AMERICAN ACADEMY
OF OPHTHALMOLOGY

20 F Street NW
Suite 400
Washington, DC
20001-6701

P.O. Box 7424
San Francisco, CA
94120-7424

T: +1 202.737.6662
aao.org

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Partnership for Quality Measurement
505 King Avenue
Columbus, OH 43201
PQMsupport@battelle.org
Via electronic delivery

Re: MUC2023-201 Cataract Removal with Intraocular Lens (IOL) Implantation

Dear Members of the 2023-2024 Pre-Rulemaking Measure Review (PRMR) Clinician Committee,

On behalf of the American Academy of Ophthalmology (AAO) representing over 20,000 ophthalmologists in the United States, we appreciate the opportunity to provide feedback on the potential revisions to the Cataract Removal with Intraocular Lens (IOL) Implantation cost measure (MUC2023-201). Our organization has been an active participant in the ongoing effort to develop episode-based cost measures that more accurately reflect the care specialists are providing to Medicare beneficiaries.

We have appreciated the iterative and collaborative process the Centers for Medicare & Medicaid Services (CMS) and Acumen, LLC have undertaken to foster development and refinement of these measures. In particular, physician leaders of our organization and other ophthalmology specialty societies, including a cataract specialist, served on the clinical expert workgroup that developed and reevaluated the cataract surgery cost measure. The Academy's rationale and recommendations for MUC2023-201 generally align with the feedback from the workgroup.

We respectfully request that CMS treat the maintenance 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. When developing and revising cost measures, we believe it is critical to account for factors affecting cost that are outside the physician's control and you will see that as a common theme throughout this response.

Our specific recommendations are provided below:

Episode Trigger

We appreciate that CPT 66982 (complex cataract surgery) has not been included in the trigger logic. The trigger code for the cataract cost measure was carefully chosen to exclude high-risk patients with an increased likelihood of needing an additional costly intervention.[1,2] This was done to ensure a level playing field between higher and lower-volume surgeons and to avoid creating a disincentive for physicians to care for complex patients.

Expanding the patient cohort by adding trigger codes would add only higher-risk cases to the measure. Due to circumstances beyond their control, ophthalmologists 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 ten cases. A single retinal detachment in a high-risk patient would unfairly disadvantage that surgeon 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 would create a disincentive to caring for them. This in turn could lead to a rise in referrals with increased program costs and patient burden with no associated improvement in outcomes.

Service Assignment

Revisions to the cataract surgery cost measure 'include the costs of additional clinically related services, such as pre-operative testing, additional telehealth services, durable medical equipment (DME), emergency department (ED) visits for ocular complaints.' **The Academy agrees with the workgroup and measure developer that it is reasonable to account for the cost of these services when truly related to the trigger code and within the episode window.**

Inclusion of Part D Drugs

While desirable, inclusion of Part D drugs at this time would seriously degrade the validity of the cataract cost measure. The workgroup agreed that including the cost of Part D drugs in the measure is not advisable.

Because drug selection is under the control of the provider, inclusion of drug costs could be a significant improvement to this measure. However, there are three critical shortcomings that need to be addressed before drug costs could be appropriately included.

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[1] Glasser D. (2019). Rewarding Cost Efficiency in Medicare's Merit-Based Incentive Payment System. Ophthalmology, 126(2), 189–191. https://doi.org/10.1016/j.ophtha.2018.09.025

[2] Pershing, S., Sandhu, A. T., Uwilingiyimana, A. S., Glasser, D. B., Morgenstern, A. S., Do, R., Choradia, N., Lin, E., Leoung, J., Shah, M., Liu, A., Lee, J., Fairchild, A., Lam, J., MaCurdy, T. E., Nagavarapu, S., Bhattacharya, J., & Routine Cataract Removal with Intraocular Lens Implantation Cost Measure Writing Committee (2023). Cataract Surgery in the Medicare Merit-Based Incentive Payment System: Episode-Based Cost Measure Development and Evaluation. Ophthalmology science, 3(4), 100315. https://doi.org/10.1016/j.xops.2023.100315

First, 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 actually were due to no information on drops purchased and used. Unless the distribution of patients with Part D coverage is uniform among providers, cost measure scores will be influenced by such factors outside of the provider's control.

