innovation and negate the incentives provided in passthrough status**.

We specifically would like to note that, while we agree with CMS' original inclusion of Omidria in the cost measure, that is because it is not recommended or necessary for routine procedures. Although, like Omidria, Dexycu and Dextenza were placed on Transitional Pass-Through (TPT) status, it is misleading to assert that their application is analogous. Omidria is necessary only in difficult and complex cases. As such, it makes sense to include Omidria as it can create wide variation in cost without meaningful benefit to patients. Conversely, Dexycu and Dextenza are widely beneficial in routine cases.

The use of Dexycu or Dextenza helps providers avoid negative outcomes related to patient capacity to adhere to postoperative care, and significantly reduces the administrative burden of that care. Dexycu and Dextenza have been a key factor in improving care for cataract patients by replacing the traditional postoperative care regimens that are difficult for patients to understand, remember, and self-administer. In fact, use of Dexycu and

[27] Donnenfeld E, Holland E. Dexamethasone Intracameral Drug-Delivery Suspension for Inflammation Associated with Cataract Surgery: A Randomized, Placebo-Controlled, Phase III Trial. *Ophthalmology*. 2018;125(6):799-806. doi:10.1016/j.ophtha.2017.12.029

[28] Tyson SL, Bafna S, Gira JP, et al. Multicenter randomized phase 3 study of a sustained-release intracanalicular dexamethasone insert for treatment of ocular inflammation and pain after cataract surgery. *J Cataract Refract Surg*. 2019;45(2):204-212. doi:10.1016/j.jcrs.2018.09.023

[29] Larsen J, Whitt T, Parker B, Swan R. A Randomized, Controlled, Prospective Study of the Effectiveness and Safety of an Intracanalicular Dexamethasone Ophthalmic Insert (0.4 Mg) for the Treatment of Post-Operative Inflammation in Patients Undergoing Refractive Lens Exchange (RLE). *Clin Ophthalmol*. 2021;15:2211-2217. Published 2021 May 27. doi:10.2147/OPTH.S311070

Dextenza has become standard of care in European countries[30] given the significant positive impact they have on patient outcomes.

Current traditional postoperative cataract care regimens require substantial counseling to explain to patients and caregivers – in aggregate, the amount of time required is equivalent to the workload of a full-time staff member.[31] **Traditional post-operative care for patients with limited dexterity is also a significant issue, considering the advanced age of patients undergoing cataract removal.[32]**

We do not identify any additional intra- or peri-operative drugs that should be included in this measure.

[6. Are there any Part D drugs related to cataract surgery that should be considered for inclusion in the Cataract Removal measure?]

Currently, we strongly oppose the inclusion of Part D drugs in this measure as the prices of Part D drugs are outside of physician control. There are two important reasons for our current opposition to the addition of Part D drugs in this measure's cost calculation – a lack of experience in MIPS with inclusion of Part D drugs in cost measures and a lack of reliable and proven infrastructure for real-time benefits analysis available to providers.

Novelty of Part D Drugs in MIPS Cost Measures and Unintended Consequences

Only three MIPS Cost measures include Part D drugs – Diabetes, Asthma/COPD, and Sepsis. All three of these measures are currently in their first year in the MIPS program. Seeing as the inclusion of Part D drugs in cost measures is being piloted by the above measures, we need to see how these new measures operate under MIPS. With the Cost category worth 30% of the MIPS Final Score, the stakes are high. **To ensure that we avoid any widespread unintended consequences, we strongly encourage CMS to evaluate the results of this pilot year of the Cost measures with Part D drug costs included. We ask CMS to collect and share data reflecting the impact of those additions before expanding the inclusion of Part D drug costs to other measures.**

There are several negative unintended consequences that we currently see as possible outcomes. The first of these represents a significant detriment to patient care. This is the

[30] Javitt JC. Intracameral Antibiotics Reduce the Risk of Endophthalmitis after Cataract Surgery: Does the Preponderance of the Evidence Mandate a Global Change in Practice?. *Ophthalmology*. 2016;123(2):226-231. doi:10.1016/j.ophtha.2015.12.011

[31] https://www.ophthalmologytimes.com/view/dexamethasone-inserts-after-cataract-surgery-saves-time-in-patient-counseling-surgical-planning

[32] https://www.healio.com/news/ophthalmology/20211217/using-intracanalicular-dexamethasone-insert-after-cataract-surgery-saves-office-time

unintended consequence on market drug costs. If clinicians move patients to a new drug to reduce the contribution of Part D drug costs on this measure, that drug price will, naturally, increase based on free market economics.[33] This would cause a chain reaction of constantly switching to new Part D medications without a medical rationale. This is not only burdensome for clinicians, but, more importantly, it can be extremely deleterious to patient health and care.[34,35]

A second unintended consequence we foresee is that the addition of Part D medication costs will have no impact on costs but will negatively impact clinician Cost scores. We agree that drug pricing is a serious problem, but clinicians do not have the power to lower these costs. Given this lack of control and the potential unwillingness to constantly change patient medications to treat a patient according to the clinician's Cost score, rather than the patient's needs, it is possible that this addition will have no impact on costs whatsoever. Even if clinicians do switch patients to cheaper medications, as noted above, free market economic principles, and our experience with drug prices in this country, show that those drugs will have price increases to match the new demand.

We agree that drug prices are a problem that must be addressed. **We think a more viable and practical approach is to go to Congress and push for legislation to allow for CMS to negotiate drug prices, and we will steadfastly support CMS in these efforts in any way we can.**

Insufficient Infrastructure Available to Clinicians

We applaud CMS for the inclusion of the Real-Time Benefit Tool (RTBT) to the CY 2022 Medicare Advantage and Part D final rule, as this will allow providers to educate their clients on their drug costs easily. To date, the RTBT only requires plan sponsors to provide RTBT integration for only one system of electronic prescribing or health records. Seeing as CEHRT consists of many platforms with variation in function, this does not equate to all providers having equivalent access to this valuable information. Including Part D costs before the RTBT functionality becomes universally available would force providers to spend time investigating each individual patient's Part D plan and prescription medication costs each time they write a prescription. **At this time, the changes discussed regarding Part D costs would substantially increase physician burden. In future years – when real-time, API-integrated Part D formularies are widely available and usable – including Part D medication costs would be**

[33] https://www.commonwealthfund.org/publications/journal-article/2019/jul/perverse-incentives-why-brand-name-drugs-can-cost-less
[34] Straka RJ, Keohane DJ, Liu LZ. Potential Clinical and Economic Impact of Switching Branded Medications to Generics. Am J Ther. 2017;24(3):e278-e289. doi:10.1097/MJT.0000000000000282
[35] https://www.uspharmacist.com/article/ophthalmic-medications-the-safety-and-efficacy-of-brandname-versus-generic-formulations

significantly less burdensome and more in line with CMS' Patients Over Paperwork Initiative.

3.1.6 Comment Number 6

- **Date:** 5/26/2022
- **Submitter Name, Credentials, and Organization:** Jacob Goodman, Manager at American Academy of Ophthalmology
- **Comment Text:**

We thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on the reevaluation of the Routine Cataract Removal with Intraocular Lens (IOL) Implantation measure. As the leading society in ophthalmology with 27,000 members, the American Academy of Ophthalmology (the Academy) understands the need for cost measures that appropriately reflect the impact that providers have on the cost of patient care.

We respectfully request that CMS treat the reevaluation of any cost measures similar to their initial development, with the involvement of relevant medical specialty stakeholders. This should include consideration of current practice patterns, gaps in patient care, recognition of factors that are and are not within the control of the physician, potential impact on quality of care, validity testing, reliability, and fairness. The initial development of the cataract episode-based cost measure exemplified this collaboration. In this process, ophthalmology, optometry, primary care, and anesthesia participated and provided input, resulting in the creation of an equitable measure that allows providers to maintain a high level of quality care.[36,37]

Cross-cutting questions

[1. Should there be any changes to the patient cohort for the measures, as defined by trigger codes and exclusions? For instance, given the set of cost measures in MIPS, are there any gaps in care that could appropriately be filled by expanding the scope of an existing measure? Has clinical practice changed how these conditions and procedures are performed in a way that the patient cohort would need updating?]

CMS is seeking stakeholder feedback on potential opportunities to refine measures so similar types of care are measured together and that gaps are minimized. This includes additional trigger codes and/or eliminating exclusions to meet this end. The Academy believes that either of these

[36] Glasser D. Rewarding cost efficiency in Medicare's Merit-based Incentive Payment System. Ophthalmology, 126:189-191, 2019.
[37] 2 Pershing S, Sandhu AT, Uwilingiyimana A-S, Glasser DB, Morgenstern AS, Do R, Choradia N, Lin E, Leoung J, Shah M, Liu A, Lee J, Lam J, MaCurdy TE, Nagavarapu S, Bhattacharya J. Cataract surgery in the Medicare Merit-based Incentive Payment System: Episode-based cost measure development and evaluation. Am J Ophthalmol, in press.

changes applied to the cataract cost measure would be counterproductive, as reiterated in our response to Question 3. Although we lack experience in other specialties, these concerns should be addressed in all cost measures. In particular, expanding patient cohorts that include higher-risk and inherently higher-cost cases would place providers who care for those patients at risk for an unfair comparison to those who limit their practice to less complex cases. This would create a disincentive to caring for more complex patients, potentially resulting in increased referrals, increased program costs for repeated evaluations, and increased patient time and travel burden.

