May 20, 2022

Re: Episode-based Cost Measures: Call for Public Comment for Measure Reevaluation

Dear Administrator Brooks-LaSure,

MarsdenAdvisors (MA) is submitting our comments on the Episode-based Cost Measures Call for Public Comment for Measure Reevaluation. MA is a consulting and software company that helps small to medium sized specialty practices implement and manage EHR technology and comply with quality reporting requirements, such as those in the Merit-based Incentive Payment System (MIPS). We support over 1,000 clinicians in quality compliance and reporting nationwide.

We appreciate the thought that went into this call for public comment, however we are concerned with the extensive changes to the Cataract Cost measure discussed in the document. In addition, we have suggestions on attribution refinement for midlevel providers.

In our comments, we will answer survey questions for this measure and address additional issues not covered by the survey questions.

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Survey Questions:

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%**[1] **) of cataract surgeries performed in the United States**.

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.**

    b. **CMS' Concern About Unintended Consequences**

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

[1] 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

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 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.

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

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[2] 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.

[2] 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

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 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.[3] [4] [5] 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**.

While innovative medications like Omidria, Dexycu and Dextenza are sources of significant cost variation, we agree with CMS original inclusion of Omidria in the cost measure, as it is not

[3] 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

[4] 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

[5] 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

recommended or necessary for routine procedures. There are similarities in history between Dexycu and Dextenza and Omidria, with all three originating with Transitional Pass-Through Status but 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.

The benefits of both Dexycu and Dextenza are more relevant to routine cases**. Use of Dexycu or Dextenza helps providers avoid negative outcomes related to patient capacity to adhere with 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 Dextenza has become standard of care in European countries[6] 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.[7] **Traditional post-operative care for patients with limited dexterity is also a significant issue, considering the advanced age of patients undergoing cataract removal.[8]**

While all three of these medications are under TPT or special payment status, both Dexycu's and Dextenza's TPT status are set to expire shortly. CMS has declared Dexycu to be ineligible for the special payment status that Omidria has as an alternative to opioid medications. We understand CMS' stance on Dexycu due to its FDA indications as solely an anti-inflammatory drug. Dextenza, however, is indicated for pain management[9] just like Omidria. We urge CMS to consider applying a similar special payment status to Dextenza as they have with Omidria. This would enable the continued provision of high-value care to Medicare beneficiaries and incentivize the avoidance of unnecessary opioid use.

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

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[6] 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

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

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

[9] https://www.touchophthalmology.com/cataract-surgery/journal-articles/noncompliance-with-prescribed-eyedrop-regimens-among-patients-undergoing-cataract-surgery-prevalence-consequences-and-solutions/#article

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 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.[10] 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. [11] [12]

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

[10] https://www.commonwealthfund.org/publications/journal-article/2019/jul/perverse-incentives-why-brand-name-drugs-can-cost-less

[11] 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

[12] https://www.uspharmacist.com/article/ophthalmic-medications-the-safety-and-efficacy-of-brandname-versus-generic-formulations

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.**

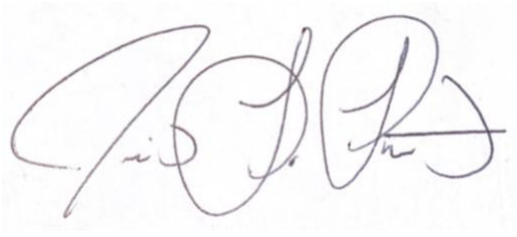
Insufficient Infrastructure Available to Clinicians

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

Conclusion

We appreciate the opportunity to work with CMS and Acumen to improve clinician cost measurement in the Merit-based Incentive Payment System. If you have questions or need any additional information regarding any portion of these comments, please contact Dr. Jessica Peterson, VP of Health Policy at MarsdenAdvisors at jessica@marsdenadvisors.com.

Sincerely,



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