Second, 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 generic and branded 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 different relative drug costs, it is inconceivable for providers to be able to track them in real time for their cataract surgery patients. 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 is impossible in today's environment. Even if cost data were 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 prescribing physician.

Third, there must be a reliable supply of available drugs. Frequent and recurrent drug shortages in the ophthalmic space limit the choice of medications available at any given time. Shortages are unpredictable, outside of the provider's control, and are increasingly common. Shortages also may be regional, making system-wide comparisons of costs unreliable.

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 Part D drug costs at this time. We would be pleased to engage in a dialog to address these limitations.

Inclusion of Part B Drugs

The revised measure specifications also reflect changes to the way in which clinically related Part B medications with separate payment statuses are assigned to the episode. The clinical expert workgroup recommended treating all clinically related Part B medications similarly (i.e., either including all or none); however, they did not reach a consensus on whether to assign the costs of clinically related Part B medications. Ultimately, both HCPCS J1096, *Dexamethasone, Lacrimal Ophthalmic Insert, 0.1 Mg* (Dextenza) and J1097, *Phenylephrine 10.16 Mg/Ml And Ketorolac 2.88 Mg/Ml Ophthalmic Irrigation Solution, 1 Ml* (Omidria) have been included in the proposed assigned services rules.

Through discussions in the workgroup and internally, our position on inclusion of Dextenza as an assigned service has evolved. While Dextenza and Omidria serve

different purposes for a cataract surgery patient, they are both separately payable in the ambulatory surgery center through designation as non-opioid pain management drugs that function as surgical supplies, thus contributing to higher facility costs when those agents are administered. While it has been suggested that these separately payable drugs may improve outcomes or reduce/eliminate the need for postoperative steroid drops, it is exceedingly difficult to quantify the effect on episode cost with the data and tools currently available. We are unaware of high-quality published evidence that outcomes are improved or cost savings are achieved because of use of either drug. To treat these drugs differently in relation to episode cost calculation unfairly singles out physicians who use Omidria.

We agree that assignment rules should be applied consistently for Part B medications with separate payment statuses, thus Dextenza and Omidria should be included in the calculation of episode cost.

We agree with the workgroup that as other clinically relevant Part B medications with separate payment statuses become available, they should be considered for inclusion in the cost measure through the annual maintenance process.

It may seem inconsistent to exclude Part D drugs and include Part B drugs, particularly when some Part B drugs may substitute for some postoperative Part D drugs. However, the cost differential is significant. In the absence of evidence for superior outcomes with either regimen, we are less concerned that a financial incentive will favor sub-par care.

Exclusions & Risk Adjustment Variables

Earlier this year, the workgroup discussed changing the methods to account for patient heterogeneity (i.e., exclusions and risk adjustment variables) in the cataract cost measure. Acumen presented analyses showing that the excluded and risk-adjusted episodes have similar observed costs compared to all episodes included in the current measure specifications and that some of the most frequently occurring conditions within the Patients with Ocular Conditions Impacting Case Complexity risk adjustment variable have similar or lower observed costs compared to all episodes included in the measure (e.g., macular degeneration, certain forms of glaucoma, and Type 2 diabetes mellitus with non-proliferative retinopathy). Based off Acumen's models, the workgroup recommended to no longer exclude nor risk adjust for certain common conditions with similar cost profiles to all observed episodes. They also recommended that certain conditions were infrequent and/or clinically distinct from the overall patient cohort and should be excluded from the measures (e.g., traumatic cataract).

The Academy cautiously supports the removal of some diagnoses, including macular degeneration, and the subset of open angle glaucoma diagnoses, from the exclusions and risk adjustment variables. However, we recommend that type 2 diabetes with non-proliferative retinopathy remain risk adjusted. Despite Acumen's projections and the workgroup's endorsement of removing this group of diagnoses, we remain concerned that patients with diabetic retinopathy present a higher risk of increased cost. Diabetic retinopathy frequently worsens after uncomplicated cataract surgery, necessitating additional referrals to retinal

specialists, serial ocular coherence tomography testing, and occasionally intravitreal anti-VEGF injections. Although the injections are not captured in the measure, the visits and tests for management is included. These costs are not within the surgeon's control.