In addition, with a measure qualification threshold of only 10 cases, there are significant numbers of lower-volume providers who would be particularly exposed to an adverse score with only one high-risk case. It may not be possible to risk-adjust these cases in a way that protects lower-volume providers from an unfair penalty. An alternative would be to increase the measure qualification threshold, thereby diluting the impact of a single outlier case. However, that would reduce the number of providers eligible for a cost measure score.

[2. Are there any updates that should be made to the measure-specific risk adjustors, such as to reflect changes in clinical practice or to align with other cost measures used in MIPS?]

We do not believe that changes should be made to measure-specific risk adjustors at this time. When valid data is available to reflect changes in clinical practice, it could be appropriate to update measure specific risk adjustors. However, that may unfairly place lower-volume providers at increased risk for an adverse score. Although CMS' current data shows that cost-adjustment are "accurately accounting for patient risk" and that "testing shows that predictive ratios for each of the Wave 1 measures are centered around 1.00," that does not mitigate the risk of a single poor outcome for low-volume providers. Additionally, when observed to expected cost ratios are close to 1.00, adjustments are unlikely to be meaningful. This is discussed in greater detail below.

Questions specific to the Routine Cataract Removal with Intraocular Lens (IOL) Implantation cost measure

[Question 3. Should additional trigger codes be added to align with related quality measures? If so, which codes?]

Additional trigger codes should not be added to align with the quality measures. The trigger codes and exclusions for the cataract cost measure were carefully chosen to exclude high-risk patients with an increased likelihood of needing an additional costly intervention.[38,39] This was done to ensure a level playing field between higher and lower-volume providers and to avoid creating a disincentive for providers to care for complex patients. Expanding the patient cohort by adding trigger codes or removing exclusions would add only higher-risk cases to the measure. Due to circumstances beyond their control, providers who care for these patients will be at increased risk for an adverse cost measure score. This is also a concern for lower-volume surgeons who can qualify for the measure with as few as 10 cases. A single retinal detachment in a high-risk patient would unfairly disadvantage that provider simply due to lack of a large enough case volume to average out high-cost outlier events.

The increased risk of a financial penalty associated with complex patients could create a disincentive to caring for them. This in turn can lead to a rise in referrals with increased program costs and patient burden with no associated improvement in outcomes.

CMS also proposes harmonization of trigger codes between the cataract quality measures Q191 and Q303 and the cataract cost measure, with a goal of creating an ophthalmology MIPS Value Pathway (MVP). We have concerns with adding trigger codes to align these measures. All the additional trigger codes are associated with a greater risk of subsequent costly interventions. Our concern with adding these cases is detailed above. In addition, except for CPT 66982, which is the very definition of a high-risk complex case, the additional procedures (CPT 66840, 66850, 66852, 66920, 66930, 66940, 66983) are all low volume, making it unlikely that their addition would significantly increase the numbers of cases measured or providers eligible for a cost score.

[Question 4. Based on the similarity of the cost profiles and the potential to cover more patients undergoing cataract removal procedures, is including complex cases an appropriate approach? If so, what are other updates that would be needed to the measure; for example, should these codes indicating significant ocular conditions be added as a risk adjustor? Are there services that are currently not included in the measure that would be important to include to reflect the care for complex procedures?]

The Academy does not support the addition of complex cases to the cost measure for the reasons noted above. CMS notes that "exclusions are the primary driver for approximately fifty percent of triggered episodes being excluded from the final measure." They found an observed to

[38] Glasser D. Rewarding cost efficiency in Medicare's Merit-based Incentive Payment System. Ophthalmology, 126:189-191, 2019.
[39] Pershing S, Sandhu AT, Uwilingiyimana A-S, Glasser DB, Morgenstern AS, Do R, Choradia N, Lin E, Leoung J, Shah M, Liu A, Lee J, Lam J, MaCurdy TE, Nagavarapu S, Bhattacharya J. Cataract surgery in the Medicare Merit-based Incentive Payment System: Episode-based cost measure development and evaluation. Am J Ophthalmol, in press.

expected (O/E) cost ratio for excluded cases close to 1.00, concluding that the removal of exclusions would significantly increase the number of included episodes without distorting the comparability of episodes within the current system. They further conclude that including these more complex cases could safeguard against unspecified unintended consequences.

The Academy disagrees with both conclusions. Rather than safeguarding against unintended consequences, expanding the cohort to include high-risk cases will increase the risk by placing providers at greater risk of being penalized for working to care for the most vulnerable patients. It would create a disincentive to care for patients with comorbidities known to be associated with complications.

The finding that the O/E cost ratio of excluded cataract cost measure cases is close to 1.00 is likely due to the scarcity of high-cost outlier events rather than a lack of increased costs associated with those events. In a large dataset, an uncommon expensive complication such as a single retinal detachment is lost in the noise. For the individual healthcare provider, these rare but expensive cases can occur due to factors entirely outside of their control. Providers with large enough caseloads to qualify for a cost measure score but too small to average out the additional costs from a single atypical case will be at risk of being unfairly penalized.

Further, the O/E cost ratio close to 1.00 for excluded cases suggests that any risk adjustment factor would be negligible, leaving providers at risk for outlier cases. Increasing the minimum case count to qualify for a cost measure score could help moderate the possible impact of outlier events. An increased reporting threshold would ensure an outlier case has a lower net impact on a provider's results. However, it would reduce the number of providers eligible for a cost score and would still subject providers to consequences resulting from factors outside of their control.

[Question 5. Should medications including Dexycu and Dextenza be included in the Cataract Removal measure? Are there any other intra- or peri-operative drugs that should be considered for inclusion in the Cataract Removal measure?]

Dexycua and Dextenza should not be included in the cataract removal cost measure unless the prescription drugs that they can replace are also included. Including those prescription drugs in the measure is problematic at this time, as described in our response to Question 6.

Dexycu and Dextenza are corticosteroids administered during cataract surgery that can reduce or eliminate the need for postoperative steroid drops. For patients that have difficulty administering drops, they may offer the only alternative to missed doses. Including the cost of these drugs, without including the cost of the postoperative eyedrop alternative, would not accurately reflect true costs and would disadvantage use of the intraoperative medication.

In contrast, Omidria is an expensive alternative to other medications bundled into the facility fee which are used to dilate the pupil. Its clinical advantage over these other medications is

limited to cases with abnormal pupil dilation or intraoperative floppy iris syndrome. These cases are currently excluded from the cost measure, so there is no penalty for its use when medically necessary. While Omidria also has an FDA indication for the reduction of postoperative pain, it does not replace any postoperative medications. It represents an unnecessary cost in routine cases. Therefore, it is also appropriate to include Omidria in the cost measure.

[Question 6. Are there any Part D drugs related to cataract surgery that should be considered for inclusion in the Cataract Removal measure?]

While desirable, inclusion of Part D drugs at this time would seriously degrade the validity of the cataract cost measure. For Part D drugs to be considered as part of the cost measure, it is critical to ensure that all drug costs associated with cataract surgery are accurately incorporated. Selective inclusion of only certain drugs will induce bias into the measurement. Further, it might result in the unintended consequence of incentivizing utilization of unincluded drugs for non-clinical reasons. Without including Part B drugs and drugs prescribed to patients who do not have Part D coverage, the measure cannot be fairly assumed to be representative of a provider's total drug costs for all of their Medicare patients.

Drugs used in conjunction with cataract surgery, including those administered pre-, intra-, and post-operatively, would likely be responsible for most of the difference in episode costs were they to be included in the cataract cost measure. Because drug selection is under the control of the provider, the inclusion of drug costs could be a significant improvement to this measure. However, there are three critical shortcomings that would need to be addressed before drug costs could be appropriately included.

First, all relevant drugs must be included in the measure, whether administered pre-, intra-, or post-operatively. Some drugs that are administered intraoperatively (e.g., intra- or peri-ocular steroids, nonsteroidal anti-inflammatory drugs (NSAIDS), or antibiotics) may replace or reduce the need for pre- or post-operative drops.There would be a potential financial incentive for the utilization of any drug that is not included in the measure, an unintended consequence.

Second, accurate drug cost data must be available for all cases included in the measure. CMS may have access to Part B and Part D drug claims data. However, currently there is no way to capture drug costs for patients who do not have Part D coverage. These patients would have to be excluded from the measure, otherwise, their drug costs will appear lower than they really are due to the lack of data. Unless the distribution of patients with Part D coverage is uniform among providers, cost measure scores will be influenced by factors outside of the provider's control.

Third, drug costs must be transparent and immediately available to providers at the time that care is rendered for them to have control over those costs. The most used drug classes associated with cataract surgery are corticosteroids, antibiotics, NSAIDs, and intraocular pressure lowering

medications. Multiple options exist in each class. When faced with a choice of several different drugs in a class, providers currently have no way of knowing which are more or less expensive. With the broad range of Part D plans, each having their own different drug costs, it is inconceivable for providers to easily track them. Further, prices for a given drug under a given plan can vary as the carrier negotiates with pharmacy benefit managers and others for more favorable rates. Today's least-cost alternative may be tomorrow's highest-cost option. Tracking these changes would place an enormous burden on practices and would simply be impossible in today's environment. Even if cost data was instantly available, providers would be faced with a conflict between doing what is best for the patient or what is best for the carrier.

This suggests that the appropriate point of control may be at the drug source rather than the provider. While the Academy believes that drug costs are a critical issue, it does not appear that any of the essential conditions listed above are being met, making it inadvisable to include additional drug costs at this time. We would be pleased to engage in a dialog to address these limitations.

3.1.7 Comment Number 7

- **Date:** 26/05/2022
- **Submitter Name, Credentials, and Organization:** Arash Mansouri, MD, Medical Director at Access Eye Centers
- **Comment Text:**

[3. Should additional trigger codes be added to align with related quality measures? If so, which codes?]

No

[4. Based on the similarity of the cost profiles and the potential to cover more patients undergoing cataract removal procedures, is including complex cases an appropriate approach? If so, what are other updates that would be needed to the measure; for example, should these codes indicating significant ocular conditions be added as a risk adjustor? Are there services that are currently not included in the measure that would be important to include to reflect the care for complex procedures?]

No

[5. Should medications including Dexycu and Dextenza be included in the Cataract Removal measure? Are there any other intra- or peri-operative drugs that should be considered for inclusion in the Cataract Removal measure?]

No

[6. Are there any Part D drugs related to cataract surgery that should be considered for inclusion in the Cataract Removal measure?]

No

3.1.8 Comment Number 8

- **Date:** 05/27/2022
- **Submitter Name, Credentials, and Organization:** Owen Bishop, Executive Director, Market Access at Ocular Therapeutix, Inc
- **Comment Text:**

On behalf of Ocular Therapeutix, Inc. (Ocular), we are submitting this comment to address the Merit-based Incentive Payment System (MIPS) measure reevaluation for the Routine Cataract Removal with Intraocular Lens Implantation measure (Cataract Removal measure). As we understand it, this measure is being considered for comprehensive reevaluation and the call for comment on this includes specific questions for commenters to address. We appreciate the opportunity to comment on this measure and we offer the following recommendations, which we explain in more detail below:

1. Medications, whether covered under Medicare Part B or Medicare Part D should not be included in the Cataract Removal measure to avoid disincentives for physicians to prescribe the most clinically beneficial medications based on patient needs.

2. Dextenza® should not be included in the Cataract Removal measure because the product is furnished in a separate procedure that begins after the cataract procedure has been completed.

3. Should any medications nonetheless be included in the Cataract Removal measure, to avoid encouraging the use of some drugs over another, all drugs should be included.

I. Background

Dextenza, a corticosteroid intracanalicular insert, offers Medicare beneficiaries an important alternative to eye drops for the treatment of post-surgical ocular inflammation and pain. Dextenza is physician-administered immediately following the ocular surgery, thereby eliminating the burden of topical eye drop application. Furthermore, Dextenza does not contain anti-microbial preservatives and does not contain benzalkonium chloride.

For the procedure to deliver Dextenza, the product is inserted through the punctum, a natural opening in the eye lid, and into the canaliculus. An anesthetic is applied to the punctal area. The punctum and lacrimal system are dilated to determine the anatomical angle of the lacrimal system and to stretch the punctal opening and lacrimal system for insertion, being careful not to perforate the tissue. The surrounding tissue is dried and the lid is stabilized for insertion; this often requires a technician to assist. An applicator or forceps is used to insert the drug-eluting

insert through the punctum into the canaliculus. The insert is positioned to sit 1-2 mm below the punctal opening and is repositioned following initial insertion. Following insertion, Dextenza resorbs slowly through the course of treatment and exits the nasolacrimal system without the need for removal.

II. Discussion

The call for comment on the Cataract Removal measure includes a section (3.2.2) on assigning medication costs to the episode. That document notes that there are no Part D costs included in the measure currently. It also notes that medications are not required by the Centers for Medicare & Medicaid Services (CMS) to be included, and that medications "may be assigned" to the episode under certain conditions. We urge Acumen not to include any medications in the measure so that physicians can retain the flexibility, undeterred by financial considerations that come with inclusion in the measure, to utilize the most appropriate product for the individual patient. Dextenza, in particular, is inappropriate for inclusion in the measure since it is furnished as part of a procedure that is distinct from the cataract procedure. Finally, should Acumen move forward with including medications in the Cataract Removal measure, we recommend that it include all Part B and Part D medications so that there is a level playing field among the medications in the physician's arsenal.

A. No Medication Costs Should be Assigned to the Cataract Removal Measure

Under the current Cataract Removal measure, we understand that the inclusion of medications has altered physician practice patterns, with some discontinuing the prescribing of those medications that are in the measure. While we understand the laudable goals underlying the MIPS program, what is occurring is not consistent with those goals. For example, one stated goal is to drive improvement in health outcomes.[40] However, when there are financial penalties associated with prescribing medications without regard to the clinical benefits of those medications, and that causes physicians not to prescribe those products, that can lead to diminished, not improved, health outcomes. This is particularly the case here given that physicians have no control over the cost of medications. Inclusion of medications in the Cataract Removal measure would incentivize physicians to either not prescribe a product that will improve health outcomes, or to choose a cheaper medication that is not as clinically beneficial. Accordingly, we recommend that no medications be included in the Cataract Removal measure so that physicians can continue to prescribe the medications that they believe are most clinically beneficial for their patients.

[40] *See* Traditional MIPS Overview, available at https://qpp.cms.gov/mips/traditional-mips#:~:text=MIPS%20was%20designed%20to%20tie,reduce%20the%20cost%20of%20care.

B. Dextenza Should Not Be Included in the Cataract Removal Measure

According to the call for comment, medications administered during the intra- or perioperative period may be assigned to episode groups. Under this standard, Dextenza does not warrant inclusion because of the separate nature of the procedure in which the product is inserted.Specifically, as noted earlier, this insertion procedure is a distinctly separate procedure from a cataract procedure that requires additional time following the completion of the cataract procedure. During cataract surgery, an incision is made into the cornea and the patient's cloudy natural lens is removed either by emulsification in place or by cutting it out and an artificial intraocular lens is implanted in its place. Subsequently, the surgical drape and speculum are removed which marks the natural conclusion to all processes related to lens extraction and replacement (i.e., the cataract surgery). Depending on the incision size, the wound may be closed with a suture. Once the cataract procedure is completed, insertion of Dextenza can begin. The insertion occurs at the lacrimal punctum, which is part of the external anatomy of the eye located at the junction of the eyelid margin; both upper and lower lids have a punctum. The surgeon thoroughly dilates the punctum, dries the areas and inserts Dextenza. The Dextenza insertion procedure is separate and distinct and is not part of the cataract procedure as it does not utilize, in any way, the incision made for the cataract procedure and is only performed when the the cataract procedure has been completed.

As noted, the insertion of Dextenza is accomplished in a different part of the eye than the cataract procedure and performed after the cataract procedure has been completed. It is thus entirely separate and neither intraoperative nor perioperative such that it is not appropriate for inclusion in the Cataract Removal measure.

C. If Any Medications Costs Are Assigned to the Cataract Removal Measure, All Such Costs Should be Assigned

While we believe that no medications should be include in the Cataract Removal measure, and certainly based on the pertinent standards, Dextenza should not be so included, if the decision is made to include any medications in the measure, it should be an across-the-board decision. Any other result would incentivize physicians to use drugs not included in the measure, instead of drugs included in the measure.

While there are laudable goals to achieve through the MIPS program, they should not come at the expense of enabling physicians to have the flexibility to utilize the appropriate medications in the care of their patients. Dextenza provides an example of the importance of this need for options. In regard to many ophthalmic procedures, it is important to be able to treat ocular inflammation and pain following surgery. Historical options consisted primarily of patient-administered eye drops that were plagued by patient adherence issues, improper instillation (including missing the eye), instilling an incorrect number of drops, bottle tip contamination with

ocular surface contact, and failure to wash hands prior to patient-administered topical therapy.[41] Additionally, topical steroid drops contain preservatives, like benzalkonium chloride, which is toxic to the ocular surface and may lead to inflammation and damage to the tear film. Dextenza eliminates the burden of topical eye drop application and does not contain anti-microbial preservatives.

In addition, Dextenza does not contain benzalkonium chloride (BAK), which is the most common anti-microbial preservative in topical medications (eye drops). This preservative also causes toxic effects to the eye itself by unleashing free radicals, inducing cell death, and promoting inflammatory cytokines. Side effects attributed to BAK include tear film disruption, ocular surface disease, changes in conjunctival cell differentiation, and corneal toxicity. All these side effects would affect patient's quality of life and add to the overall ophthalmic treatment costs during the patient's lifetime. Preservative-free Dextenza circumvents these problems, and addresses compliance issues.

It is thus important for physicians to have a full range of options (with Dextenza as an example, but not the only example) to combat postoperative pain and inflammation. If only certain medications were to be included in the Cataract Removal measure, that could create incentives to use (or not use) certain medications solely because of exclusion (or inclusion) in the measure. Such interference with physician choice would be an unacceptable component of the MIPS program and thus if any drugs that qualify for inclusion under applicable standards are included, then all must be.

Ocular greatly appreciates the opportunity to comment on this public call for comment on MIPS measure reevaluation. In an effort to ensure continued beneficiary access to needed ocular medications, we recommend that medications not be included in the Cataract Removal measure, noting in particular that Dextenza does not meet the stated standards for inclusion.