Including patients with macular degeneration and primary open-angle glaucoma should increase eligible cases significantly, which reduces the risk of a single complicated episode negatively skewing a surgeon's overall episode cost when there is a small sample size. This should be particularly helpful to ophthalmologists who barely meet the case minimum threshold of ten episodes currently. **We agree that removing these diagnoses from the exclusion and risk adjustment lists should result in increasing numbers of eligible cases and providers without subjecting providers to increased risk for variation in cost outside the surgeon's control.**

We feel strongly that the totality of these changes should be closely monitored to confirm the fidelity of Acumen's projections to current, real-world practice. We have heard from members that the risk adjustment calculation seems like a black box, making it difficult to understand how episode costs are determined. While we are currently supportive of the changes proposed for exclusions and risk adjustment, we request that CMS publish educational resources (e.g., fact sheets, live webinars) on how risk adjustment variables impact episode costs to improve confidence in the measure calculation.

We would like to recommend the addition of capsular glaucoma, H40.14X, to the list of exclusions. Patients with severe enough pseudoexfoliation to cause glaucoma are more prone to lax zonules and higher risk surgery. This increases the risk of postoperative IOL dislocation after uncomplicated cataract surgery, requiring an additional procedure to fixate the lens. These are uncommon enough that the cases should be excluded rather than risk adjusted.

Additionally, we recommend that CMS risk adjust for social determinants of health ICD-10 codes that can make it more difficult for patients to access and/or comply with treatment, including but not limited to:

- Z56.0 - Unemployment, unspecified
- Z59.01 - Sheltered homelessness
- Z59.02 - Unsheltered homelessness
- Z59.1 – Inadequate Housing
- Z59.10 – Inadequate housing, unspecified
- Z59.11 – Inadequate housing environmental temperature
- Z59.12 – Inadequate housing utilities
- Z59.7 Insufficient social insurance and welfare support
- Z59.82 – Transportation insecurity
- Z59.86 – Financial insecurity
- Z59.87 – Material hardship due to limited financial resources, not elsewhere classified
- Z59.89 – Other problems related to housing and economic circumstances

<u>Concerns About Scoring and Performance Feedback Process</u>

The Academy has appreciated being a part of the cost measure development process. We hope to continue collaborating on the future of the cataract surgery cost measure, and any others being created for MIPS eligible ophthalmologists. However, we would like to see improvements in the scoring and feedback process for the Merit-based Incentive Payment System (MIPS) program.

In late summer, members alerted the Academy to concerns with the scores they received on the cataract surgery episode-based cost measure as a part of their performance year 2022/ payment year 2024 score previews. 2022 is the first performance year that many ophthalmologists were scored on MIPS cost measures. Many were surprised by low scores because they did not receive performance feedback in previous years. Issues with duplicate services initially appearing in the patient-level data files also added to the confusion.

We appreciated the teams from the Center for Clinical Standards and Quality and Acumen meeting with us and the American Society of Cataract and Refractive Surgery on October 24th to discuss our concerns. During the meeting, we shared concerns that the patient-level data files lack the data needed to improve performance on the measure. We recommended the addition of date of service and rendering provider fields to future performance year reports. We also asked that a member of the Acumen team walk our staff through real-world examples of the cost measure calculation so that we can educate our members.

Lack of meaningful feedback erodes trust in the accuracy and validity of the reports and scores. It runs counter to the intent of the measure, and makes it appear as a black box designed to reduce program costs at the expense of clinicians rather than to improve cost performance. **Before the cataract cost measure is applied for the 2023 performance year and beyond, we strongly recommend that the application of the measure be reviewed carefully with the clinical expert panel that developed the measure so that any inconsistencies in service attribution are corrected.**

The nation's ophthalmologists are committed to finding a solution that does not threaten our patients' access to vision-restoring surgery, and our organizations welcome the opportunity to work with CMS to develop sensible cost measures. We look forward to working with you on these issues during the upcoming rulemaking cycle. To set up a meeting or if you have any questions or concerns, please contact Brandy M. Keys, MPH, AAO Director of Health Policy at bkeys@aao.org or 202-737-6662 ext. 815.

Sincerely,

Michael X. Repka, MD, MBA
AAO Medical Director for
Governmental Affairs

David B. Glasser, MD
AAO Secretary for Federal Affairs