3.1.9 Comment Number 9

- **Date:** 5/25/2022
- **Submitter Name, Credentials, and Organization:** Philip Fraterrigo, MD, Fraterrigo Eye Physicians & Surgeons, PLLC (individual)
- **Comment Text:**

Recently, I became aware that CMS was considering adding Dextenza as an espisode-based MIPS cost measure. I'd like to provide some input based on my use of the product for our elderly

[41] An JA, Kasner O, Samek DA, Lévesque V. Evaluation of eyedrop administration by inexperienced patients after cataract surgery. *J Cataract Refract Surg*. 2014;40(11):1857-1861.

patients since 2019 and why I think adding Dextenza as an espisode-based cost measure is unwarranted.

Pass through status is typically granted by Health and Human Services Department to allow access to newly approved FDA drugs and devices. It has always been my understanding that the goal of pass through was to incentivize innovation and to allow for real world testing of products that could advance the field of medicine. In the case of Dextenza, the experiment has worked. Dextenza provides a medical solution to a specific patient population by creating a platform that delivers a precise dose of medication automatically.

The reality is that prior to the introduction of Dextenza there was no product on the market to address the problem of compliance. Compliance to most, means taking a medication as prescribed by your doctor, but in the elderly population it is not that simple. Decades of clinical experience have shown us that in this demographic there are many factors that affect compliance. Physical and cognitive issues are the obvious impediment that come to mind with respect to adherence to a post op medication regimen, but other barriers exist as well. While some patients have family, friends or caretakers that can fill the gap and help guide them through the process others do not. All of those factors are what led our practice to initially test the product. The real world affect that these tests had on our patients are what made us decide to establish Dextenza as our standard of care.

The impact of adding Dextenza as a MIPS cost measure will undoubtedly have far reaching affects. Doctors will not invest the time or take the risk of testing a new product if they will be penalized financially for taking that risk. In essence, by including pass through products as a cost measure you would be assigning a financial penalty to their use. If CMS adds this penalty to pass through products, they would be defeating the main purpose of the passo-through program. Innovation often leads to further advancement and initial cost should not be the only factor in determining value. The FDA has already expanded the indication for Dextenza to the treatment of allergic conjunctivitis. This platform itself could be further developed to treat chronic conditions such as glaucoma or dry eye. If so, this could lead to actual cost savings within CMS over time. None of this will happen if CMS now decides that the cost of new products should be part of the calculation for MIPS reporting. I strongly discourage adding Dextenza as a cost measure for MIPS reporting. While it may seem that this decision will only affect a specific product in a specific field of medicine, what it actually does is set a precedent for the development of future products in all fields of medicine.

3.1.10 Comment Number 10

- **Date:** 5/27/2022
- **Submitter Name, Credentials, and Organization:** Jill Sage, Chief of Quality Affairs, American College of Surgeon (ACS)

- **Comment Text:**

On behalf of the 82,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) and Acumen, LLC on the Episode-Based Cost Measure Comprehensive Reevaluation process.

The ACS is a scientific and educational association of surgeons founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. With our more than 100-year history in developing policy recommendations to optimize the delivery of surgical services, lower costs, achieve high quality care, and make the U.S. healthcare system more effective and accessible, we believe that we can offer valuable insight to the agency as it explores ways to evaluate and develop cost measure methodologies.

CMS and its contractor, Acumen, LLC, are gathering input on eight episode-based cost measures that are being considered for comprehensive reevaluation. The episode-based cost measures being considered for comprehensive reevaluation are:

- Elective Outpatient Percutaneous Coronary Intervention (PCI)
- Intracranial Hemorrhage or Cerebral Infarction
- Knee Arthroplasty
- Simple Pneumonia with Hospitalization
- ST-Evaluation Myocardial Infarction (STEMI) with Percutaneous Coronary Intervention (PCI)
- Screening/Surveillance Colonoscopy
- Revascularization for Lower Extremity Chronic Critical Limb Ischemia
- Routine Cataract Removal with Intraocular Lens Implantation

The measures being reviewed were added to the Merit-based Incentive Payment System (MIPS) in the 2019 MIPS Performance Year. In our following comments, the ACS offers feedback on the overall episode-based cost measure strategy and the development of these measures. Since the implementation of episode-based cost measures in MIPS, ACS has advocated for the need to measure cost and quality over the same episode of care in order for patients to assess value and for consistency across CMS cost and price initiatives, such as Hospital Price Transparency, Transparency in Coverage and most recently the Good Faith Estimates (GFEs) required by the No Surprises Act. When costs or price are measured using different units and that information is subsequently presented to patients, the result is confusion and parsing of accountability. This is precisely what will occur with public reporting of MIPS cost and final scores as required under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) when compared to the GFEs and estimates for shoppable services required under other statutes. For example, a physician may have a high or low cost score on the narrow

MIPS measure, but the GFE, which takes into account the broader context of services, may show the opposite. This dilutes the ability to build value and develop coordinated efforts to control costs. Furthermore, while parsing costs into individual care team members may be expedient for accountability and scoring in a payment system, it may actually be deleterious to the overall effort around cost control through vehicles such as price transparency and value-based payment models. **We believe that for the Cost category of MIPS to be meaningful, the measures used must be not only reliable, but also actionable. They should provide information on how a physician or care team currently uses resources and allows for comparisons with others who may leverage their resources differently.**

Over the years, ACS Fellows have participated in various cost measure development subcommittees, and we receive consistent feedback that the current process used for developing MIPS cost measures is not structured to truly measure cost or offer actionable results. During the development process, subcommittees are required to follow a single, basic framework, regardless of condition or patient population. **We do not believe that physician cost, quality, and overall value can be evaluated using a one-size-fits-all approach. Procedures and patient populations are vastly different and cannot always be evaluated for appropriateness in the same manner.** In some limited cases, care consists of a set of discrete, non-connected services which may be best priced individually or as a small set of summary services. Care for many conditions, however, can be complex, involving large teams with overlapping services. At times, this can result in overuse, duplication, or redundancies in care. These more complex episodes are best priced using standardized definitions of what services might be included and rules regarding how these services are attributed when care episodes overlap. This grouper logic must be consistent with the patient experience of care rather than parsed to the individual service provider. Care may also result in complications or sequelae adding additional complexity. These aspects of pricing models require advanced grouper logic that is capable of accounting for all these elements. Finally, using Medicare's Hierarchical Condition Category (HCC) logic, it is possible to reflect risk profiles onto patient groups so that low, intermediate, and high-risk patient price models are available.

The ACS has developed these capabilities for meaningful price transparency. Our work in price transparency and production costs of care (which helps to make price information more actionable) is being piloted in more than 10 institutions. This pilot provides these institutions with enhanced information on price variability and resulted in efforts to understand their institutional production costs relative to price to drive improvement. These are the types of actionable results that are essential if we are to entice care delivery to meet the Congressional intent for optimal resource use in healthcare. Due to MACRA requirements for the public reporting of MIPS final and category scores, CMS' episode-based cost measures are among a list of methodologies being employed in the spirit of price transparency.

When CMS-maintained cost measures are used in payment incentive programs, the results differ significantly from real price experienced by the patient. The assignment of services applies an accountability logic that fits a payment program but does nothing to inform healthcare providers about true variations in price nor patients about how much they can expect to pay. In the current episode-based cost measure accountability processes, services for which clinicians feel they lack direct control have frequently been removed, even though the total cost of care and the price of care for the patient will include these services. It may seem rational to object to potential penalties for excessive cost when an individual clinician is not the cause of the expense. However, the lack of shared accountability will distract from team efforts to optimize care. Multiple episode groupers are currently in use, each with its own different way to express price. Some are more hospital centric, such as DRG-based grouper. The DRG-based grouper logic differs from the logic used in the CMS episode-based measures and is even more constrained; these methods do not provide patients or clinicians with a workable understanding of price variation. Others use artificial intelligence (AI) and machine learning (ML) to define levels of associated services based on a triggering care event or service; however, they lack a clinically vetted logic that can establish what services should be assigned to each episode. More advanced groupers are CPT-based and consider the impacts of event rates, sequela or complications related to care, and provide risk-adjusted pricing.

Even if CMS' goal is to provide information solely for a payment incentive program, the current design of the episode-based cost measures is limited to only providing a meld of services that are not distinctive and safe for use in accountable incentive programs. In other words, the current approach dilutes the actionable variation of the most complex care by limiting evaluation to core services. Creating a consistent methodology for cost and price assessment could serve to benefit multiple goals, including price transparency, that would meet the market's needs for informing patients, practitioner review of price drivers, identification and reaction to trusted variations, GFEs, episode-based contracting, etc. It is important to have true total cost of care represented using clinically vetted applied service lists, shared and split accountability, event rate and sequela reporting to have the clearest, most comprehensive understanding of price possible. These should be CPT-based and promoted as a consistent standard for federal and commercial use as openly available applied grouper logic.

To put this in the larger context for optimizing the cost of healthcare, price transparency is a progressive series of steps. The first step begins with measuring the price of an individual service such as an office visit, lab test or imaging service. The natural extension of this is to combine the services together into an episode that is meaningful to patients--the sum of all typical services. To become shoppable services, the episode definitions need to be standardized so that a patient can compare typical care based on the experience of actual patients and inclusive of all the services across multiple sites of care. From episodes for shoppable services, price information

can progress further to inform the development of APMs using the same standardized episodes. The APM version will require deeper consideration of risk-based pricing in order to be inclusive of low, intermediate, and high-risk patients with price differences. The final step is to add in quality for the condition under treatment and move to value-based health care. None of the current MIPS approaches enable this sort of progression.

In conclusion, if MIPS has a cost or price methodology that is incomplete and differs from GFE requirements in the No Surprises Act, the Hospital Price Transparency Program, the Transparency in Coverage Program and even commercial insurers proprietary methodologies, there will continue to be confusion that significantly stunts the benefits Congress expects from price transparency. **ACS urges CMS to assess and compare the impacts of the current approach to episode-based cost measures, a more inclusive approach, and an advanced grouper logic. They should then consider how the goals for MIPS cost measurement compare to the goals for price transparency for patients. Assessing the impact of the various methodologies will allow CMS to identify if their objectives for MIPS payment incentives are met in the same way that advanced grouper logic meets patients' needs for price transparency and GFEs.**

3.1.11 Comment Number 11

- **Date:** 5/27/2022
- **Submitter Name, Credentials, and Organization:** Monica Wright, MHA, CPC, CPMA, CPCO, Manager, Coding and Reimbursement at Society for Cardiovascular Angiography & Interventions
- **Comment Text:**

The Society for Cardiovascular Angiography and Interventions (SCAI) appreciates this opportunity to provide our comments on the episode-based cost measures for elective outpatient coronary intervention (PCI) and ST-elevation myocardial infarction (STEMI) with percutaneous coronary intervention. SCAI is a non-profit professional association with over 4,500 members representing interventional cardiologists and cardiac catheterization teams in the United States. SCAI promotes excellence in interventional cardiovascular medicine through education, representation, and the advancement of quality standards to enhance patient care. SCAI appreciates that the measures are discrete episodes with clear triggers and 30 day accountability. However, SCAI does have concerns that are detailed below.

Elective PCI: In 2018, the American College of Cardiology National Cardiovascular Data CathPCI Registry (which collects data from about 85% of US cath labs) registered 260,827 coronary interventions in outpatients that would fit the triggers for this bundle. Generally about half of percutaneous coronary interventions (PCIs) in this registry are of Medicare age, and only 60% of Medicare patients have fee-for-service Medicare, so this suggests that this bundle will

apply to about 78,000 Medicare patients per year. Averaged over 5000 interventional cardiologists, this leads to the conclusion that the average cardiologist participating in this bundle will have their quality assessed on just 15 PCIs. We are concerned this may not reliably distinguish high-quality physicians from low-quality physicians. In contrast, about 800,000 Americans have a heart attack every year. SCAI has previously suggested that CMS should focus on more common diseases such as acute MI, or more common procedures.

Furthermore, SCAI has pointed out that while 50,000 cardiologists in the US treat heart attacks, only 5000 perform PCI. SCAI has questioned whether responsibility for performance should be focused on the 10% of US cardiologists performing PCI. We believe this is an unfair burden to place on a small fraction of practicing cardiologists.

List of Triggers: Code numbers and descriptors are flipped: descriptor listed for 92920 is for really 92921 and the descriptor for listed for 92921 is really for 92920. The same mistake was made for 92928-92929.

After an interventionalist performs a PCI, care is provided to the patient most commonly by other physicians, often physicians from other groups, and often by physicians from other specialties. So it is unfair to attribute care provided after the PCI to the cardiologist performing the PCI, who often has no control over the services assigned to this bundle.

Service Assignment: Many of the disorders "attributable" to a PCI have no obvious connection to the procedure. Some of the more inappropriate include the following:

Table 3. Service Assignment Suggestions

Excel Spreadsheet Line	Code	Explanation
872	H81	Disorder of vestibular function
940	R50	Fever of unknown origin
942	E86	Volume depletion
1087	D50	Iron deficiency anemia
1412	D65	DIC
1517	K55	Vascular disorder of the intestine

Overall Benefit of the Bundle: In Sandhu's analysis of this bundle cited below, the lowest cost quintile of physicians produced a cost of $10,920.[42] The highest quintile produced a cost of $11,017. The difference, $97 or 0.9%, was enough for an academic publication but begs the question of whether these differences are clinically significant. Studies such as this usually show regression to the mean: the highest and lowest performers seldom occupy those positions two years in a row. Thus we question whether this methodology distinguishes consistently high-cost physicians from low-cost physicians.

[42] Sandhu AT, Do R, Lam J, Blankenship JC, VanDecker W, Rich J, Gonzales O, Wu L, Pershing S, MaCurdy TE, Bhattacharya J, Nagavarapu S. Development of elective outpatient percutaneous coronary intervention episode-based cost measure. Circ Cardiovasc Qual Outcomes 2021;14e006461. DOI: 10.1161/circoutcomes.119.006461.

Reporting to Participants: Participants noted that their assigned risk score was provided with little context. More decile context to risk score would be helpful along with more transparency on score derivation for NPI/TIN.

Clinical subthemes (complications, readmissions, ancillary testing, SNF/DME) in this episode and the cost decile of each subtheme were not easily accessible to participants. Without these, participants had no "actionable data " to focus on for local appropriate cost savings.

Additionally, many physicians that work in hospitals or as a part of larger groups had not seen a cost report and therefore had no idea about their score or needed improvement. Ensuring scores are easily accessible and understandable by all participants is essential for future improvement.

STEMI PCI: In 2018, the ACC NCDR CathPCI Registry reported 127,824 STEMI PCI patients, of which half are presumably Medicare age. Thus it appears that 64,000 Medicare patients per year would be eligible for this bundle. The American Medical Association Relative Value Update Committee database lists 36,067 claims for STEMI PCI, suggesting the NCDR estimate may be high. Furthermore, these bundles apply to only the 60% of Medicare patients that are not in Medicare Advantage plans, further reducing the number of patients to which this bundle will apply. A bundle for which only 21,000 to 38,000 persons per year are eligible seems of little value. Distributed over 5000 interventional cardiologists, it is likely that the average cardiologist will perform STEMI PCI on just 4-7 eligible patients per year. A typical medical group has 4 interventional cardiologists – so that group's quality assessment will be based on just 16-28 patients. That seems too small to reliably distinguish high-quality/cost from low-quality/cost groups. As noted above, small data sets inherently include large amounts of variability over time. We suspect that these will fail to reliably identify consistently high performers and would ask that Acumen review the data received since 2019 to confirm our suspicions.

Are STEMI quality measures used to adjust the cost score in any way?

List of Triggers: The triggers for this are DRGs 246-251 coupled with 71 ICD-10 codes. It would be much simpler to simply use CPT code 92941 ("Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel").

Attribution: Attribution is based on who provides E/M services after the procedure. CMS' Quality Payment Program brochure for STEMI PCI lists an example where 8 clinicians provide an E/M service to the patient. The bundle is is attributed to the group that provides 5 of the 8 E/M services. The current average length of stay for STEMI is 2-3 days, so E/M services

typically include a history/physical, 1 progress note, and a discharge summary. How will attribution be assigned if 3 persons with 3 different TINs each see a patient once? A breakdown of attribution by specialty should be reviewed to ensure the measure is being attributed appropriately.

Service Assignment: Some of the disorders "attributable" to a PCI have no obvious connection to the procedure. Some of the more inappropriate include the following:

Table 4. Service Assignment Suggestions

Excel Spreadsheet Line	Code	Explanation
276	R78	Findings of drugs in blood
314	D50	Fe deficiency anemia

Reporting to Participants: Participants noted that their assigned risk score was provided with little context. More decile context to risk score would be helpful along with more transparency on score derivation for NPI/TIN. Clinical subthemes (complications, readmissions, ancillary testing, SNF/DME) in this episode and the cost decile of each subtheme were not easily accessible to participants. Without these, participants had no "actionable data " to focus on for local appropriate cost savings.

Additionally, many physicians that work in hospitals or as a part of larger groups had not seen a cost report and therefore had no idea about their score or needed improvement. Ensuring scores are easily accessible and understandable by all participants is essential for future improvement.

Summary

We note that these two bundles have 1100 – 1600 services assigned to each bundle to calculate cost, with about 240 exclusions and 115 risk adjustors. We are concerned that any construct this complicated may be poorly understood by physicians or administrators, may be difficult to administrate, may have administrative costs that outweigh its benefits, and may rapidly become obsolete as technology and practice evolve.

We calculate that both measures will yield about 15 patients to each individual (NPI) or group (TIN). We question whether 15 measures per year will reliably distinguish high-quality from low-quality providers, and whether performance will be consistent from year to year versus regressing to the mean. Now that data has been collected for these measures, we ask for confirmation that the numbers have exceeded these estimates to be proven significant.

A "patient who is more than 1-year post-acute MI" would be more of a heterogenous and inclusive grouping. It has been our experience that most outcomes measures and treatments are best validated in the post revascularization grouping as opposed to the medically managed group. We suggest these measures be evaluated and incorporated in place of elective PCI and STEMI PCI.

3.1.12 Comment Number 12

- **Date:** 5/28/2022
- **Submitter Name, Credentials, and Organization**: Janis M. Orlowski, MD, MACP, Chief Health Care Officer, Association of American Medical Colleges
- **Comment Text:**

AAMC (The Association of American Medical Colleges) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on the Episode-Based Cost Measure Comprehensive Reevaluation. The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members comprise all 155 accredited U.S. and 16 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals employed across academic medicine, including more than 191,000 full-time faculty members, 95,000 medical students, 149,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. In 2022, the Association of Academic Health Centers and the Association of Academic Health Centers International merged into the AAMC, broadening the AAMC's U.S. membership and expanding its reach to international academic health centers. Learn more at aamc.org.

The AAMC appreciates CMS's dedication to revaluating and updating the eight cost measures listed below added to the Merit Incentive Payment System (MIPS) in performance year 2019, to ensure the measures accurately reflect the cost of patient care:

- Elective Outpatient Percutaneous Coronary Intervention (PCI)
- Intracranial Hemorrhage or Cerebral Infarction
- Knee Arthroplasty
- Simple Pneumonia with Hospitalization
- ST-Elevation Myocardial Infarction (STEMI) with PCI
- Screening/Surveillance Colonoscopy
- Revascularization for Lower Extremity Chronic Critical Limb Ischemia
- Routine Cataract Removal with Intraocular Lens Implantation

Cost Measures Should Include Appropriate Risk Adjustment for Social Risk Factors

These eight episode cost measures are risk-adjusted by demographic variables, such as age, and comorbidities by using Hierarchical Condition Categories (HCC) data, and other clinical characteristics. Of special concern is that none of the cost measures are adjusted to account for

health-related social risk factors. In addition to differences in patient clinical complexity, health-related social needs can drive differences in average episode costs.

The National Academies of Science, Engineering and Medicine and the HHS Assistant Secretary for Planning and Evaluation have clearly acknowledged that social risk factors such as housing instability, low income, and health literacy may explain adverse outcomes and higher costs. Without accounting for these factors, the scores of physicians that treat patients with health-related social needs will be negatively and unfairly impacted and their performance will not be accurately reflected by their score. Physicians at academic medical centers (AMCs) often care for patients from under resourced and underinvested communities who are sicker, poorer, and have more complex medical needs than many patients treated elsewhere. **We request that these measures be adjusted to account for these risk factors.**

Attribution Method Should be Clear and Transparent and Correctly Capture the Patient/Clinician Relationship

For cost measures it is critical that there be an accurate determination of the relationship between a patient and a clinician to ensure that clinicians are appropriately held responsible for their patient's outcomes and costs. This is complicated given that many patients receive care from numerous clinicians, and maybe across several facilities. Furthermore, academic medical centers and other providers have moved towards team-based care. Team-based care allows clinicians to work as a multispecialty team partnering with their patients and patient families to address medical conditions and provide comprehensive care. CMS should ensure that the attribution process encourages team-based care rather than incentivizes siloed care.

AAMC has previously urged CMS to explore better data sources and analytic techniques to support more accurate attribution.1, 2 Attribution methods should be clear, transparent, and easily understood by clinicians. **The AAMC recommends CMS establish a more clear and transparent attribution methodology to ensure the appropriate clinician is held responsible for the patient's outcomes and costs.**

3.1.13 Comment Number 13

- **Date: 5/28/2022**
- **Submitter Name, Credentials, and Organization:**
  - Samir Shah, MD, FACG, President, American College of Gastroenterology
  - John M. Indaomi, MD, AGAF, President, American Gastroenterological Association
  - Douglas K. Rex, MD, MASGE, President, American Society for Gastrointestinal Endoscopy

- **Comment Text:**

On behalf of the American College of Gastroenterology (ACG), American Gastroenterological Association (AGA), and American Society for Gastrointestinal Endoscopy (ASGE), we thank you for the opportunity to comment as the Center for Medicare & Medicaid Services (CMS) and Acumen, LLC, gather input about episode-based cost measures that have been in use in the Merit-based Incentive Payment System (MIPS) since performance year 2019 and are being considered for comprehensive reevaluation. Our comments focus on the "Screening/Surveillance Colonoscopy" episode-based cost measure.

Consideration of Inclusion of Diagnostic Colonoscopies Physician representatives from each of our societies actively participated in the "Gastrointestinal Disease Management – Medical and Surgical Clinical Subcommittee." We believe members of this subcommittee were part of a successful and deliberative process when developing the "Screening/Surveillance Colonoscopy" episode-based cost measure. Consideration of inclusion of diagnostic colonoscopies was discussed thoroughly during development of the episode, and, for the reasons described below, it was recommended that this episode incorporate screening and surveillance colonoscopy only.

The myriad of indications for diagnostic colonoscopy (e.g., abdominal pain, gastrointestinal hemorrhage, new onset inflammatory bowel disease or other colitides, abnormal CT findings) and the potential adverse events from the interventions undertaken during the procedure make it challenging to define set pre- and post- trigger periods. Additionally, costs associated with diagnostic colonoscopy vary greatly depending on the site of care delivery -- inpatient vs. outpatient, and the condition, whether acute or chronic, that is associated with the need (e.g., colorectal cancer, Crohn's disease).

It should be noted that the indication of colonoscopy in the diagnostic setting is already captured by the "Lower Gastrointestinal Hemorrhage" episode-based cost measure, which accounts for diagnostic colonoscopies performed for lower gastrointestinal bleeding. Further our societies would anticipate that other acute (i.e., unexplained diarrhea) and chronic (i.e., inflammatory bowel disease) episodes will capture the bulk of other diagnostic colonoscopy exams.

We believe grouping diagnostic colonoscopy with screening and surveillance colonoscopy would be fraught with issues, make management of the data more complex and prone to irregularity, and would risk undervaluing diagnostic colonoscopy. Further, the heterogeneity of the sites of service, ancillaries, conditions, secondary procedures, and other factors would make analysis and evaluation challenging, and it would prove difficult if not impossible to provide meaningful information to the clinician. Based on these concerns, our societies strongly recommend the scope of the "Screening/Surveillance Colonoscopy" episode-based cost measure not be expanded to include diagnostic colonoscopy.

Meaningful Measurement of and Feedback to Clinicians The "Screening/Surveillance Colonoscopy" episode-based cost measure was introduced into MIPS in the 2019 performance year. With the Cost performance category now weighted at 30% of the total MIPS score beginning with the 2022 reporting year and after two years of limited clinician experience with MIPS due to automatically receiving or applying for exemption to MIPS via the Extreme and Uncontrollable Circumstances policy, we believe it is vital to ensure the accuracy of these episodes of care and meaningfulness to clinicians. Significant revision to the measure should not be considered given that there has been limited experience with the current measure by CMS and clinicians. The goal should be the development and maintenance of each episode-based cost measure and the delivery of feedback reports that are conducted in such a way that clinicians in practices of all sizes can easily interpret the reports so that actionable steps can be identified to improve patient care and cost efficiencies. To that end, we strongly recommend CMS reconvene the clinical experts who served on the subcommittee in order to fully vet public input before making any revisions to the measure.

Updated USPSTF Colorectal Cancer Screening Guidelines Since the release of the "Screening/Surveillance Colonoscopy" episode-based cost measure, the United States Preventive Services Task force (USPSTF) has updated its colorectal cancer screening guidelines and now recommends either a screening colonoscopy every 10 years or other screening methods for adults aged 45-75 who are at average risk for developing colorectal cancer. The USPSTF recommends screening for colorectal cancer in all adults aged 50 to 75 years as a Grade A recommendation and screening for colorectal cancer in all adults aged 45 to 49 years as a Grade B recommendation.[43] Our societies strongly recommend aligning the "Screening/Surveillance Colonoscopy" episode-based cost measure with the updated recommendations.

In summary, our societies recommend the following:

- Do not expand the scope of the "Screening/Surveillance Colonoscopy" episode-based cost measure to include diagnostic colonoscopy.
- Reconvene the clinical experts who served on the subcommittee in order to fully vet public input before making any revisions to the "Screening/Surveillance Colonoscopy" episode-based cost measure.
- Align the "Screening/Surveillance Colonoscopy" episode-based cost measure with the updated USPSTF recommendations.

[43] https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening

3.1.14 Comment Number 14

- **Date:** 5/25/2022
- **Submitter Name, Credentials, and Organization:** Christine Phelps, COE, Operations Manager, Norwich Ophthalmology Group/American Society of Ophthalmic Administrators
- **Comment Text:**

[3. Should additional trigger codes be added to align with related quality measures? If so, which codes?]

Additional trigger codes should not be added to the cost measure due to their negative impact on a practice's Cost score. Complex cases are unavoidable and are not related to the surgeon's perception of the surgical difficulty but are determined by the need to employ devices or techniques not generally used. The need for hooks, a Malyugian ring, or other devices is necessary for the best outcome for the patient, it is not a chosen billing strategy.

[4. Based on the similarity of the cost profiles and the potential to cover more patients undergoing cataract removal procedures, is including complex cases an appropriate approach? If so, what are other updates that would be needed to the measure; for example, should these codes indicating significant ocular conditions be added as a risk adjustor? Are there services that are currently not included in the measure that would be important to include to reflect the care for complex procedures?]

Including complex cases to the Cost measure is not an appropriate approach.

[5. Should medications including Dexycu and Dextenza be included in the Cataract Removal measure? Are there any other intra- or peri-operative drugs that should be considered for inclusion in the Cataract Removal measure?]

Medications such as Dexycu and Dextenza should not be included in the Cataract Removal Cost measure before they are standard practice in the US.

[6. Are there any Part D drugs related to cataract surgery that should be considered for inclusion in the Cataract Removal measure?]

Part D drug costs should not be included in the Cataract Cost measure because the costs are not within the physician's control but could still have a negative impact on their Cost measure score.

3.1.15 Comment Number 15

- **Date:** 5/28/2022
- **Submitter Name, Credentials, and Organization:** Kathy Lester, JD, MPH, Attorney at Outpatient Ophthalmic Surgery Society (OOSS)

- **Comment Text:**

The undersigned physicians who care for patients requiring cataract surgery and the Outpatient Ophthalmic Surgery Society (OOSS), which represents more than 1,100 ophthalmologists, nurses, and administrators who specialize in providing high-quality ophthalmic surgical procedures performed in cost-effective outpatient environments including ambulatory surgical centers (ASCs), are pleased to provide comments as part of the current call for public comment on measure reevaluation. We encourage the Centers for Medicare & Medicaid Services (CMS) to revise the Routine Cataract Removal with Intraocular Lens (IOL) Implantation measure ("cataract resource use measure") so that it does not penalize surgeons who prescribe the non-opioid pain management medication Omidria® or other medications that are reimbursed outside of the packaged rate. Excluding these drugs from the cataract resource use measure is essential to ensuring access to patients who medically need such products and to achieving improved medical outcomes. We appreciate that CMS is actively seeking comments on whether the specifications for this measure should be reconsidered during this review cycle. We believe it should be revised by removing Omidria specifically and excluding other pass-through/separately reimbursed products.

It is important that CMS exclude all products that are reimbursed outside of the base rate through pass-through, add-on, or other similar mechanism, which is the request that the cataract surgical professional societies have consistently made. Medicare payment policy already recognizes that payment policy can result in a loss of patient access and has decided to reimburse non-opioid pain management medications outside of packaging. Quality resource use measures can also result in patients losing access to medically necessary medications, which the National Quality Forum's Measure Application Partnership recognized as a particular problem for the cataract resource use measure. CMS should revise the cataract resource use measure to eliminate the disincentive against using separately reimbursed products, especially when the reimbursement policy is promoting the Administration's policy priorities.

We are deeply concerned that the current cataract resource use measure results in a loss of access for patients to products, such as Omidria. Because Omidria is included in the specifications as a cost to be considered, despite Medicare paying separately to promote the use of non-opioid pain management medications, facilities simply cannot provide access to the drug if doing so results in a cut under the Merit-based Incentive Payment System (MIPS) program. Medications, such as Omidria, are important to our patients who would otherwise require the use of fentanyl, iris hooks, or compounded medications that the FDA has warned against using. Physicians should not be penalized when prescribing Omidria.

Removing Omidria from the measure would also result in program-wide savings to Medicare by reducing the need for post-operative eye drops, which are currently furnished under Medicare

Part D. These Part D products are a significant cost to Medicare and create a cost-sharing burden on patients. More importantly, reducing the need for post-operative eye drops improves patient compliance and leads to better clinical outcomes, especially in the area of pain management and limiting the use of opioids.

We are also concerned about the inequitable impact of the current measure, which includes only one separately reimbursed drug, and the negative effects on other separately paid drugs that might be included in the future. Medicare measures going forward should preserve patient access to these drugs, especially non-opioid pain management drugs. In any event, similarly situated drugs should be treated similarly, and CMS policy should not unfairly disadvantage one versus others.

In sum, CMS should not create a substantial disincentive to the use of Omidria when it is clinically appropriate. To protect access to Omidria, we ask that CMS remove Omidria from the cataract resource use measure and not count it toward the resource use calculation.

3.1.16 Comment Number 16

- **Date:** 5/26/2022
- **Submitter Name, Credentials, and Organization:** Liza, D'Onofrio, MBA, CRA, CNMT, RT, Senior Manager, Registry Operations at Society of Interventional Radiology
- **Comment Text:**

The Society of Interventional Radiology (SIR) appreciates the opportunity to submit feedback on the reevaluation of the cost measure: Revascularization for Lower Extremity Chronic Critical Limb Ischemia.

SIR is a professional medical association that represents approximately 8,000 members, including most U.S. physicians practicing in the specialty of vascular and interventional radiology. The Society seeks to improve lives through image guided therapy. We understand the importance of cost measures within healthcare, especially those that are relevant to interventional radiology practice. We appreciate the opportunity to be involved and represented by these measures and look forward to our continual involvement with CMS and the measures process.

Critical limb ischemia (CLI) is part of a spectrum of peripheral arterial disease that impacts a significant and increasing number of patients each year. Interventional radiologists are a critical part of the care team that treats patients with CLI.

Upon review of the current cost measure, our physicians found the form to be very concise and can be utilized by multiple specialties without bias towards a specific specialty. The review also noted the content was appropriate for the treatment of chronic critical limb ischemia. There were no specific edits noted for the episode groups, trigger codes, or risk adjustment section.

Given the importance of interventional radiologists' involvement in the care of patients with chronic critical limb ischemia, we strongly encourage CMS to include interventional radiologists during all stages of the measurement development process going forward.

Thank you again for the opportunity to comment. We encourage you to reach out if you have any questions or if we can provide any additional resources.

3.1.17 Comment Number 17

- **Date:** 5/6/2022
- **Submitter Name, Credentials, and Organization:** Elizabeth M Reeve, BA, BBA, MS in Special Education, MBA, ABD for EdD (individual)
- **Comment Text:**

[Question 1: Should there be any changes to the patient cohort for the measures, as defined by trigger codes and exclusions? For instance, given the set of cost measures in MIPS, are there any gaps in care that could appropriately be filled by expanding the scope of an existing measure? Has clinical practice changed how these conditions and procedures are performed in a way that the patient cohort would need updating?]

Service dogs are a missing link. If this link was filled, those who are getting minimum capacity dogs not trained as they should be could get better services with a correct fully trained service dog and have a better quality of life.

3.1.18 Comment Number 18

- **Date:** 5/6/2022
- **Submitter Name, Credentials, and Organization:** William Windham (individual)
- **Comment Text:**

[Question 1: Should there be any changes to the patient cohort for the measures, as defined by trigger codes and exclusions? For instance, given the set of cost measures in MIPS, are there any gaps in care that could appropriately be filled by expanding the scope of an existing measure? Has clinical practice changed how these conditions and procedures are performed in a way that the patient cohort would need updating?]

Anything pertaining to the heart, brain, eyes, vascular issues, immune systems, lungs, should be left as us, unless new techniques come along to better help the patients.

[Question 2: Are there any updates that should be made to the measure-specific risk adjustors, such as to reflect changes in clinical practice or to align with other cost measures used in MIPS?]

Any medical procedure should be in the price range, where patients with Medicare and Tri care for life, will benefit from them.

3.1.19 Comment Number 19

- **Date:** 5/27/2022
- **Submitter Name, Credentials, and Organization:** Jillian Winans, American Society of Cataract and Refractive Surgery
- **Comment Text:**

[Question 1: Should additional trigger codes be added to align with related quality measures? If so, which codes?]

ASCRS continues to support the use of CPT code 66984 as the only trigger for the cataract episode measure, as well as the current comorbidity exclusions. Routine cataract removal with 66984 requires homogeneous and comparable resources for nearly all patients. As a high-volume code, it provides enough data to identify outlier physicians who are practicing outside of established patterns.

Including other trigger codes, such as complex cataract surgery code 66982, in this cost measure will not yield comparable data to measure a physician's resource use accurately. For example, patients undergoing cataract surgery that require the use of the complex cataract code may suffer from a wide variety of ocular comorbidities or other non-ocular comorbidities, which could require varying levels of resource use depending on the condition. For instance, patients taking Tamsulosin or similar medications very frequently require the use of iris retractors, leading to the use of code 66982 instead of the usual 66984. These patients often have complications requiring further surgery, such as a vitrectomy. Complex cataract surgery may require additional supplies and increases the likelihood of potential complications, resulting in a range in value too significant to provide a homogenous patient group for a cost measure and should not be used as a trigger code.

ASCRS is also concerned that adding additional trigger codes and patients with comorbidities would disproportionally affect small ophthalmology practices. The majority of ASCRS members practice in office-based settings of solo or small groups. Adding additional trigger codes would adversely impact smaller practices that do not perform as many cataract procedures as larger practices because it could only take one costly complex case to negatively impact their Cost score. Under MIPS, the Cost category is currently worth 30%, and therefore, smaller practices that provide care to patients with complex conditions would have greater exposure to a potential penalty, as a result of the negative impact on their Cost score.

ASCRS maintains that 66984 should continue to be the only code included in the specifications as a trigger code and that no other codes should be considered.

[Question 2: Based on the similarity of the cost profiles and the potential to cover more patients undergoing cataract removal procedures, is including complex cases an appropriate approach? If so, what are other updates that would be needed to the measure; for example, should these codes indicating significant ocular conditions be added as a risk adjustor? Are there services that are currently not included in the measure that would be important to include to reflect the care for complex procedures?]

ASCRS has significant concerns regarding the inclusion of complex cataract procedures and patients with comorbidities in the episode cost measure. As we have indicated previously, without an accurate risk-adjustment methodology, CMS risks creating a system that encourages the care of less severe and uncomplicated patients and discourages the care of the sickest, most complex patients. Further, we question the validity of complex cataract procedures and standard cataract procedures having similar cost profiles. We request that this data be shared so that we can provide comprehensive and thorough comments.

Conditions such as diabetic retinopathy, macular degeneration, and glaucoma can complicate cataract surgery and may require more resources to treat adequately. For example, patients taking Tamsulosin or similar medications often have complications requiring further surgery, such as vitrectomy. In addition, those patients frequently require the use of iris retractors, leading to the use of CPT code 66982 (complex cataract procedure) instead of the usual CPT code 66984 (standard cataract procedure). However, these costs are highly variable from patient to patient and depend on the disease's condition and patient's medications. Therefore, patients with these significant ocular conditions should continue to be excluded. It would not be fair to compare cases with significant ocular conditions to less complicated cataract surgeries. Nor would it provide meaningful comparison, as the costs associated with treating comorbidities are outside the physician's control. ASCRS maintains that ocular comorbidity exclusions continue to be excluded in the cataract episode cost measure to ensure meaningful comparisons and not penalize physicians who treat patients with comorbidities.

Furthermore, ASCRS is very concerned that if CMS removed exclusions for complex cataract procedures and significant ocular conditions in the cataract cost episode measure, then the sickest and most vulnerable patients, whose care is often more complex and expensive, are at risk of losing access to care. Some cataract surgeons are in high-volume practices where they may avoid the problem of adverse risk selection, while others are not and may choose to see lower-risk cataract patients to avoid being penalized for the extra costs needed to treat high-risk cataract patients. Choosing a course of treatment for a patient to not adversely impact a resource use score becomes a problematic ethical dilemma for a physician who wants to uphold his or her sworn duties. However, if a physician does not keep these considerations in mind, it may impact the overall viability of his or her practice, and thereby the ability to care for other patients. Not

only would this situation place physicians in an ethical quandary, the day-to-day task of monitoring the cost of care for each patient will add considerably to the already heavy regulatory burdens physicians face. If the cataract cost measure does not include appropriate risk adjustment, the physicians who care for the most complicated and sickest patients, who are most likely to have a poorer outcome, will be more likely to be penalized. If physicians know that treating certain high-risk patients may negatively impact their score, they may choose not to treat those patients. Removing exclusions may create scenarios where physicians are forced to make individual cost calculations, prior to treatment, to estimate how the patient may affect their Cost score. We urge CMS to continue to exclude complex cataract procedures and patients with comorbidities in the cataract episode measure, to ensure patients have access to timely care.

Lastly, we question the validity of the assertion that complex cataract procedures and standard cataract procedures have similar cost profiles. The costs of a standard cataract procedure and complex cataract procedure are highly variable and dependent on the patient's comorbidities and condition. We request that this data be made public, so we can examine and provide thorough comments.

[Question 3: Should medications including Dexycu and Dextenza be included in the Cataract Removal measure? Are there any other intra- or peri-operative drugs that should be considered for inclusion in the Cataract Removal measure?]

ASCRS continues to be opposed to including any pass-through drugs in the cost episode measures. ASCRS is concerned that if pass-through drugs like Dexycu and Dextenza are included in the cataract episode measure, it will disincentivize surgeons from using the drugs and negatively impact the utilization data CMS collects during the pass-through period for this purpose. Ultimately, including any Medicare Part B drugs on pass-through in the episode measure defeats the purpose of pass-through.

Pass-through status, which can be granted for up to 3 years, is a vital tool in ensuring that new, innovative, and expensive drugs are introduced to the market. CMS uses this utilization data during the pass-through period to calculate the increase in the ambulatory payment classification (APC) group to account for the drug once the drug comes off pass-through and is bundled into the facility payment. Pass-through status helps introduce a new and expensive drug into the marketplace that is used during or immediately after surgical procedures with an average estimated cost that exceeds a certain percentage of the procedure’s ambulatory payment classification (APC) payment amount. It is initially put on pass-through status and paid separately for up to three years under Medicare Part B. This encourages the use of new drugs in the facility by allowing physicians time to become familiar with their use without adding to facility costs. Separate payment for pass-through drugs is also essential to ASCs because their lower facility reimbursements would make it difficult to afford these new, high-cost drugs.

During the pass-through period, CMS measures the utilization of the drug and, when the drug goes off pass-through status, adjusts the reimbursement level for the bundled facility fee based on the utilization data gathered and the formula. To set the price of the APC group, CMS uses charges on claims and data from cost reports to calculate the average cost of providing a specific service, which includes all packaged items and services, including drug costs, and then groups the service in with other services that have a similar cost or are clinically comparable. CMS then calculates an average cost for all grouped services to set the price for the APC group. When a drug comes off pass-through, its price is included in the cost data for the service. Therefore, when CMS calculates the average price for the service, the utilization of the drug will impact the average cost of the service: the higher the utilization, the higher the average price, and vice versa. Pass-through status allows CMS to gather data not influenced by other factors. If drugs on pass-through status are included in the measure, physicians mindful of their score on the cataract surgery cost measure will modify their use of the drug for reasons other than clinical appropriateness, and thus impact the gathering of utilization data, thereby defeating the purpose of pass-through.

Specifically, the FDA-approved drugs administered during cataract surgery that are now on pass-through have a post-operative indication, such as post-operative pain and inflammation and/or other sequela of the surgery and eliminate the need for some or all post-operative eye drops which are covered under Medicare Part D. Reducing or eliminating the need for post-operative eye drops represents substantial cost savings both to the Medicare program and the patient. In addition, eliminating the need for post-operative eye drops improves patient compliance and leads to better clinical outcomes. However, since Part D costs are not currently a factor in the cataract episode measure, using these Medicare Part B pass-through medications during cataract surgery and including them in the episode calculation would increase the total episode cost and would inaccurately designate the surgeon as high cost. Beyond the primary goal of preserving pass-through status to ensure accurate utilization calculations, we believe including these drugs with a post-operative indication on pass-through would go against the goal of the episode-based cost measures of encouraging physicians to make more efficient use of resources.

Furthermore, including any pass-through drugs in the cataract episode-based cost measure will stifle innovation. Innovation in cataract surgery is currently focused on developing treatments that are administered at the time of surgery and have a post-operative indication. Developing a new drug for FDA approval is an expensive, time-consuming, and risky proposition for manufacturers. A key factor in their decisions to develop drugs is a reasonable assurance there will be a market for the drug once it is approved. Without certainty that using these drugs will not negatively impact physicians' MIPS scores, and thus discourage physicians from using them, manufacturers will be unwilling to continue innovating in this area. We urge CMS to exclude all pass-through drugs from the cataract episode-based measure, which will

encourage manufacturers to continue developing innovative treatments that improve outcomes and reduce patient burden.

ASCRS maintains that episode-based cost measures are a more effective method of measuring clinician resource use than population-based measures because they only include the costs of care within the physician's control. However, physicians have no control over the cost of drugs as they enter the market, and therefore, including the cost of these drugs in the measure is contrary to the goals of episodic-based measurement. To ensure that clinicians are not penalized for using drugs on pass-through and that pass-through status is preserved to collect accurate, market-based utilization data, we recommend that any FDA-approved Medicare Part B drug administered during, or at the end of, cataract surgery that is on pass-through status be excluded from the cataract surgery episode-based cost measure.

In summary, we believe including drugs with a post-operative indication on pass-through would go against the goal of the episode-based cost measures of encouraging physicians to make more efficient use of resources. In addition, we believe that including these drugs in the episode measure could stifle ongoing innovation. Therefore, to ensure that clinicians are not penalized for using drugs on pass-through and that pass-through status is preserved to collect accurate, market-based utilization data, we recommend that CMS exclude any FDA-approved Medicare Part B drug administered during or at the end of cataract surgery that is on pass-through status.

[Question 4: Are there any Part D drugs related to cataract surgery that should be considered for inclusion in the Cataract Removal measure?]

ASCRS maintains that Part D drug costs, which include post-operative drops, should continue to be excluded in the cataract cost measure. To our knowledge, CMS does not have the capability to standardize all Part D drug cost variations and, therefore, they should not be included in the cataract cost measure. There are too many variables in Part D costs outside the physician's control, making meaningful comparisons unattainable.

Physicians have no control over the negotiations between drug manufacturers, pharmacy benefit managers (PBMs), and insurers that will ultimately determine Part D prescription drug costs. Variables in Part D drug costs include the insurance plan, the plan's formulary, and the negotiations between the insurers and the drug's manufacturer, among dozens of other factors. These negotiations surrounding prescription drug costs are private, and to our knowledge no public transparency exists. Further, CMS has not created a methodology to standardize all of the variables that will impact Part D prescription drugs. For these reasons, physicians should not be held accountable or penalized for costs over which they have no control.

Additionally, we are concerned that including Part D prescription drug costs in the cataract cost measure may inappropriately penalize physicians who select the most medically appropriate

treatment for their patients. As we previously mentioned, FDA-approved drugs administered during cataract surgery with a post-operative indication, including those that are on pass-through, are replacing the need for self-administered post-operative eye drops that are prescribed after cataract surgery. However, there are instances where an ophthalmologist would prescribe self-administered post-operative drops rather than administering a drug with a post-operative indication at the time of surgery. For example, a patient may be allergic to an active ingredient in a drug that would be administered at the time of cataract surgery. Since the patient is allergic to an ingredient in the medication, the ophthalmologist would not use it during surgery. Instead, the patient would be prescribed self-administered post-operative eye drops that do not contain the ingredient with which the patient is intolerant.

It is essential that CMS recognize that the most appropriate methodology for determining cost should be flexible to allow for choice of a treatment option that is best for the patient and will lead to better outcomes, rather than determine a resource use score solely based on the cost of care. ASCRS maintains that physicians should not be held accountable for costs over which they have no control.

3.1.20 Comment Number 20

- **Date:** 5/27/2022
- **Submitter Name, Credentials, and Organization:** Maria Blase, MA, Practice Administrator at California Eye Professionals Medical Group Inc
- **Comment Text:**

Currently over 90% of Cataract surgeries are billed using 66984. Including additional lesser used CPT codes and Part D drugs would negatively impact the Cost measures and penalize Practices performing lower volumes of cataract surgeries. This is not fair or equitable.